

WHAT IS CLAIMED IS:

1. Use of a GM-CSF antagonist in the manufacture of a medicament ~~A method~~ for treating a subject infected with 2019 coronavirus (SARS-CoV-2) and treating and/or preventing inflammation-induced lung injury in a subject infected with the coronavirus (SARS-CoV-2), the method comprising administering to the subject a therapeutically effective amount of a GM-CSF antagonist wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody lenzilumab, Namilumab, Otilimab, Gimsilumab, or TJM2 (TJ003234); wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab; or wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.
2. ~~The method of claim 1, wherein the GM-CSF antagonist is anti hGM-CSF antibody Lenzilumab.~~
3. ~~The method of claim 1, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~
4. ~~The method of claim 1, wherein the GM-CSF antagonist is an anti GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~
5. ~~The method of claim 1, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~
6. The method ~~use~~ of claim 1, ~~further comprising administering wherein the medicament is to be administered with~~ a therapeutically effective amount of an anti-viral agent, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;
wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555;

wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia), wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat; and/or

wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S-protein of SARS-CoV-2.

~~7. — The method of claim 6, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~8. — The method of claim 6, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~9. — The method of claim 6, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~10. — The method of claim 9, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~11. — The method of claim 9, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~12. — The method of claim 6, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S-protein of SARS-CoV-2.~~

133. The ~~method-use~~ of claim 1, ~~further comprising administering to the subject~~wherein the medicament is to be administered with a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified ~~mNRA-mRNA~~ BNT162b2 Tozinameran (INN) (Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2) Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof;

a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2

inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2;

a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject; and/or

wherein the GM-CSF antagonist is anti-hGM-CSF antibody lenzilumab.

~~14. The method of claim 13, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~

~~15. The method of any of claims 1-14, further comprising administering to the subject a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~16. The method of claim 1, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~17. A method for treating a subject infected with 2019 coronavirus (SARS-CoV-2), the method comprising administering to the subject a therapeutically effective amount of a GM-CSF antagonist and a therapeutically effective amount of an anti-viral agent.~~

~~18. The method of claim 17, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~

~~19. The method of claim 17, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~20. The method of claim 17, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~21. The method of claim 17, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~22. The method of claim 17, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482/EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~23. The method of claim 17, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

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~~24. The method of claim 17, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~25. The method of claim 24, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimune; Aluvia).~~

~~26. The method of claim 24, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~27. The method of claim 17, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S protein of SARS-CoV-2.~~

~~28. The method of claim 17, further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified mRNA BNT162b2 Tozinameran (INN) (Pfizer BioNTech), adenovirus based vaccine AZD1222 (recombinant ChAdOx1 adenoviral~~

~~vector encoding the SARS-CoV-2 spike protein antigen; Oxford AstraZeneca), Covishield (ChAdOx1-nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373, an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.~~

29. — ~~The method of claim 17, wherein the GM-CSF antagonist is anti hGM-CSF antibody Lenzilumab.~~

30. — ~~The method of any of claims 17-29, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

31. — ~~The method of claim 1, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist~~

(vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.

32. — ~~A method for preventing and/or treating inflammation induced lung injury in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a GM-CSF antagonist.~~

33. — ~~The method of claim 32, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~

34. — ~~The method of claim 32, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

35. — ~~The method of claim 32, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

36. — ~~The method of claim 32, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

37. — ~~The method of claim 32, further comprising administering a therapeutically effective amount of an anti-viral agent.~~

38. — ~~The method of claim 37, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

39. — ~~The method of claim 37, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

40. — ~~The method of claim 37, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

41. — ~~The method of claim 40, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

42. — ~~The method of claim 40, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

43. — ~~The method of claim 37, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S protein of SARS-CoV-2.~~

44. — ~~The method of claim 32, further comprising administering to the subject a therapeutically effective amount of an anti SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologies), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified mRNA BNT162b2 Tozinameran (INN) (Pfizer BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2) Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based~~

~~on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech); SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.~~

~~45. The method of claim 44, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~

~~46. The method of any of claims 32-45, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~47. The method of claim 32, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~48. A method for preventing and/or treating inflammation-induced lung injury in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a GM-CSF antagonist and a therapeutically effective amount of an anti-viral agent.~~

~~49. The method of claim 48, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~

~~50. The method of claim 48, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~51. The method of claim 48, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~52. The method of claim 48, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~53. The method of claim 48, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist~~

leronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482/EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.

54. ~~The method of claim 48, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

55. ~~The method of claim 48, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

56. ~~The method of claim 55, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

57. ~~The method of claim 55, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

58. ~~The method of claim 48, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S-protein of SARS-CoV-2.~~

59. ~~The method of claim 48, further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified mRNA BNT162b2 Tozinameran (INN) (Pfizer BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1-nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication incompetent adenovirus type 26 (Ad26) vectored vaccine encoding~~

~~SARS-CoV-2) Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.~~

~~60. The method of claim 48, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~

~~61. The method of any of claims 48-60, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~62. The method of claim 48, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~63. A method for preventing and/or treating cytokine release syndrome (CRS) and/or toxicity induced by CRS in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a GM-CSF antagonist.~~

- ~~64. The method of claim 63, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~
- ~~65. The method of claim 63, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~
- ~~66. The method of claim 63, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~
- ~~67. The method of claim 63, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~
- ~~68. The method of claim 63, further comprising administering a therapeutically effective amount of an anti-viral agent.~~
- ~~69. The method of claim 68, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin-mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~
- ~~70. The method of claim 68, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~
- ~~71. The method of claim 68, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~
- ~~72. The method of claim 71, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~
- ~~73. The method of claim 71, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

74. —The method of claim 68, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S-protein of SARS-CoV-2.

75. —The method of claim 63, further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside-modified mRNA BNT162b2 Tozinameran (INN) (Pfizer BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-competent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S-protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.

76. —The method of claim 75, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.

~~77. The method of any of claims 63-76, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~78. The method of claim 63, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~79. A method for preventing and/or treating cytokine release syndrome (CRS) and/or toxicity induced by CRS in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a GM-CSF antagonist and a therapeutically effective amount of anti-viral agent.~~

~~80. The method of claim 79, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~

~~81. The method of claim 79, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~82. The method of claim 79, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~83. The method of claim 79, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~84. The method of claim 79, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin-mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482/EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~85. The method of claim 79, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the~~

~~mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~86. The method of claim 79, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~87. The method of claim 86, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimune; Aluvia).~~

~~88. The method of claim 86, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~89. The method of claim 79, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S protein of SARS-CoV-2.~~

~~90. The method of claim 79, further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified mRNA BNT162b2 Tozinameran (INN) (Pfizer BioNTech), adenovirus based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1-nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom,~~

China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.

91. ~~The method of claim 90, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~

92. ~~The method of any of claims 79-91, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

93. ~~The method of claim 79, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

94. ~~A method for treating a subject infected with a coronavirus (SARS-CoV-2) comprising administering to the subject a therapeutically effective amount of GM-CSF antagonist and~~The use of claim 1, wherein the medicament is to be administered with a therapeutically effective amount of oxygen transporter.

95. ~~The method-use~~ of claim 94, wherein the oxygen transporter is BXT25 and/or wherein the GM-CSF antagonist is anti-hGM-CSF antibody lenzilumab.

