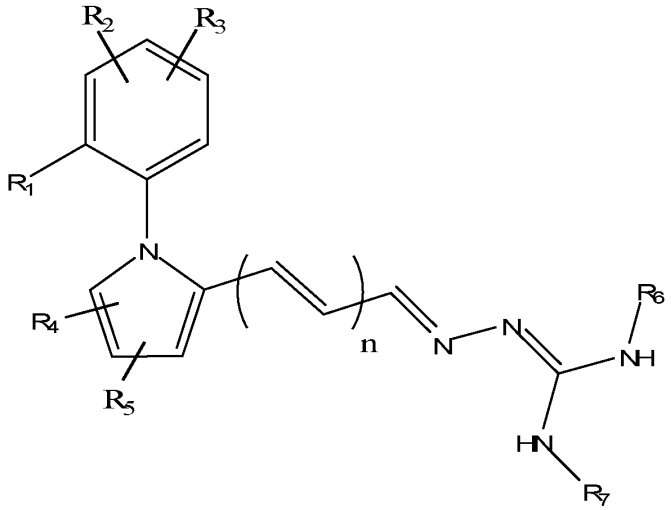
Claims

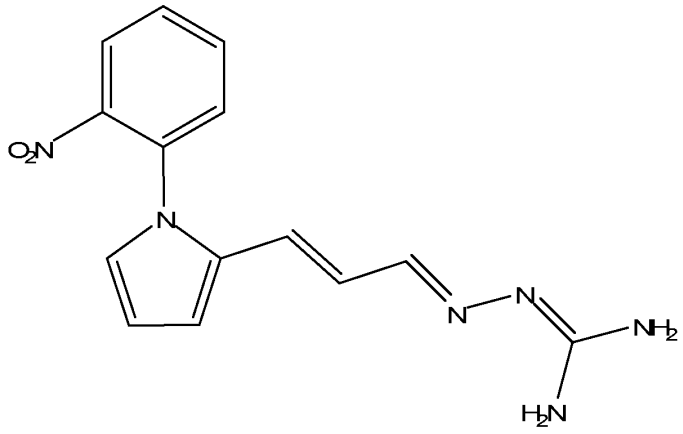
1. A composition comprising a compound of formula (I):



formula (I)

including tautomeric and stereoisomeric forms thereof; wherein n is 1; and R1 is CF3, CCl3, F, Cl, NO2 or CN, and R2, R3, R4, R5, R6, and R7 are hydrogen; or a pharmaceutically acceptable derivative thereof,
for use in the treatment of viral diseases or disorders.

2. The composition for the use according to claim 1, wherein the compound is of formula (II):



formula (II)

including tautomeric and stereoisomeric forms thereof; or a pharmaceutically acceptable derivative thereof.

3. The composition for use according to any of the preceding claims, wherein said compound is selected from the group consisting of {3-[1-(2-nitrophenyl)-1H-pyrrol-2-yl]-allylidene}-aminoguanidine and (*E*)-*N*-*trans*-{3-[1-(2-nitrophenyl)-1H-pyrrol-2-yl]-allylidene}-aminoguanidine, or a pharmaceutically acceptable salt thereof.

4. The composition for use according to any of the preceding claims, wherein said pharmaceutically acceptable derivative thereof is a pharmaceutically acceptable salt thereof, such as a pharmaceutically acceptable salt of an inorganic acid or an organic acid.

5. The composition for use according to claim 4, wherein said organic acid is selected from the group consisting of: formic acid, acetic acid, trichloroacetic acid, trifluoroacetic acid, propionic acid, benzoic acid, cinnamic acid, citric acid, fumaric acid, glycolic acid, lactic acid, maleic acid, malic acid, malonic acid, mandelic acid, oxalic acid, picric acid, pyruvic acid, salicylic acid, succinic acid, methanesulfonic acid, ethanesulfonic acid, tartaric acid, ascorbic acid, pamoic acid, bismethylene salicylic acid, ethanedisulfonic acid, gluconic acid, citraconic acid, aspartic acid, stearic acid, palmitic acid, EDTA, glycolic acid, p-aminobenzoic acid, glutamic acid, benzenesulfonic acid and p-toluenesulfonic acid.

