We claim:

1. Use of a composition comprising dendrimers complexed, covalently conjugated, or intra-molecularly dispersed or encapsulated with one or more therapeutic or prophylactic agents in the manufacture of a medicament for treating or preventing one or more symptoms of severe inflammation in an organ of a subject in need thereof, wherein the composition is to be administered to the subject in an amount effective to treat, alleviate or prevent one or more symptoms of the severe inflammation.

2. The use of claim 1, wherein the severe inflammation is systemic inflammation involving multiple organs, tissues, and/or cell types of a body of the subject.

3. The use of claim 1 or 2, wherein the severe inflammation is associated with sepsis or septic shock.

4. The use of any one of claims 1-3, wherein the severe inflammation is caused by any mechanism of macrophage activation including macrophage activation syndrome.

5. The use of any one of claims 1-4, wherein the severe inflammation is associated with multi-organ dysfunction including neuroinflammation.

6. The use of any one of claims 1-5, wherein the severe inflammation is associated with over-reactive M1 macrophages and/or elevations in proinflammatory markers selected from the group consisting of IL-6, CRP, ferritin, and IL-1b.

7. The use of any one of claims 1-6, wherein the severe inflammation is characterized by cytokine storm.

8. The use of any one of claims 1-7, wherein the severe inflammation is associated with acute lung injury (ALI) and/or acute respiratory distress syndrome (ARDS) associated with or arising from ventilator use, viral infection, sepsis, or systemic bacterial infections in a subject in need thereof have been established.

9. The use of claim 8, wherein the therapeutic agent is covalently conjugated, or intra-molecularly dispersed or encapsulated with in an amount effective to treat, alleviate or prevent one or more symptoms of acute lung injury or acute respiratory distress syndrome.

10. The use of claim 8 or 9, wherein the acute lung injury is ventilator-induced lung injury.

11. The use of claim 8 or 9, wherein the acute respiratory distress syndrome is caused by infection with a virus.

12. The use of claim 11, wherein the virus is SARS-COVID-2.

13. The method of any one of claims 1-12, wherein the dendrimers are hydroxyl-terminated dendrimers.

14. The use of any one of claims 1-13, wherein the dendrimers are generation 4, generation 5, or generation 6 poly(amidoamine) dendrimers.

15. The use of any one of claims 1-14, wherein the therapeutic agent is an anti-inflammatory agent.

16. The use of any one of claims 1-15, wherein the therapeutic agent is N-acetyl cysteine.

17. The use of any one of claims 1-16, wherein the composition is to be administered in an amount effective to reduce inflammation in the lung.

18. The use of any one of claims 1-17, wherein the composition is to be administered in an amount effective to reduce vascular leakage or vascular permeability in the lung, increase alveolar cell integrity or endothelial cell integrity in the lung, increase the ratio of arterial oxygen to the fraction of inspired oxygen (PaO_2/FiO_2), increase pulse oximetry-based peripheral blood oxygen saturation (SpO_2)/FiO2 (SpO_2/FiO_2) ratios, and/or reduce bronchoalveolar lavage (BAL) protein levels or bronchoalveolar lavage cell count.

19. The use of any one of claims 1-18, wherein the composition is to be administered in an amount effective to reduce one or more pro-inflammatory cells, chemokines, and/or cytokines in the lung.

20. The use of claim 19, wherein the composition is to be administered in an amount effective to reduce one or more pro-inflammatory chemokines selected from the group consisting of MCP-1, CXCL-8, CXCL-1, CXCL-5, and CCL-2.

21. The use of claim 19, wherein the composition is to be administered in an amount effective to reduce one or more pro-inflammatory cytokines

selected from the group consisting of C-reactive protein (CRP), ferritin, IL-6, TNF-α, IL-12, IL-1β, and IL-18.

22. The use of claim 19, wherein the one or more pro-inflammatory cells are M1-like macrophages.

23. The use of any one of claims 1-22, wherein the composition is formulated for intravenous, subcutaneous, or intramuscular administration.

24. The use of any one of claims 1-22, wherein the composition is formulated for delivery enterally or to a mucosal surface such as the lungs.

25. The use of claim 24, wherein the composition is to be administered via intravenous, subcutaneous, or intramuscular route.

26. The use of any one of claims 1-25, wherein the composition is to be administered prior to, in conjunction, subsequent to, or in alternation with treatment with one or more additional therapies or procedures.

27. The use of claim 26, wherein the one or more additional therapies are selected from the group consisting of antimicrobials, surfactant, and corticosteroids.

28. The use of claim 27, wherein the one or more additional procedures are selected from the group consisting of prone positioning, recruitment maneuver, inhalation of NO, extracorporeal membrane oxygenation (ECMO), intubation, and/or inhalation of PGI_2.

29. The use any one of claims 1-28, wherein the composition is in an amount between about 0.1 mg/kg body weight of the subject, and about 40 mg/kg body weight of the subject.

30. The use of claim 16, wherein the composition is in an amount between about 2 mg/kg body weight of the subject, and about 8 mg/kg body weight of the subject, and

wherein the composition is to be administered by subcutaneous injection.

31. The use of claim 16, wherein the dendrimer conjugated to N-acetyl cysteine is in an amount between about 20 mg/kg body weight of the subject, and about 40 mg/kg body weight of the subject, and

wherein the composition is to be administered by intravenous infusion.

32. The use of any one of claims 1-31, wherein the composition comprises one or more of histidine pH 5.5, and trehalose dihydrate.

33. A pharmaceutical composition for the use of any one of claims 1-32.

34. The pharmaceutical composition of claim 33, wherein the composition is lyophilized.

35. A kit comprising

(1) one or more single unit dose of a composition comprising dendrimers covalently conjugated with one or more anti-inflammatory agents, and

(2) instructions on how the dose is to be administered for treatment of acute lung injury.

36. A pharmaceutical formulation for treating Severe Acute Respiratory Distress Syndrome in a subject, comprising

generation-4, hydroxyl-terminated PAMAM dendrimers complexed, covalently conjugated, or intra-molecularly dispersed or encapsulated with N-acetyl cysteine, histidine pH 5.5, and trehalose dihydrate,

wherein the formulation is in an amount for administration up to about 40 mg/kg body weight of the subject.

37. The pharmaceutical formulation of claim 36 in an amount of from about 2 mg/kg body weight of the subject to about 8 mg/kg body weight of the subject for administration by subcutaneous injection.

38. The pharmaceutical formulation of claim 36 in an amount of from about 20 mg/kg body weight of the subject to about 40 mg/kg body weight of the subject for administration by intravenous infusion.

39. The pharmaceutical formulation of any one of claims 36-38, wherein the formulation is in a volume between 0.1 ml and 10 ml, preferably 2.5 ml.

40. The pharmaceutical formulation of any one of claims 36-39, wherein the formulation is lyophilized.