96. ~~The method of claim 94, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~
97. ~~The method of claim 94, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~
98. ~~The method of claim 94, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~
99. ~~The method of claim 94, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~
100. ~~The method of claim 94, further comprising administering an anti-viral agent selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin-mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~
101. ~~The method of claim 94, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~
102. ~~The method of claim 94, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~
103. ~~The method of claim 102, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~
104. ~~The method of claim 102, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~
105. ~~The method of claim 94, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (epd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~106. — A method for treating and/or preventing inflammation-induced lung injury in a subject infected with a coronavirus (SARS-CoV-2) comprising administering to the subject a therapeutically effective amount of GM-CSF antagonist and a therapeutically effective amount of oxygen transporter.~~

~~107. — The method of claim 106, wherein the oxygen transporter is BXT25.~~

~~108. — The method of claim 106, wherein the GM-CSF antagonist is anti-hGM-CSF antibody Lenzilumab.~~

~~109. — The method of claim 106, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~110. — The method of claim 106, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~111. — The method of claim 106, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~112. — The method of claim 106, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~113. — The method of claim 106, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~114. — The method of claim 106, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~115. — The method of claim 107, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimune; Aluvia).~~

~~116. The method of claim 107, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~117. The method of claim 106, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (epd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~1186. The use of claim 1A method for treating a subject infected with 2019 coronavirus (SARS-CoV-2), the method comprising administering to the subject, wherein the GM-CSF antagonist is formulated as a pharmaceutical composition comprising a therapeutically effective amount of a the GM-CSF antagonist, wherein the pharmaceutical composition is administered comprises the GM-CSF antagonist at a dose of from 1200 mg to 1800 mg for administration over 24 hours.~~

~~119. The method of claim 118, wherein the GM-CSF antagonist is neutralizing anti hGM-CSF antibody Lenzilumab.~~

~~1207. The method use of claim 1186, wherein the pharmaceutical composition comprises the GM-CSF antagonist is administered at a dose of 400 mg for administration every 8 hours for a total of three doses over 24 hours for three days;~~

~~wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 600 mg for administration every 8 hours for a total of three doses over 24 hours for one day;~~

~~wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 800 mg for administration every 12 hours for a total of two doses over 24 hours for one day; or~~

~~wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 1800 mg for administration as a single dose for one day.~~

~~121. The method of claim 118, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~122. The method of claim 118, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours for one day.~~

~~123. The method of claim 118, wherein the GM-CSF antagonist is administered at a dose of 1800 mg as a single dose for one day.~~

~~124. The method of claim 118, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~125. The method of claim 118, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~126. The method of claim 118, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~1278. The method use of claim ~~118~~6, further comprising administering wherein the medicament is to be administered with a therapeutically effective amount of an anti-viral agent;~~

~~wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;~~

~~wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555;~~

~~wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug; wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia);~~

~~wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat;~~

~~wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S-protein of SARS-CoV-2.~~

~~128. The method of claim 127, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin-mimetic Brilacidin, CCR5-antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482/EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~129. The method of claim 127, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~130. The method of claim 127, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~131. The method of claim 130, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimune; Aluvia).~~

~~132. The method of claim 130, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~133. The method of claim 127, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor-binding domain (RBD) of S-protein of SARS-CoV-2.~~

~~1349. The method-use of claim ~~1186~~, wherein the medicament is to be administered with further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified ~~mNRA-mRNA~~ BNT162b2 Tozinameran (INN) (Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-~~

CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof;

a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2;

a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject; and/or

wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody lenzilumab.

~~135.—The method of claim 134, wherein the GM-CSF antagonist is neutralizing anti hGM-CSF antibody Lenzilumab.~~

~~136.—The method of any of claims 118-135, further comprising administering to the subject a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~137.—The method of claim 118, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~138.—A method for treating a subject infected with 2019 coronavirus (SARS-CoV-2), the method comprising administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of a GM-CSF antagonist, wherein the pharmaceutical composition is administered at a dose of from 1200 mg to 1800 mg over 24 hours, and a therapeutically effective amount of an anti-viral agent.~~

~~139.—The method of claim 138, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~140.—The method of claim 138, wherein the GM-CSF antagonist is administered at a dose of 400 mg every 8 hours for a total of three doses over 24 hours for three days.~~

~~141.—The method of claim 138, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~142.—The method of claim 138, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours for one day.~~

~~143.—The method of claim 138, wherein the GM-CSF antagonist is administered at a dose of 1800 mg as a single dose for one day.~~

~~144.—The method of claim 138, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~145.—The method of claim 138, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~146.—The method of claim 138, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~147.—The method of claim 138, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482/EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~148.—The method of claim 138, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~149.—The method of claim 138, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~150.—The method of claim 149, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~151.—The method of claim 149, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~152.—The method of claim 138, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor-binding domain (RBD) of S protein of SARS-CoV-2.~~

~~153.—The method of claim 138, further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified mRNA BNT162b2 Tozinameran (INN)~~

~~(Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2) Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.~~

154. — ~~The method of claim 153, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

155. — ~~The method of any of claims 138-154, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~156.—The method of claim 138, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~157.—A method for preventing and/or treating inflammation-induced lung injury in a subject in need thereof, the method comprising administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of a GM-CSF antagonist, wherein the pharmaceutical composition is administered at a dose of from 1200 mg to 1800 mg over 24 hours.~~

~~158.—The method of claim 157, wherein the GM-CSF antagonist is neutralizing anti hGM-CSF antibody Lenzilumab.~~

~~159.—The method of claim 157, wherein the GM-CSF antagonist is administered at a dose of 400 mg every 8 hours for a total of three doses over 24 hours for three days.~~

~~160.—The method of claim 157, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~161.—The method of claim 157, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours for one day.~~

~~162.—The method of claim 157, wherein the GM-CSF antagonist is administered at a dose of 1800 mg as a single dose for one day.~~

~~163.—The method of claim 157, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~164.—The method of claim 157, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~165.—The method of claim 157, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~166.—The method of claim 157, further comprising administering a therapeutically effective amount of an anti-viral agent.~~

~~167.—The method of claim 47, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist~~

leronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.

~~168. The method of claim 166, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~169. The method of claim 166, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~170. The method of claim 169, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~171. The method of claim 169, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~172. The method of claim 166, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S-protein of SARS-CoV-2.~~

~~173. The method of claim 157, further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified mRNA BNT162b2 Tozinameran (INN) (Pfizer BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication incompetent adenovirus type 26 (Ad26) vectored vaccine encoding~~

~~SARS-CoV-2) Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.~~

~~174.—The method of claim 173, wherein the GM-CSF antagonist is neutralizing anti hGM-CSF antibody Lenzilumab.~~

~~175.—The method of any of claims 157-174, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~176.—The method of claim 157, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (epd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~177.—A method for preventing and/or treating inflammation-induced lung injury in a subject in need thereof, the method comprising administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of a GM-CSF antagonist, wherein the~~

~~pharmaceutical composition is administered at a dose of from 1200 mg to 1800 mg over 24 hours, and a therapeutically effective amount of an anti-viral agent.~~

~~178.—The method of claim 177, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~170.—The method of claim 177, wherein the GM-CSF antagonist is administered at a dose of 400 mg every 8 hours for a total of three doses over 24 hours for three days.~~

~~180.—The method of claim 177, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~181.—The method of claim 177, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours for one day.~~

~~182.—The method of claim 177, wherein the GM-CSF antagonist is administered at a dose of 1800 mg as a single dose for one day.~~

~~183.—The method of claim 177, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~184.—The method of claim 177, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~185.—The method of claim 177, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~186.—The method of claim 177, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482/EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~187.—The method of claim 177, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~188.—The method of claim 177, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~189.—The method of claim 188, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~190.—The method of claim 188, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~191.—The method of claim 177, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S protein of SARS-CoV-2.~~

~~192.—The method of claim 177, further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified mRNA BNT162b2 Tozinameran (INN) (Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1-nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2) Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800~~

~~(Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.~~

193.—~~The method of claim 192, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

194.—~~The method of any of claims 177-193, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

195.—~~The method of claim 177, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

196.—~~A method for preventing and/or treating cytokine release syndrome (CRS) and/or toxicity induced by CRS in a subject in need thereof, the method comprising administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of a GM-CSF antagonist, wherein the pharmaceutical composition is administered at a dose of from 1200 mg to 1800 mg over 24 hours.~~

197.—~~The method of claim 196, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

198.—~~The method of claim 196, wherein the GM-CSF antagonist is administered at a dose of 400 mg every 8 hours for a total of three doses over 24 hours for three days.~~

~~199.—The method of claim 196, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~200.—The method of claim 196, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours.~~

~~201.—The method of claim 196, wherein the GM-CSF antagonist is administered at a dose of 1800 mg as a single dose for one day.~~

~~202.—The method of claim 196, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~203.—The method of claim 196, wherein the toxicity induced by CRS is ARDS, myocarditis, Kawasaki's Disease, Kawasaki Shock Syndrome, Multisystem Inflammatory Syndrome in Children (MIS-C), encephalopathy, and disseminated intravascular coagulation (DIC).~~