6. The composition for use according to any claims 4 to 5, wherein said organic acid is acetic acid, succinic acid, tartaric acid or propionic acid.

7. The composition for use according to claim 4, wherein said inorganic acid is selected from the group consisting of: hydrochloric acid, hydrobromic acid, hydroiodic acid, phosphoric acid, sulphuric acid and nitric acid.

8. The composition for use according to claim 6, wherein said organic acid is acetic acid.

9. The composition for use according to any of the preceding claims, wherein said compound is selected from the group consisting of {3-[1-(2-nitrophenyl)-1H-pyrrol-2-yl]-allylidene}-aminoguanidinium acetate and (*E*)-*N*-*trans*-{3-[1-(2-nitrophenyl)-1H-pyrrol-2-yl]-allylidene}-aminoguanidinium acetate.

10. The composition for use according to any of the preceding claims, wherein said compound is (*E*)-*N*-*trans*-{3-[1-(2-nitrophenyl)-1H-pyrrol-2-yl]-allylidene}-aminoguanidinium acetate (AP1189).

11. The composition for use according to any of the preceding claims, wherein said compound:
    i) is an agonist of one or more MC receptors,
    ii) is an agonist of the MC1R and MC3R, and/or
    iii) is a biased agonist of the MC1R and MC3R.

12. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is symptomatic viral diseases and disorders.

13. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is symptomatic COVID-19.

14. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 comprise one or more respiratory symptoms.

15. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 comprise one or more respiratory symptoms selected from the group consisting of cough, dry cough, dyspnea, respiratory illness, respiratory dysfunction, respiratory failure, respiratory syndrome and 2019-nCoV acute respiratory disease (2019-nCoV ARD).

16. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 comprise viral pneumonia, including mild pneumonia, pneumonia, pneumonia with abnormal findings and novel coronavirus pneumonia (NCP).

17. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 is severe disease.

18. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 is critical disease.

19. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 present with elevated levels of one or more pro-inflammatory cytokines, such as IL-6 and/or IL-1β.

20. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 is COVID-19 with respiratory failure.

21. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 is COVID-19 with acute respiratory distress syndrome (ARDS).

22. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 is COVID-19 with systemic inflammatory distress syndrome (SIDS).

23. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 require mechanical ventilation.

24. The composition for use according to any of the preceding claims, wherein said symptomatic COVID-19 is COVID-19 induced pulmonary insufficiency

25. The composition for use according to any of the preceding claims, wherein said COVID-19 induced pulmonary insufficiency is defined as a need for supplementary oxygen to maintain normal saturation.

26. The composition for use according to any of the preceding claims, wherein said COVID-19 induced pulmonary insufficiency is defined as SaPO2 lower than 93% on spontaneous respiration.

27. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders are inflammatory viral diseases or disorders, such as virally induced inflammatory conditions, such as virally induced inflammation, such as virally induced hyperinflammation.

28. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is virally induced inflammation in one or more organs, such as virally induced hyperinflammation in one or more organs.

29. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is viral diseases or disorders with local inflammation or with a local inflammatory condition, such as a local inflammatory condition in one or more organs.

30. The composition for use according to any of the preceding claims, wherein said hyperinflammation is characterized as C-reactive protein (CRP) >100 mg/l or ferritin 900 ng/ml.

31. The composition for use according to any of the preceding claims, wherein said one or more organs are selected from the group consisting of lungs, the respiratory tract, kidney, liver, pancreas, spleen, exocrine glands, endocrine glands, lymph nodes, brain, heart, muscles, bone marrow, skin, skeleton, bladder, reproduction organs including the phallopian tubes, eye, ear, vascular system, the gastroinstestinal tract including small intestines, colon, rectum, canalis analis and the prostate gland.

32. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with inflammation in the respiratory system, such as in the lungs and/or respiratory tract.

33. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with one or more respiratory symptoms.

34. The composition for use according to any of the preceding claims, wherein said one or more respiratory symptoms are selected from the group consisting of cough, dry cough, dyspnea, impaired oxygenation, respiratory illness, respiratory dysfunction, respiratory failure, respiratory syndrome and acute respiratory disease (ARD).

