CLAIMS

What is claimed is:

1. Use of a formulation comprising dendrimers complexed to, covalently conjugated to, or having intra-molecularly dispersed or encapsulated therein, one or more therapeutic or prophylactic agents in the manufacture of a medicament for treating or preventing one or more symptoms of a kidney injury, disease, and/or disorder in a subject in need thereof,

wherein the dendrimer-agent formulation is to be administered in an amount effective to treat, alleviate or prevent one or more symptoms of the kidney injury, disease, and/or disorder.

2. The use of claim 1, wherein the kidney injury, disease and/or disorder is an acute or chronic kidney disease.

3. The use of claim 1 or 2, wherein the kidney injury, disease and/or disorder is caused by ischemia/reperfusion injury.

4. The use of claim 3, wherein the kidney injury, disease and/or disorder is caused by a condition selected from the group consisting of infection, sepsis, ischemia-reperfusion injury, diabetic complications, hypertension, obesity, autoimmunity diabetes, high blood pressure, heart failure, kidney disease, liver disease, and cancer.

5. The use of any one of claims 1-4, wherein the dendrimers are hydroxyl-terminated dendrimers.

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

7. The use of any one of claims 1-6, wherein the therapeutic agent is an anti-inflammatory agent.

8. The use of any one of claims 1-6, wherein the therapeutic agent is a PPAR-δ agonist.

9. The use of claim 8, wherein the PPAR-δ agonist is GW0742, GW0742-amide derivative and GW0742-ester derivative, GW0742-amide derivative, or GW0742-ester derivative.

10. The use of claim 7, wherein the anti-inflammatory agent is selected from the group consisting of N-acetylcysteine, steroidal anti-inflammatory drugs, non-steroidal drugs, cyclosporine, tacrolimus, rapamycin, SGLT2 inhibitors, LPA1 receptor antagonists, vasopression V2-receptor antagonists, endothelian receptor antagonists, and uric acid transporter inhibitors.

11. The use of any one of claims 1-10, wherein the formulation is to be administered in an amount effective to reduce inflammation in the kidney.

12. The use of any one of claims 1-10, wherein the formulation is to be administered in an amount effective to reduce tubular damage, tubular epithelial flattening, tubular dilatation, and tubular epithelial cell necrosis, and/or apoptosis in the kidneys.

13. The use of any one of claims 1-10, wherein the formulation is to be administered in an amount effective to reduce serum levels of creatinine and/or blood urea nitrogen (BUN); to reduce urine NGAL and/or KIM-1 content; and/or to improve glomerular filtration rate (GFR).

14. The use of any one of claims 1-10, wherein the formulation is to be administered in an amount effective to reduce the amount or presence of one or more pro-inflammatory cells, chemokines, and/or cytokines in the kidney.

15. The use of claim 14, wherein the formulation is to be administered in an amount effective to reduce one or more pro-inflammatory cytokines selected from the group consisting of TNF-α, IFN-γ, IL-6, IL-1β, IL-23, and IL-17.

16. The use of any one of claims 1-15, wherein the formulation comprises a therapeutic, prophylactic or diagnostic agent selected from the group consisting of chemotherapeutic agents, anti-angiogenic agents, anti-excitotoxic agents, inhibitors of glutamate formation/release, anti-VEGF agents including aflibercept, immunomodulators such as

rapamycin, uric acid transporter (URAT1) inhibitors, vasopression V2-receptor antagonists, endothelin receptor antagonists, subtype 2 sodium-glucose transport protein (SGLT2) inhibitor, and LPA1 receptor antagonists.

17. The use of any one of claims 1-16, wherein the formulation is formulated for intravenous, subcutaneous, or intramuscular administration.

18. The use of any one of claims 1-16 wherein the formulation is formulated for enteral administration.

19. The use of any one of claims 1-16, wherein the formulation is to be administered via the intravenous, subcutaneous, or intramuscular route.

20. The use of any one of claims 1-19, wherein the formulation is to be administered prior to, in conjunction, subsequent to, or in alternation with treatment with one or more additional therapies or procedures.

21. The use of claim 20, wherein the one or more additional procedures include administration of intravenous fluids and/or hemodialysis.

22. A kit comprising

(1) one or more single unit dose of a composition comprising dendrimers covalently conjugated with one or more PPAR-δ agonists, and

(2) instructions on how the dose is to be administered for treatment of one or more kidney injuries, diseases, and/or conditions.

23. A composition comprising a compound that comprises a dendrimer conjugated to a PPAR-δ agonist through an ester, ether, or amide linkage, wherein the dendrimer comprises a high density of surface hydroxyl groups.

24. The composition of claim 23, wherein the PPAR-δ agonist is conjugated to the ester, ether, or amide linkage through a spacer.

25. The composition of claim 24, wherein the spacer comprises alkyl groups, heteroalkyl groups, or alkylaryl groups.

26. The composition of claim 24 or 25, wherein the spacer comprises a peptide.

27. The composition of any one of claims 24-26, wherein the spacer comprises polyethylene glycol.

28. The composition of any one of claims 23-27, wherein conjugation of the PPAR-δ agonist occurs on less than 50% of total available surface functional groups of the dendrimer prior to the conjugation.

29. The composition of any one of claims 23-28, wherein conjugation of the PPAR-δ agonist occurs on less than occurs on less than 5%, less than 10%, less than 20%, less than 30%, or less than 40% of total available surface functional groups of the dendrimer prior to the conjugation.

30. The composition of any one of claims 23-29, wherein the PPAR-δ agonist is an indanylacetic acid derivative.

31. The composition of any one of claims 23-30, wherein the PPAR-δ agonist is GW0742.

32. The composition of any one of claims 23-31, wherein the PPAR-δ agonist is a GW0742-amide derivative or a GW0742-ester derivative.

33. The composition of any one of claims 23-32, wherein the dendrimer comprises poly(amidoamine), polypropylamine (POPAM), polyethylenimine, polylysine, polyester, iptycene, aliphatic poly(ether), and/or aromatic polyether.

34. The composition of any one of claims 23-33, wherein the dendrimer is a poly(amidoamine) dendrimer.

35. The composition of any one of claims 23-34, wherein the dendrimer is a generation 4, generation 5, or generation 6 poly(amidoamine) dendrimer.

36. The composition of any one of claims 23-35, wherein the zeta potential of the compound is between -25 mV and 25 mV.

37. The composition of any one of claims 23-36, wherein the zeta potential of the compound is between -20 mV and 20 mV, between -10 mV and 10 mV, between -10 mV and 5 mV, between -5 mV and 5 mV, or between -2 mV and 2 mV.

38. The composition of any one of claims 23-37, wherein the surface charge of the compound is neutral or near-neutral.

39. The composition of any one of claims 23-38, wherein the dendrimer conjugated to the PPAR-δ agonist through an ether or amide linkage.

40. The composition of any one of claims 23-39, wherein the dendrimer conjugated to the PPAR-δ agonist through an ether linkage.

41. The composition of any one of claims 23-40 for use as a medicament.