~~204.—The method of claim 196, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~205.—The method of claim 196, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~206.—The method of claim 196, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~207.—The method of claim 196, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~208.—The method of claim 196, further comprising administering a therapeutically effective amount of an anti-viral agent.~~

~~209.—The method of claim 208, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~210.—The method of claim 208, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the~~

~~SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~211. The method of claim 208, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~212. The method of claim 211, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~213. The method of claim 211, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~214. The method of claim 208, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor-binding domain (RBD) of S-protein of SARS-CoV-2.~~

~~215. The method of claim 196, further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified mRNA BNT162b2 Tozinameran (INN) (Pfizer BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-~~

~~CoV-2 Vaccine (Vero-Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.~~

216.—~~The method of claim 215, wherein the GM-CSF antagonist is neutralizing anti hGM-CSF antibody Lenzilumab.~~

217.—~~The method of any of claims 196-216, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

218.—~~The method of claim 196, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

219.—~~A method for preventing and/or treating cytokine release syndrome (CRS) and/or toxicity induced by CRS in a subject in need thereof, the method comprising administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of a GM-CSF antagonist, wherein the pharmaceutical composition is administered at a dose of from 1200 mg to 1800 mg over 24 hours, and a therapeutically effective amount of anti-viral agent.~~

220.—~~The method of claim 219, wherein the GM-CSF antagonist is neutralizing anti hGM-CSF antibody Lenzilumab.~~

~~221.—The method of claim 219, wherein the GM-CSF antagonist is administered at a dose of 400 mg every 8 hours for a total of three doses over 24 hours for three days.~~

~~222.—The method of claim 219, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~223.—The method of claim 219, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours.~~

~~224.—The method of claim 219, wherein the GM-CSF antagonist is administered at a dose of 1800 mg as a single dose for one day.~~

~~225.—The method of claim 219, wherein the toxicity induced by CRS is ARDS, myocarditis, Kawasaki's Disease, Kawasaki Shock Syndrome, Multisystem Inflammatory Syndrome in Children (MIS-C), encephalopathy, and disseminated intravascular coagulation (DIC).~~

~~226.—The method of claim 219, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~227.—The method of claim 219, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~228.—The method of claim 219, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~229.—The method of claim 219, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~230.—The method of claim 219, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~231. The method of claim 219, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~232. The method of claim 231, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~233. The method of claim 231, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~234. The method of claim 219, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S protein of SARS-CoV-2.~~

~~235. The method of claim 219, further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified mRNA BNT162b2 Tozinameran (INN) (Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800~~

(Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.

236.—The method of claim 235, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.

237.—The method of any of claims 219-236, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.

238.—The method of claim 219, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.

23910. A method for treating a subject infected with a coronavirus (SARS-CoV-2) comprising administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of a GM-CSF antagonist The use of claim 6, wherein the pharmaceutical composition comprises the GM-CSF antagonist is administered at a dose of from 1200 mg to 1800 mg for administration over 24 hours, and a therapeutically effective amount of an oxygen transporter.

24011. The method-use of claim 23910, wherein the oxygen transporter is BXT25.

241.—The method of claim 239, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.

~~242~~12. The ~~method-use~~ of claim ~~239~~10, wherein the pharmaceutical composition comprises the GM-CSF antagonist ~~is administered~~ at a dose of 400 mg for administration every 8 hours for a total of three doses over 24 hours for three days;

wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 600 mg for administration every 8 hours for a total of three doses over 24 hours for one day;

wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 800 mg for administration every 12 hours for a total of two doses over 24 hours; or

wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 1800 mg for administration as a single dose for one day.

~~243. The method of claim 239, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~244. The method of claim 239, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours.~~

~~245. The method of claim 239, wherein the GM-CSF antagonist is administered at a dose of 1800 mg as a single dose for one day.~~

~~246. The method of claim 239, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~247. The method of claim 239, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~248. The method of claim 239, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~249~~13. The ~~method-use~~ of claim ~~239~~10, ~~further comprising administering wherein the medicament is to be administered with~~ a therapeutically effective amount of an anti-viral agent;

wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;

wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555;

wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug; wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia); wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.

~~250.— The method of claim 249, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin-mimetic Brilacidin, CCR5-antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~251.— The method of claim 249, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~252.— The method of claim 249, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~253.— The method of claim 252, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~254.— The method of claim 252, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

25514. The ~~method-use~~ of claim 23910, ~~further comprising administering to the subject wherein the medicament is to be administered with~~ a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified ~~mNRA-mRNA~~ BNT162b2 Tozinameran (INN) (Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof;

a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2

inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2;

a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject; and/or

wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody lenzilumab.

~~256. The method of claim 255, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~257. The method of any of claims 239–256, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~258. The method of claim 239, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~259. A method for treating and/or preventing inflammation-induced lung injury in a subject infected with a coronavirus (SARS-CoV-2) comprising administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of a GM-CSF antagonist, wherein the pharmaceutical composition is administered at a dose of from 1200 mg to 1800 mg over 24 hours, and a therapeutically effective amount of an oxygen transporter.~~

~~260. The method of claim 259, wherein the oxygen transporter is BXT25.~~

~~261. The method of claim 259, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~262. —The method of claim 259, wherein the GM-CSF antagonist is administered at a dose of 400 mg every 8 hours for a total of three doses over 24 hours for three days.~~

~~263. —The method of claim 259, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~264. —The method of claim 259, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours for one day.~~

~~265. —The method of claim 259, wherein the GM-CSF antagonist is administered at a dose of 1800 mg as a single dose for one day.~~

~~266. —The method of claim 259, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~267. —The method of claim 259, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~268. —The method of claim 259, wherein the GM-CSF antagonist is anti GM-CSF receptor antibody Mavrilimumab.~~

~~269. —The method of claim 259, further comprising administering a therapeutically effective amount of an anti-viral agent.~~

~~270. —The method of claim 269, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482/EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~271. —The method of claim 269, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~272. —The method of claim 269, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~273.—The method of claim 272, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~274.—The method of claim 272, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~275.—The method of claim 259, further comprising administering to the subject a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified mRNA BNT162b2 Tozinameran (INN) (Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1-nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof.~~

~~276. The method of claim 275, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~277. The method of any of claims 259-276, further comprising administering to the subject a therapeutically effective amount of (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~278. The method of claim 259, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~279~~15. Use of a GM-CSF antagonist in the manufacture of a medicament~~A method~~ for predicting and preventing a cytokine release syndrome (CRS) and/or inflammation-induced lung injury (ARDS) in a subject infected with 2019 coronavirus (SARS-CoV-2), wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody lenzilumab; wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234); wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002; or wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab; ~~the method-use further~~ comprising:

- a) measuring a level of oxygen saturation by pulse oximetry (SpO₂) of the subject and/or
- b) performing a chest x-ray or computed tomography (CT) scan,

wherein a measured level of the SpO₂ of $\leq 94\%$ and/or presence of airspace opacity on chest x-ray or ground-glass opacity on CT scan indicate the subject has COVID-19 pneumonia, and

(i) the subject has CRS or is at high risk of developing CRS; and/or

(ii) the subject has a severe risk factor for developing ARDS,

wherein the subject has CRS or is at high risk of developing CRS, wherein the high risk of developing CRS is a risk that is 2.3 times greater than the risk of developing CRS when a measured

level of the SpO₂ is > 94% and/or the subject does not have dyspnea and/or has clear lungs on chest x-ray or on CT scan, and/or the subject has the severe risk for developing ARDS, wherein the severe risk for developing ARDS is 2.3 times greater than the risk for developing ARDS when a measured level of the SpO₂ is > 94% and/or the subject does not have dyspnea and/or has clear lungs on chest x-ray or on CT scan; and

c) ~~administering—wherein a pharmaceutical composition comprising a therapeutically effective amount of a GM-CSF antagonist is to be administered~~ to (i) the subject having CRS or at high risk of developing CRS and/or (ii) the subject having the severe risk factor for developing ARDS ~~a pharmaceutical composition comprising a therapeutically effective amount of a GM-CSF antagonist~~, wherein the pharmaceutical composition comprises the GM-CSF antagonist ~~is administered at~~ a dose of from 1200 mg to 1800 mg for administration over 24 hours.