35. The composition for use according to any of the preceding claims, wherein said respiratory symptom is respiratory failure.

36. The composition for use according to any of the preceding claims, wherein said respiratory symptom is selected from the group consisting of respiratory failure type 1, respiratory failure type 2, acute respiratory failure and chronic respiratory failure.

37. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is acute respiratory distress syndrome (ARDS).

38. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is severe disease.

39. The composition for use according to any of the preceding claims, wherein said severe disease present with one or more of dyspnoea, increased respiratory frequency, reduced blood oxygen saturation and/or lung infiltrates.

40. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is critical disease.

41. The composition for use according to any of the preceding claims, wherein said critical disease present with one or more of respiratory failure, septic shock, and/or multiple organ dysfunction (MOD) or multiple organ failure (MOF).

42. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is viral bronchiolitis.

43. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is viral pneumonia.

44. The composition for use according to any of the preceding claims, wherein said viral pneumonia is selected from the group consisting of mild pneumonia, pneumonia, and pneumonia with abnormal findings.

45. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is pulmonary insufficiency.

46. The composition for use according to any of the preceding claims, wherein said pulmonary insufficiency is defined as a need for supplementary oxygen to maintain normal saturation.

47. The composition for use according to any of the preceding claims, wherein said pulmonary insufficiency is defined as $SaPO_2$ lower than 93% on spontaneous respiration.

48. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders require mechanical ventilation.

49. The composition for use according to any of the preceding claims, wherein said mechanical ventilation include protective mechanical ventilation, high-flow nasal oxygen (HFNO) and non-invasive ventilation (NIV).

50. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is viral diseases or disorders with systemic inflammation.

51. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is systemic inflammatory distress syndrome (SIDS).

52. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is acute respiratory distress syndrome (ARDS) and systemic inflammatory distress syndrome (SIDS).

53. The composition for use according to any of the preceding claims, wherein said treatment reduces the time to recovery.

54. The composition for use according to any of the preceding claims, wherein said treatment promotes inflammatory resolution.

55. The composition for use according to any of the preceding claims, wherein said treatment reduce the risk of development of severe inflammation

56. The composition for use according to any of the preceding claims, wherein said treatment reduces the risk of development of severe acute respiratory distress syndrome (ARDS).

57. The composition for use according to any of the preceding claims, wherein said treatment reduces the requirement for supplementary oxygen to maintain normal saturation.

58. The composition for use according to any of the preceding claims, wherein said treatment reduces the risk of developing a need for more intensive pulmonary support.

59. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders have elevated levels of one or more cytokines, such as one or more pro-inflammatory cytokines, such as IL-6 and/or IL-1β.

60. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with a cytokine storm (hypercytokinemia).

61. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with multisystem organ failure caused by viral hypercytokinemia.

62. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with cytokine release syndrome (CRS).

63. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with renal inflammation and/or renal dysfunction.

64. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with acute renal failure or chronic renal failure.

65. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with end-stage renal disease.

66. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders are selected from the group consisting of viral kidney infection (pyelonephritis), viral urinary tract infection (UTI) and/or viral kidney inflammation (nephritis).

67. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with bladder infection and/or bladder inflammation (cystitis), such as severe haemorrhagic cystitis or urinary obstruction.

68. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with liver infection and/or liver inflammation (hepatitis), such as acute hepatitis and chronic hepatitis, and liver cirrhosis.

69. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with pancreas infection and/or pancreas inflammation (pancreatitis).

70. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with intestinal infection and/or intestinal inflammation, such as of the small intestine and/or of the large intestine.

71. The composition for use according to any of the preceding claims, wherein said intestinal inflammation is colitis or enteritis.

72. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with brain infection and/or brain inflammation.

73. The composition for use according to any of the preceding claims, wherein said brain inflammation is encephalitis; progressive multifocal leukoencephalopathy (PML); or inflammation of the white matter of the brain at one or multiple locations.

74. The composition for use according to any of the preceding claims, for treatment of viral diseases or disorders with eye infection and/or eye inflammation.

75. The composition for use according to any of the preceding claims, wherein said eye inflammation is retinitis.

76. The composition for use according to any of the preceding claims, for treatment of virally-induced spleen enlargement/atrophy.