~~280.—The method of claim 279, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~281~~16. The ~~method use~~ of claim ~~279~~15, wherein the pharmaceutical composition comprises the GM-CSF antagonist ~~is administered~~ at a dose of 400 mg for administration every 8 hours for a total of three doses over 24 hours for three days;

wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 600 mg for administration every 8 hours for a total of three doses over 24 hours for one day; or

wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 800 mg for administration every 12 hours for a total of two doses over 24 hours.

~~282.—The method of claim 279, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~283.—The method of claim 279, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours.~~

~~284.—The method of claim 279, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~285.—The method of claim 279, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~286.—The method of claim 279, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

~~287~~17. ~~The method use of claim 279~~15, ~~further comprising administering wherein the medicament is to be administered with~~ a therapeutically effective amount of an anti-viral agent;

~~wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;~~

~~wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555;~~

~~wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug; wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia); wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat;~~

~~wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S-protein of SARS-CoV-2.~~

~~288.—The method of claim 287, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~289.—The method of claim 287, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the~~

~~SARS-CoV-2 spike protein wherein the mAbs comprise REGN COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~290. The method of claim 287, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~291. The method of claim 290, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~292. The method of claim 290, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~293. The method of claim 287, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S-protein of SARS-CoV-2.~~

29418. The method-use of claim 27915, further comprising administering to the subject wherein the medicament is to be administered with a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified ~~mRNA~~ mRNA BNT162b2 Tozinameran (INN) (Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom,

China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof;

a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2;

a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject; and/or

wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody lenzilumab.

295. — ~~The method of claim 294, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

296. — ~~The method of any of claims 279-295, further comprising administering to the subject a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~297. The method of claim 279, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~29819. Use of a GM-CSF antagonist in the manufacture of a medicament~~A method for reducing time to recovery of a subject infected with 2019 coronavirus (SARS-CoV-2) and alleviating the immune-mediated CRS in the subject, wherein the method comprising administering to the subject medicament comprises a pharmaceutical composition comprising a therapeutically effective amount of a the GM-CSF antagonist, wherein the pharmaceutical composition ~~is administered~~ atcomprises a dose of from 1200 mg to 1800 mg for administration over 24 hours, wherein the time to recovery of the subject is reduced by at least 33% compared to time to recovery of a second subject administered a therapeutically effective amount of an antiviral agent without administration of a GM-CSF antagonist; wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody lenzilumab, Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234); wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab; or wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.

~~299. The method of claim 298, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~30020. The method-use~~ of claim ~~29819~~, wherein the pharmaceutical composition comprises the GM-CSF antagonist ~~is administered~~ at a dose of 400 mg for administration every 8 hours for a total of three doses over 24 hours for three days;

wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 600 mg for administration every 8 hours for a total of three doses over 24 hours for one day;

wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 800 mg for administration every 12 hours for a total of two doses over 24 hours for one day; or

wherein the pharmaceutical composition comprises the GM-CSF antagonist at a dose of 1800 mg for administration as a single dose for one day.

~~301. The method of claim 298, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~302.—The method of claim 298, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours for one day.~~

~~303.—The method of claim 298, wherein the GM-CSF antagonist is administered at a dose of 1800 mg as a single dose for one day.~~

~~304.—The method of claim 298, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002.~~

~~305.—The method of claim 298, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~306.—The method of claim 298, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

30721. The method use of claim 29819, further comprising administering wherein the medicament is to be administered with a therapeutically effective amount of an anti-viral agent;

wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;

wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555;

wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug; wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia); wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat; and/or

wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S-protein of SARS-CoV-2.

~~308. The method of claim 307, wherein the anti-viral agent is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~309. The method of claim 307, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~310. The method of claim 307, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~311. The method of claim 310, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimune; Aluvia).~~

~~312. The method of claim 310, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~313. The method of claim 307, wherein the anti-viral agent is SARS-CoV neutralizing antibody CR3022 that binds and neutralizes a receptor binding domain (RBD) of S-protein of SARS-CoV-2.~~

31422. The method-use of claim 29819, wherein the antiviral agent administered for administration to the second subject is selected from the group consisting of Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Remdesivir (GS-5734), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;

wherein the antiviral agent administered to the second subject comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV, wherein the

mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555;

wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug; wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia); wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.

~~315. The method of claim 298, wherein the antiviral agent administered to the second subject comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS CoV, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS CoV 2 spike protein wherein the mAbs comprise REGN COV2 (casirivimab and imdevimab), BGB DXP593, CT P59, VIR 7831, LY CoV016, and LY CoV555.~~

~~316. The method of claim 298, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~317. The method of claim 316, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~318. The method of claim 316, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~319~~23. The ~~method~~use of claim ~~298~~19, wherein the GM-CSF antagonist is lenzilumab and the antiviral agent administered to the second subject is Remdesivir (GS-5734), and wherein the time to recovery of the subject is reduced by at least 50% compared to the time to recovery of the second subject administered the therapeutically effective amount of the antiviral agent without administration of lenzilumab; or

wherein the GM-CSF antagonist is lenzilumab and the antiviral agent administered to the second subject is a combination of lopinavir and ritonavir (Lopimune; Aluvia), and wherein the time to recovery of the subject is reduced by at least 50% compared to the time to recovery of the second subject administered the therapeutically effective amount of the antiviral agent without administration of lenzilumab.

~~320. The method of claim 298, wherein the GM-CSF antagonist is lenzilumab and the antiviral agent administered to the second subject is a combination of lopinavir and ritonavir (Lopimune; Aluvia), and wherein the time to recovery of the subject is reduced by at least 50% compared to the time to recovery of the second subject administered the therapeutically effective amount of the antiviral agent without administration of lenzilumab.~~

~~321~~24. The ~~method use~~ of claim 298~~19~~, ~~further comprising administering to the subject wherein the medicament is to be administered with~~ a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified ~~mNRA-mRNA~~ BNT162b2 Tozinameran (INN) (Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COV2.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of

the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof;

a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2;

a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject; and/or

wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody lenzilumab.

~~322. The method of claim 321, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~323. The method of any of claims 298-322, further comprising administering to the subject a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~324. The method of claim 298, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

325. Use of a GM-CSF antagonist in the manufacture of a medicament ~~A method~~ for reducing time to clinical improvement or time to recovery of a subject infected with 2019 coronavirus (SARS-CoV-2), wherein the medicament comprises~~the method comprising administering to the subject~~ a pharmaceutical composition comprising a therapeutically effective amount of ~~a~~the GM-CSF antagonist, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody lenzilumab, Namilumab, Otilimab, Gimsilumab, or TJM2 (TJ003234); anti-GM-CSF receptor antibody Mavrilimumab; chimeric GM-CSF neutralizing antibody KB002 or mouse antibody LMM102, wherein the time to clinical improvement or time to recovery of the subject is reduced by at least 40% compared to the time to clinical improvement or time to recovery of a control subject treated with standard of care and is not administered a GM-CSF antagonist, wherein the subject and the control subject each have severe or critical COVID-19 pneumonia;

wherein the clinical improvement comprises at least two points on an 8-point ordinal clinical outcome scale and time to recovery comprises obtaining/reaching a 6, 7, or 8 score wherein the 8-point ordinal outcome scale is a clinical status of the subject consisting of scores: 1) death; 2) hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO); 3) hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) hospitalized, requiring supplemental oxygen; 5) hospitalized, not requiring supplemental oxygen and requiring ongoing medical care; 6) hospitalized, not requiring supplemental oxygen and no longer requiring ongoing medical care; 7) not hospitalized and having a limitation of activities; and 8) not hospitalized and having no limitations of activities; and

wherein the COVID-19 pneumonia is severe COVID-19 pneumonia as determined by radiographic assessment or by low-flow oxygen requirement or wherein the COVID-19 pneumonia is critical COVID-19 pneumonia as determined by the need for high-flow oxygen or non-invasive positive pressure ventilation support.

326. —~~The method of claim 325, wherein the clinical improvement comprises at least two points on an 8 point ordinal clinical outcome scale and time to recovery comprises obtaining/reaching a 6, 7, or 8 score wherein the 8 point ordinal outcome scale is a clinical status of the subject consisting of scores: 1) death; 2) hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO); 3) hospitalized, on non invasive ventilation or high flow oxygen devices; 4) hospitalized, requiring supplemental oxygen; 5) hospitalized, not requiring~~

~~supplemental oxygen and requiring ongoing medical care; 6) hospitalized, not requiring supplemental oxygen and no longer requiring ongoing medical care; 7) not hospitalized and having a limitation of activities; and 8) not hospitalized and having no limitations of activities.~~

~~32726. The method-use of claim 32525, wherein medical care of the standard of care is COVID-19 related medical care and/or medical care not related to COVID-19;~~

~~wherein the standard of care of the control subject comprises administration of a therapeutically effective amount of an anti-viral agent, a steroid, hydroxychloroquine (HCQ), an anti-interleukin-6 (IL-6) receptor monoclonal antibody, azithromycin, an immunoglobulin, intravenous immunoglobulin (IVIG), a convalescent plasma comprising COVID 19 immune serum, a statin, and combinations thereof;~~

~~wherein the anti-viral agent comprises Remdesivir (GS-5734), GS-441524, ribavirin, Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist leronlimab (PRO140), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;~~

~~wherein the anti-IL6 receptor monoclonal antibody comprises tocilizumab or sarilumab; and/or~~

~~wherein the IVIG comprises human immune globulin g.~~

~~328. The method of claim 325, wherein the standard of care of the control subject comprises administration of a therapeutically effective amount of an anti-viral agent, a steroid, hydroxychloroquine (HCQ), an anti-interleukin-6 (IL-6) receptor monoclonal antibody, azithromycin, an immunoglobulin, intravenous immunoglobulin (IVIG), a convalescent plasma comprising COVID-19 immune serum, a statin, and combinations thereof.~~

~~329. The method of claim 328, wherein the anti-viral agent comprises Remdesivir (GS-5734), GS-441524, ribavirin, Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist leronlimab (PRO140), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~330. The method of claim 328, wherein the anti-IL6 receptor monoclonal antibody comprises tocilizumab or sarilumab.~~

~~331. The method of claim 328, wherein the IVIG comprises human immune globulin g.~~

33227. The ~~method-use~~ of claim 32525, wherein ratio of oxygen saturation by pulse oximetry (SpO_2) to fraction of inspired oxygen (FiO_2) of the subject administered the GM-CSF antagonist improves within one day of administration of the GM-CSF antagonist compared to the (SpO_2)/(FiO_2) of the control subject;

wherein acute respiratory distress syndrome (ARDS) of the subject administered the GM-CSF antagonist improves within one day of administration of the GM-CSF antagonist and ARDS is reduced over time by at least day 4 post-GM-CSF antagonist administration compared to the ARDS improvement and reduction over time by at least day 4 of the control subject, wherein reduction in the ARDS comprises a change in a ratio of $\text{SpO}_2/\text{FiO}_2$ from less than 315 to a ratio of $\text{SpO}_2/\text{FiO}_2$ 315 or higher;

wherein an elevated serum C-reactive protein (CRP) level of the subject administered the GM-CSF antagonist is reduced by at least 50% within one to two days of administration of the GM-CSF antagonist compared to reduction in the elevated serum CRP level, over the same timeframe, in the control subject, wherein the elevated serum CRP level is above the upper limit of normal (>8.0 mg/L);

wherein the change in absolute lymphocyte counts (ALC) of the subject administered the GM-CSF antagonist are at least 1000-fold greater compared to the ALC of the control subject;

wherein time to discharge of the subject is 40%-50% faster in the subject administered the GM-CSF antagonist compared to the time to discharge of the control subject;

wherein serum IL-6 concentration of the subject administered the GM-CSF antagonist is reduced by at least 50% in the subject on or by day 4 after administration of the GM-CSF antagonist compared to the reduction in the serum IL-6 concentration of the subject on or by day 4 of the control subject;

wherein incidence of invasive mechanical ventilation (IMV) and/or death of the subject administered the GM-CSF antagonist is reduced by 80% on a relative basis and is reduced by 33% on an absolute risk reduction compared to the IMV and/or death of the control subject, wherein invasive mechanical ventilation-free survival of a subject administered the GM-CSF antagonist is increased by 40% to 80% on an relative basis compared to the invasive mechanical ventilation-free survival of the control subject; and/or

wherein the time to clinical improvement or time to recovery of the subject administered the GM-CSF antagonist is reduced by at least 50% compared to the time to clinical improvement or time to recovery of a control subject.

~~333.—The method of claim 325, wherein acute respiratory distress syndrome (ARDS) of the subject administered the GM-CSF antagonist improves within one day of administration of the GM-CSF antagonist and ARDS is reduced over time by at least day 4 post-GM-CSF antagonist administration compared to the ARDS improvement and reduction over time by at least day 4 of the control subject, wherein reduction in the ARDS comprises a change in a ratio of SpO₂/FiO₂ from less than 315 to a ratio of SpO₂/FiO₂ 315 or higher.—~~

~~334.—The method of claim 325, wherein an elevated serum C reactive protein (CRP) level of the subject administered the GM-CSF antagonist is reduced by at least 50% within one to two days of administration of the GM-CSF antagonist compared to reduction in the elevated serum CRP level, over the same timeframe, in the control subject, wherein the elevated serum CRP level is above the upper limit of normal (>8.0 mg/L).~~

~~335.—The method of claim 325, wherein the change in absolute lymphocyte counts (ALC) of the subject administered the GM-CSF antagonist are at least 1000-fold greater compared to the ALC of the control subject.~~

~~336.—The method of claim 325, wherein time to discharge of the subject is 40%–50% faster in the subject administered the GM-CSF antagonist compared to the time to discharge of the control subject.~~

~~337.—The method of claim 325, wherein serum IL-6 concentration of the subject administered the GM-CSF antagonist is reduced by at least 50% in the subject on or by day 4 after administration of the GM-CSF antagonist compared to the reduction in the serum IL-6 concentration of the subject on or by day 4 of the control subject.~~

~~338.—The method of claim 325, wherein incidence of invasive mechanical ventilation (IMV) and/or death of the subject administered the GM-CSF antagonist is reduced by 80% on a relative basis and is reduced by 33% on an absolute risk reduction compared to the IMV and/or death of the control subject, wherein invasive mechanical ventilation-free survival of a subject administered~~

~~the GM-CSF antagonist is increased by 40% to 80% on an relative basis compared to the invasive mechanical ventilation-free survival of the control subject.~~

~~339. The method of claim 325, wherein the COVID-19 pneumonia is severe COVID-19 pneumonia as determined by radiographic assessment or by low flow oxygen requirement.~~

~~340. The method of claim 325, wherein the COVID-19 pneumonia is critical COVID-19 pneumonia as determined by the need for high-flow oxygen or non-invasive positive pressure ventilation support.~~

~~341. The method of claim 325, wherein the time to clinical improvement or time to recovery of the subject administered the GM-CSF antagonist is reduced by at least 50% compared to the time to clinical improvement or time to recovery of a control subject.~~

~~342~~28. The ~~method~~use of claim ~~325~~25, wherein the subject administered the GM-CSF antagonist and the control subject each have clinical and/or biomarker evidence for increased risk of progression to respiratory failure;

wherein the clinical evidence for increased risk of progression to respiratory failure comprises fever, CRP > 100 mg/L, lymphocytopenia, hypotension, shock, capillary leak syndrome, pulmonary edema, disseminated intravascular coagulation, a hypoxemia value of arterial oxygen of under 60 mmHg, a pulse oximeter reading (SpO₂) of less than or equal to 94%, the subject requiring supplemental oxygen, a radiological progression of pneumonia shown in chest radiographs as multifocal consolidation and/or shown on CT images as ground-glass opacity, multi-organ dysfunction/failure, and/or ARDS shown radiologically by a diffuse lung damage; and/or

wherein the biomarker evidence for increased risk of progression to respiratory failure comprises abnormal levels of liver enzymes, coagulation markers, albumin, creatinine phosphokinase and lactate dehydrogenase; elevated levels above the upper limit of normal levels of at least one cytokine/chemokine selected from the group consisting of GM-CSF, G-CSF, MCD, IL-1 α , IFN- γ , IL-7, FMS-related tyrosine kinase 3 ligand (FLT-3L), IL-1 α , IL-6, and IL-12p70, MCP-1, IP10, MIP1 α , and MIP1 β ; and/or a ferritin level of > 300 mcg/L.