77. The composition for use according to any of the preceding claims, for treatment of virally-induced diffuse lymphoid organ atrophy.

78. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders are caused by a viral infection.

79. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders are caused by a viral infection selected from the group consisting of Severe Acute Respiratory Syndrome CoronaVirus 2 (SARS-CoV-2), SARS-CoV, MERS-CoV, the dengue virus and influenza virus (including Type A, Type B and Type C).

80. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders are caused by dengue virus.

81. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is dengue hemorrhagic fever or dengue shock syndrome.

82. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders are caused by influenza virus.

83. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders are caused by a virus selected from the group consisting of SARS-CoV-2, SARS-CoV and MERS-CoV.

84. The composition for use according to any of the preceding claims, for use in the treatment of viral diseases or disorders in a subject with an immunodeficiency.

85. The composition for use according to any of the preceding claims, wherein said subject with an immunodeficiency is selected from a subject with a T cell deficiency, including a primary immunodeficiency of T cells such as severe combined immunodeficiency (SCID), Omenn syndrome, and Cartilage–hair hypoplasia, and a secondary immunodeficiency of T cells such as those caused by HIV/AIDS, cancer chemotherapies, lymphoma, and glucocorticoid therapy.

86. The composition for use according to any of the preceding claims, for use in the treatment of viral diseases or disorders in a subject from a high-risk population, including HSCT patients (Hematopoietic stem-cell transplantation), SOT patients (solid organ transplant), elderly subjects and very young subjects.

87. The composition for use according to any of the preceding claims, wherein said composition comprises, separately or together, one or more additional active pharmaceutical ingredients, such as one or more additional active pharmaceutical ingredients used for the treatment of viral diseases or disorders.

88. The composition for use according to any of the preceding claims, wherein said one or more additional active pharmaceutical ingredients are active pharmaceutical ingredients used for the treatment of symptomatic COVID-19.

89. The composition for use according to any of the preceding claims, wherein said composition is an add-on therapy to one or more additional therapies used for the treatment of viral diseases or disorders.

90. The composition for use according to any of the preceding claims, wherein said viral diseases or disorders is treated with oxygen on nasal catheter, such as oxygen on nasal catheter with flow between 2-5 LO_2/min, and/or mechanical ventilation.

91. The composition for use according to any of the preceding claims, wherein said compound is administered in an amount of 1 mg to 1000 mg per day, such as 1 to 5 mg, 5 to 10 mg, 10 to 15 mg, 15 to 20 mg, 20 to 30 mg, 30 to 60 mg, 60 to 80 mg, 80 to 100 mg, 100 to 130 mg, 130 to 160 mg, 160 to 200 mg, 200 to 240 mg, 240 to 280 mg, 280 to 320 mg, 320 to 360 mg, 360 to 400 mg, 400 to 440 mg, 440 to 500 mg, 500 to 560 mg, 560 to 620 mg, 620 to 680 mg, 680 to 740 mg, 740 to 800 mg, 800 to 860 mg, 860 to 920 mg, 920 to 980 mg, 980 to 1000 mg, for example 500 to 1000 mg per day.

92. The composition for use according to any of the preceding claims, wherein said compound is administered in an amount of 100 mg once daily, 200 mg once daily, 300 mg once daily, 400 mg once daily, 500 mg once daily, 600 mg once daily, 700 mg once daily, 800 mg once daily, 900 mg once daily or 100 mg once daily.

93. The composition for use according to any of the preceding claims, wherein said compound is administered in an amount of 100 mg once daily.

94. The composition for use according to any of the preceding claims, wherein said compound is administered in an amount of 100 mg two times daily (BID) or 100 mg three times daily (TID).

95. The composition for use according to any of the preceding claims, wherein said compound is administered in an amount of 200 mg two times daily (BID) or 200 mg three times daily (TID).

96. The composition for use according to any of the preceding claims, wherein said compound is administered as a once daily oral dosing of 100 mg AP1189.

97. The composition for use according to any of the preceding claims, wherein said composition is pharmaceutically safe.

98. The composition for use according to any of the preceding claims, for the treatment, amelioration and/or alleviation of viral diseases or disorders.