~~343. The method of claim 342, wherein the clinical evidence for increased risk of progression to respiratory failure comprises fever, CRP > 100 mg/L, lymphocytopenia, hypotension, shock,~~

~~capillary leak syndrome, pulmonary edema, disseminated intravascular coagulation, a hypoxemia value of arterial oxygen of under 60 mmHg, a pulse oximeter reading (SpO₂) of less than or equal to 94%, the subject requiring supplemental oxygen, a radiological progression of pneumonia shown in chest radiographs as multifocal consolidation and/or shown on CT images as ground-glass opacity, multi-organ dysfunction/failure, and/or ARDS shown radiologically by a diffuse lung damage.~~

344. — ~~The method of claim 342, wherein the biomarker evidence for increased risk of progression to respiratory failure comprises abnormal levels of liver enzymes, coagulation markers, albumin, creatinine phosphokinase and lactate dehydrogenase; elevated levels above the upper limit of normal levels of at least one cytokine/chemokine selected from the group consisting of GM-CSF, G-CSF, MCD, IL-1 α , IFN- γ , IL-7, FMS-related tyrosine kinase 3 ligand (FLT-3L), IL-1 α , IL-6, and IL-12p70, MCP-1, IP10, MIP1 α , and MIP1 β ; and/or a ferritin level of > 300 mcg/L.~~

~~345~~29. The ~~method-use~~ of claim ~~325~~, wherein the subject administered the GM-CSF antagonist and the control subject each have at least one risk factor associated with poor outcome selected from the group consisting of age at or over 60 years, smoking history, cardiovascular disease, diabetes, chronic kidney disease, chronic lung disease, high BMI, and at least one elevated biomarker inflammatory marker;

~~wherein the at least one elevated biomarker inflammatory marker comprises CRP, serum ferritin, D-dimer, IL-6 or lactate dehydrogenase;~~

~~wherein the subject and the control subject each require oxygen supplementation without mechanical intervention;~~

346. — ~~The method of claim 325, wherein the at least one elevated biomarker inflammatory marker comprises CRP, serum ferritin, D-dimer, IL-6 or lactate dehydrogenase.~~

347. — ~~The method of claim 325, wherein the subject and the control subject each require oxygen supplementation without mechanical ventilation.~~

~~348~~30. The ~~method-use~~ of claim ~~325~~, wherein the pharmaceutical composition ~~is administered at comprises~~ a total dose of from 1200 mg to 1800 mg over 24 hours;

wherein the GM-CSF antagonist is to be administered at a dose of 400 mg every 8 hours for a total of three doses over 24 hours for three days;

wherein the GM-CSF antagonist is to be administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day;

wherein the GM-CSF antagonist is to be administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours for one day; or

wherein the GM-CSF antagonist is to be administered as a single dose of 1800 mg.

~~349.—The method of claim 325, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~350.—The method of claim 325, wherein the GM-CSF antagonist is administered at a dose of 400 mg every 8 hours for a total of three doses over 24 hours for three days.~~

~~351.—The method of claim 325, wherein the GM-CSF antagonist is administered at a dose of 600 mg every 8 hours for a total of three doses over 24 hours for one day.~~

~~352.—The method of claim 325, wherein the GM-CSF antagonist is administered at a dose of 800 mg every 12 hours for a total of two doses over 24 hours for one day.~~

~~353.—The method of claim 325, wherein the GM-CSF antagonist is administered as a single dose of 1800 mg~~

~~354.—The method of claim 325, wherein the GM-CSF antagonist is chimeric GM-CSF neutralizing antibody KB002 or mouse antibody LMM102.~~

~~355.—The method of claim 325, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~356.—The method of claim 325, wherein the GM-CSF antagonist is anti-GM-CSF receptor antibody Mavrilimumab.~~

35731. The method use of claim 325, wherein the medicament is to be administered with further comprising administering a therapeutically effective amount of an anti-viral agent to the subject administered the GM-CSF antagonist and/or to the control subject;

wherein the anti-viral agent comprises Remdesivir (GS-5734), GS-441524, ribavirin, Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;

wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV or the spike protein of SARS-CoV-2, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555; and/or

wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug; wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia); wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.

~~358. The method of claim 257, wherein the anti-viral agent comprises Remdesivir (GS-5734), GS-441524, ribavirin, Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~359. The method of claim 257, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV or the spike protein of SARS-CoV-2, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~360. The method of claim 257, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~361. — The method of claim 360, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimune; Aluvia).~~

~~362. — The method of claim 360, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~36332. The method-use of claim 35731, wherein the GM-CSF antagonist is lenzilumab and the antiviral agent administered to the subject administered the lenzilumab and/or to the control subject is Remdesivir (GS-5734), and wherein the time to recovery of the subject administered the lenzilumab and the anti-viral agent is reduced by at least 40% compared to the time to recovery of the control subject administered the antiviral agent without administration of lenzilumab; or wherein the time to recovery of the subject administered the lenzilumab and the anti-viral agent is reduced by at least 50% compared to the time to recovery of the control subject; and~~

~~wherein the GM-CSF antagonist is lenzilumab and the antiviral agent administered to the subject administered the lenzilumab and/or to the control subject is a combination of lopinavir and ritonavir (Lopimune; Aluvia), and wherein the time to recovery of the subject administered the lenzilumab and the anti-viral agent is reduced by at least 40% compared to the time to recovery of the control subject administered the antiviral agent without administration of lenzilumab; or wherein the time to recovery of the subject administered the lenzilumab and the anti-viral agent is reduced by at least 50% compared to the time to recovery of the control subject administered the antiviral agent without administration of lenzilumab.~~

~~364. — The method of claim 363, wherein the time to recovery of the subject administered the lenzilumab and the anti-viral agent is reduced by at least 50% compared to the time to recovery of the control subject.~~

~~365. — The method of claim 357, wherein the GM-CSF antagonist is lenzilumab and the antiviral agent administered to the subject administered the lenzilumab and/or to the control subject is a combination of lopinavir and ritonavir (Lopimune; Aluvia), and wherein the time to recovery of the subject administered the lenzilumab and the anti-viral agent is reduced by at least 40% compared to the time to recovery of the control subject administered the antiviral agent without administration of lenzilumab.~~

~~366. The method of claim 365, wherein the time to recovery of the subject administered the lenzilumab and the anti-viral agent is reduced by at least 50% compared to the time to recovery of the control subject administered the antiviral agent without administration of lenzilumab.~~

~~36733. The method use of claim 325, wherein the medicament is to be administered with further comprising administering~~ a therapeutically effective amount of an anti-viral agent, a steroid, hydroxychloroquine (HCQ), azithromycin, an anti-interleukin-6 (IL-6) receptor monoclonal antibody, an immunoglobulin, intravenous immunoglobulin (IVIG), a statin, and/or combinations thereof to the subject administered the GM-CSF antagonist;

wherein the anti-viral agent comprises Remdesivir (GS-5734), GS-441524, ribavirin, Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist leronlimab (PRO140), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;

wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV or SARS-CoV2, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555;

wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug; wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia); wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat; and/or

wherein the IVIG comprises human immune globulin g.

~~368. The method of claim 367, wherein the anti-viral agent comprises Remdesivir (GS-5734), GS-441524, ribavirin, Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist leronlimab (PRO140), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~369. The method of claim 367, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV or SARS-CoV2, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~370. The method of claim 367, wherein the IVIG comprises human immune globulin g.~~

~~371. The method of claim 367, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~372. The method of claim 371, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~373. The method of claim 371, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~37434. The method-use of claim 325, wherein the medicament is to be administered with further comprising to the subject~~ a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified ~~mRNA~~ mRNA BNT162b2 Tozinameran (INN) (Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COVS.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2 Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus

Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof;

a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2;

a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject; and/or wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody lenzilumab.

~~375. —The method of claim 374, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~376. —The method of any of claims 325-375, further comprising administering to the subject a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~377. The method of claim 325, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

~~37835. Use of a GM-CSF antagonist in the manufacture of a medicament A method for treating a subject infected with 2019 coronavirus (SARS-CoV-2) for a time period beyond an initial acute hyper-inflammatory period, wherein the medicament comprises the method comprising administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of thea GM-CSF antagonist, wherein the GM-CSF antagonist is anti-hGM-CSF antibody lenzilumab, Namilumab, Otilimab, Gimsilumab, or TJM2 (TJ003234); or the GM-CSF antagonist is anti-GM-CSF alpha receptor antibody Mavrilimumab;~~

~~wherein the time period beyond the initial acute hyper-inflammatory period is from 21 days to 13 weeks after onset of the initial acute hyper-inflammatory period;~~

~~wherein the initial acute hyper-inflammatory period occurs about 5 to 12 days after onset of symptoms of infection with SARS-CoV-2;~~

~~wherein the symptoms of infection with SARS-CoV-2 occur 2 to 14 day after exposure to SARS-CoV-2, wherein the symptoms of infection with SARS-CoV-2 comprise fever, chills, cough without fever, shortness of breath, difficulty breathing, fatigue, muscle aches, body aches, headache, back ache, loss of taste and/or smell, sore throat, congestion, runny nose, nausea, vomiting, diarrhea, abdominal pain, or combinations thereof.~~

~~379. The method of claim 378, wherein the time period beyond the initial acute hyper-inflammatory period is from 21 days to 13 weeks after onset of the initial acute hyper-inflammatory period.~~

~~380. The method of claim 379, wherein the initial acute hyper-inflammatory period occurs about 5 to 12 days after onset of symptoms of infection with SARS-CoV-2.~~

~~381. The method of claim 380, wherein the symptoms of infection with SARS-CoV-2 occur 2 to 14 day after exposure to SARS-CoV-2, wherein the symptoms of infection with SARS-CoV-2 comprise fever, chills, cough without fever, shortness of breath, difficulty breathing, fatigue,~~

~~muscle aches, body aches, headache, back ache, loss of taste and/or smell, sore throat, congestion, runny nose, nausea, vomiting, diarrhea, abdominal pain, or combinations thereof.~~

~~38236. The method-use of claim 37835, wherein the onset of the initial acute hyper-inflammatory period is determined by plasma of the subject comprising below normal lower level of absolute lymphocyte counts, elevated level of CRP, serum ferritin, D-dimer, IL-6, liver enzymes, albumin, creatinine phosphokinase, lactate dehydrogenase, inflammatory cytokine, troponin, myeloid cells, or combinations thereof;~~

~~wherein the elevated levels of the inflammatory cytokine comprise elevated levels of IL-6, G-CSF, GM-CSF, MCP-1, MIP-1 α , MIP-1 β , MIG, IP-10, MDC, IL-1 α , IL-8, IL-10, IFN- γ , IL-7, FLT-3L, IL-1 α , IL-12p70 or combinations thereof;~~

~~wherein the below normal lower level of absolute lymphocyte counts (ALC) comprises an ALC of $0.95 \times 10^9/L$ or less, wherein the below normal lower level of ALC occurs about 4 to 8 days after onset of symptoms of infection with SARS-CoV-2;~~

~~wherein the elevated levels of the myeloid cells comprise CD14+ myeloid cells;~~

~~wherein the onset of the initial acute hyper-inflammatory period is further determined by the subject having dyspnea and hypoxia, wherein the dyspnea occurs about 5 to 9 days after onset of symptoms of infection with SARS-CoV-2;~~

~~wherein the onset of the initial acute hyper-inflammatory period is further determined by the subject manifesting with Acute Respiratory Distress Syndrome (ARDS), wherein the ARDS occurs about 8 to 12 days after onset of symptoms of infection with SARS-CoV-2; wherein the ARDS further comprises the subject having severe lung inflammation and lung damage;~~

~~wherein the onset of the initial acute hyper-inflammatory period is further determined by abnormal lung computed tomography (CT) scans; and/or~~

~~wherein the onset of the initial acute hyper-inflammatory period is further determined by abnormal lung computed tomography (CT) scans.~~

~~383. The method of claim 382, wherein the elevated levels of the inflammatory cytokine comprise elevated levels of IL-6, G-CSF, GM-CSF, MCP-1, MIP-1 α , MIP-1 β , MIG, IP-10, MDC, IL-1 α , IL-8, IL-10, IFN- γ , IL-7, FLT-3L, IL-1 α , IL-12p70 or combinations thereof.~~

~~384.—The method of claim 382, wherein the below normal lower level of absolute lymphocyte counts (ALC) comprises an ALC of $0.95 \times 10^9/L$ or less, wherein the below normal lower level of ALC occurs about 4 to 8 days after onset of symptoms of infection with SARS-CoV-2.~~

~~385.—The method of claim 382, wherein the elevated levels of the myeloid cells comprise CD14+ myeloid cells.~~

~~386.—The method of claim 382, wherein the onset of the initial acute hyper-inflammatory period is further determined by the subject having dyspnea and hypoxia, wherein the dyspnea occurs about 5 to 9 days after onset of symptoms of infection with SARS-CoV-2.~~

~~387.—The method of claim 382, wherein the onset of the initial acute hyper-inflammatory period is further determined by the subject manifesting with Acute Respiratory Distress Syndrome (ARDS), wherein the ARDS occurs about 8 to 12 days after onset of symptoms of infection with SARS-CoV-2.~~

~~388.—The method of claim 387, wherein the ARDS further comprises the subject having severe lung inflammation and lung damage.~~

~~389.—The method of claim 382, wherein the onset of the initial acute hyper-inflammatory period is further determined by abnormal lung computed tomography (CT) scans.~~

~~390.—The method of claim 378, wherein the GM-CSF antagonist is anti-hGM-CSF antibody lenzilumab.~~

~~39137. The method-use of claim 39035, wherein the pharmaceutical composition is administered at comprises a dose of the GM-CSF antagonist of from 1200 mg to 1800 mg for administration over 24 hours.~~

~~392.—The method of claim 378, wherein the GM-CSF antagonist is an anti-GM-CSF antibody selected from the group consisting of Namilumab, Otilimab, Gimsilumab, and TJM2 (TJ003234).~~

~~393.—The method of claim 392, wherein the pharmaceutical composition is administered at a dose of from 1200 mg to 1800 mg over 24 hours.~~

~~394.—The method of claim 378, wherein the GM-CSF antagonist is anti-GM-CSF alpha receptor antibody Mavrilimumab.~~

~~395. The method of claim 394, wherein the pharmaceutical composition is administered at a dose of from 1200 mg to 1800 mg over 24 hours.~~

~~396~~38. The ~~method-use~~ of claim ~~378~~35, wherein the subject has ARDS, COVID-19 pneumonia, severe hypoxemia, lymphopenia on complete blood count, bilateral infiltrates on chest x-ray, diffuse ground glass opacities on lung CT scan, a bacterial respiratory tract infection, a fungal respiratory tract infection, mild transaminitis on liver function tests or combinations thereof prior to administration of the pharmaceutical composition;

~~wherein the subject is to be administered high-flow supplemental oxygen; wherein the high-flow supplemental oxygen administration is reduced to low-flow nasal cannula after administration of the pharmaceutical composition; and/or~~

~~wherein the subject is to be treated with a standard of care prior to administration of the pharmaceutical composition, where the standard of care comprises administration of an antibacterial agent, an antifungal agent, hydroxychloroquine and zinc, a corticosteroid or combinations thereof.~~

~~397. The method of claim 396, wherein the subject is administered high-flow supplemental oxygen.~~

~~398. The method of claim 378, wherein the subject is treated with a standard of care prior to administration of the pharmaceutical composition, where the standard of care comprises administration of an antibacterial agent, an antifungal agent, hydroxychloroquine and zinc, a corticosteroid or combinations thereof.~~

~~399. The method of claim 398, wherein the high-flow supplemental oxygen administration is reduced to low-flow nasal cannula after administration of the pharmaceutical composition.~~

~~400~~39. The ~~method-use~~ of claim ~~378~~35, wherein time to clinical improvement or time to recovery of the subject is accelerated to one week after administration of the pharmaceutical composition, the recovery comprising improvement in lymphopenia, decreased supplemental oxygen administration from high-flow to low-flow; improved mobility and accelerated time to discharge, compared to a lack of time to clinical improvement or time to recovery of the same subject treated with standard of care for 12 weeks, wherein the same subject was not administered a GM-CSF antagonist during treatment with the standard of care;

wherein the accelerated time to discharge is 16 days after administration of the pharmaceutical composition;

wherein the subject has a comorbidity, wherein the comorbidity comprises age over 65 years, male sex, type II diabetes, hypertension, cardiovascular disease, heart disease, coronary artery disease, obesity, obstructive lung disease, chronic obstructive pulmonary disease, reactive airway disease, chronic kidney disease, kidney transplantation or combinations thereof; and/or

wherein the subject is refractory to corticosteroids.

~~401. The method of claim 400, wherein the accelerated time to discharge is 16 days after administration of the pharmaceutical composition.~~

~~402. The method of claim 378, wherein the subject has a comorbidity, wherein the comorbidity comprises age over 65 years, male sex, type II diabetes, hypertension, cardiovascular disease, heart disease, coronary artery disease, obesity, obstructive lung disease, chronic obstructive pulmonary disease, reactive airway disease, chronic kidney disease, kidney transplantation or combinations thereof.~~

~~403. The method of claim 402, wherein the subject is refractory to corticosteroids.~~

~~40440. The method use of claim 37835, wherein the medicament is to be administered with further comprising administering a therapeutically effective amount of an anti-viral agent to the subject;~~
wherein the anti-viral agent comprises Remdesivir (GS-5734), GS-441524, ribavirin, Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;

wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV or the spike protein of SARS-CoV-2, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555; and/or

wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1

protease and a second drug; wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimune; Aluvia); wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.

~~405. The method of claim 404, wherein the anti-viral agent comprises Remdesivir (GS-5734), GS-441524, ribavirin, Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~406. The method of claim 404, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV or the spike protein of SARS-CoV-2, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~407. The method of claim 404, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~408. The method of claim 407, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimune; Aluvia).~~

~~409. The method of claim 407, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

41041. The method use of claim 37835, wherein the medicament is to be administered with further comprising administering a therapeutically effective amount of an anti-viral agent, a steroid, hydroxychloroquine (HCQ), azithromycin, an anti-interleukin-6 (IL-6) receptor monoclonal antibody, an immunoglobulin, intravenous immunoglobulin (IVIG), a statin, and/or combinations thereof to the subject;

wherein the anti-viral agent comprises Remdesivir (GS-5734), GS-441524, ribavirin, Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof;

wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV or SARS-CoV2, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555; and /or

wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug; wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia); wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat; and/or

wherein the IVIG comprises human immune globulin g.

~~411. — The method of claim 410, wherein the anti-viral agent comprises Remdesivir (GS-5734), GS-441524, ribavirin, Aribidol (umifenovir), Favilavir, APN01, defensin mimetic Brilacidin, CCR5 antagonist Ieronlimab (PRO140), Galidesivir (BCX4430), Molnupiravir (MK-4482 / EIDD-2801), MK-7110 (CD24Fc) and combinations thereof.~~

~~412. — The method of claim 410, wherein the anti-viral agent comprises a combination of fully human neutralizing monoclonal antibodies (mAb) against S-protein of MERS-CoV or SARS-CoV2, wherein the mAbs comprise REGN3048 and RG3051 or neutralizing monoclonal antibodies against the SARS-CoV-2 spike protein wherein the mAbs comprise REGN-COV2 (casirivimab and imdevimab), BGB-DXP593, CT-P59, VIR-7831, LY-CoV016, and LY-CoV555.~~

~~413. — The method of claim 410, wherein the IVIG comprises human immune globulin g.~~

~~414. The method of claim 410, wherein the anti-viral agent comprises a combination of antiretroviral drugs, wherein each of the antiretroviral drugs is an inhibitor of HIV-1 protease, or a combination of the inhibitor of HIV-1 protease and a second drug.~~

~~415. The method of claim 414, wherein the inhibitor of HIV-1 protease is lopinavir or a combination of lopinavir and ritonavir (Lopimmune; Aluvia).~~

~~416. The method of claim 414, wherein the combination of the inhibitor of HIV-1 protease and the second drug comprises inhibitor of HIV-1 protease, darunavir, and the second drug is an inhibitor of human CYP3A proteins, wherein the inhibitor of human CYP3A proteins is cobicistat.~~

~~41742. The method use of claim 37835, wherein the medicament is to be administered with further comprising to the subject~~ a therapeutically effective amount of an anti-SARS-CoV-2 vaccine selected from the group consisting of an intranasal SARS-CoV-2 vaccine (Altimmune), INO-4800 (Inovio Pharma and Beijing Advaccine Biotechnology Company), APN01 (APEIRON Biologics), mRNA-1273 vaccine (Moderna and the Vaccine Research Center), nucleoside modified ~~mNRA~~ mRNA BNT162b2 Tozinameran (INN) (Pfizer-BioNTech), adenovirus-based vaccine AZD1222 (recombinant ChAdOx1 adenoviral vector encoding the SARS-CoV-2 spike protein antigen; Oxford-AstraZeneca), Covishield (ChAdOx1_nCoV19) recombinant ChAdOx1 adenoviral vector encoding SARS-CoV-2 spike protein antigen (Serum Institute of India), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm / BIBP), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinovac), Ad26.COVS.S recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding SARS-CoV-2) Spike (S) protein (Janssen Pharmaceuticals Companies of Johnson & Johnson), Sputnik V Human Adenovirus Vector-based Covid-19 vaccine (The Gamaleya National Center), Ad5-nCoV Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (CanSinoBIO), EpiVacCorona Peptide antigen vaccine (Vector State Research Centre of Virology and Biotechnology, Russia), Recombinant Novel Coronavirus Vaccine (CHO) (Zhifei Longcom, China), SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (IMBCAMS, China), Inactivated SARS-CoV-2 Vaccine (Vero Cell) (Sinopharm / WIBP), an avian coronavirus infectious bronchitis virus (IBV) vaccine (MIGDAL Research Institute), a modified horsepox virus vaccine TNX-1800 (Tonix Pharmaceuticals), a recombinant subunit vaccine based on trimeric S protein (S-Trimer) of the SARS-CoV-2 coronavirus (Clover Pharmaceuticals), an oral recombinant coronavirus vaccine (Vaxart), a linear DNA vaccine based

on (i) the entire spike gene of the coronavirus or (ii) based on the antigenic portions of the coronavirus protein (Applied DNA Sciences and Takis Biotech), SARS-Cov-2 coronavirus vaccine NVX-CoV2373 (Novavax), an intramuscular vaccine INO-4700 (GLS-5300) (Inovio Pharma and GeneOne Life Science), and combinations thereof;

a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2;

a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject; and/or

wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody lenzilumab.

~~418.—The method of claim 417, wherein the GM-CSF antagonist is neutralizing anti-hGM-CSF antibody Lenzilumab.~~

~~419.—The method of any of claims 378-418, further comprising administering to the subject a therapeutically effective amount of a (1) a convalescent plasma, wherein the convalescent plasma is collected from (i) a second subject who is recovered from an infection with the SARS-CoV-2 or (ii) a pooled convalescent plasma from a plurality of subjects who are recovered from an infection with the SARS-CoV-2 or (2) purified immunoglobulins (pIVIg) from a SARS-CoV-2 inoculated transgenic animal that produces human immunoglobulins and the pIVIg contains polyclonal human antibodies to SARS-CoV-2.~~

~~420.—The method of claim 378, further comprising administering a therapeutically effective amount of a toll-like receptor (TLR) agonist, wherein the TLR agonist is a TLR7 agonist (vesatolimod or imiquimod), and/or a TLR8 agonist (cpd14b or DN052), or a TLR7/8 dual agonist (motolimod (VTX-2337) or selgantolimod (GS-9688)), to a male subject.~~

42143. The ~~method-use~~ of claim 32525, wherein relative risk of invasive mechanical ventilation (IMV) and/or death of the subject administered the GM-CSF antagonist is reduced by 30% or more compared to the IMV and/or death of the invasive mechanical ventilation-free survival of control subject treated with standard of care and not administered a GM-CSF antagonist.