WHAT IS CLAIMED:

1. A formulation comprising: (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in an amount of 0.01 to 0.15%, and hydroxypropyl β-cyclodextrin or sulfobutyl ether-beta-cyclodextrin in an amount of 99.1 to 99.99%, based on the total weight of the formulation.

2. The formulation of claim 1 comprising: (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in an amount of 0.08 to 0.15%, and hydroxypropyl β-cyclodextrin or sulfobutyl ether-beta-cyclodextrin in an amount of 99.1 to 99.9%, based on the total weight of the formulation.

3. The formulation of claim 1 or 2, comprising (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in the amount from 0.1 to 0.13% based on the total weight of the formulation.

4. The formulation of any one of claims 1-3, comprising (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in the amount of 0.12% based on the total weight of the formulation.

5. The formulation of claim 1 comprising: (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in an amount of 0.01 to 0.08%, and hydroxypropyl β-cyclodextrin in an amount of 99.40 to 99.99%, based on the total weight of the formulation.

6. The formulation of claim 1 or 5, comprising (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in the amount from 0.03 to 0.06% based on the total weight of the formulation.

7. The formulation of claim 1, comprising (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof from 0.1 to 0.13%, hydroxypropyl β-cyclodextrin from 99.1% to 99.9%, and formic acid from 0.05 to 0.1% based on total weight of the formulation.

8. The formulation of claim 1, comprising (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof from 0.01 to 0.08%, hydroxypropyl β-cyclodextrin from 99.40% to 99.99%, and formic acid from 0.1 to 0.3% based on total weight of the formulation.

9. The formulation of any one of claims 1-8 further comprising formic acid in an amount of no more than 0.5%.

10. The formulation of any one of claims 1-9, comprising a solid form of (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide).

11. The formulation of any one of claims 1-9, comprising an amorphous form of (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide).

12. A formulation comprising: (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in an amount of 0.08 to 0.15%, a citrate buffer in an amount of 3 to 6%, and hydroxypropyl

β-cyclodextrin or sulfobutyl ether-beta-cyclodextrin in an amount of 94 to 96% based on the total weight of the formulation.

13. The formulation of claim 12 comprising a solid form of (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide).

14. The formulation of claim 12 comprising an amorphous form of (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide).

15. The formulation of any one of claims 12-14, comprising (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in the amount from 0.1 to 0.13% based on the total weight of the formulation.

16. The formulation of any one of claims 12-15, comprising (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in the amount of 0.12% based on the total weight of the formulation.

17. The formulation of any one of claims 12-16, comprising citrate buffer in the amount 3%, 3.5%, 4%, 4.2%, 4.5% or 5 % based on total weight of the formulation.

18. The formulation of any one of claims 12-17, wherein citrate buffer comprises anhydrous citric acid and anhydrous sodium citrate.

19. The formulation of claim 18, comprising anhydrous citric acid in the amount from 2% to 2.5% based on total weight of the formulation.

20. The formulation of claim 18, comprising anhydrous citric acid in the amount of 2.1% based on total weight of the formulation.

21. The formulation of claim 18, comprising anhydrous sodium citrate in the amount from 2% to 2.5% based on total weight of the formulation.

22. The formulation of claim 21, comprising anhydrous sodium citrate in the amount of 2.08% based on total weight of the formulation.

23. The formulation of any one of claims 12-22, comprising hydroxypropyl β-cyclodextrin in the amount 94.5%, 95%, 95.5%, or 96% based on total weight of the formulation.

24. The formulation of any one of claims 12-23, comprising hydroxypropyl β-cyclodextrin in the amount of 95% based on total weight of the formulation.

25. The formulation of any one of claims 12-24 further comprising dimethyl sulfoxide in an amount of no more than 1.5%.

26. The formulation of any one of claims 12-15, comprising (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof from 0.1 to 0.13%, anhydrous citric acid from 2% to 2.5%, anhydrous sodium citrate from 2% to 2.5%, hydroxypropyl β-cyclodextrin from 94% to 96%, and dimethyl sulfoxide from 0.4 to 1.5% based on total weight of the formulation.

27. An aqueous formulation comprising the formulation of any one of claims 1-26 and a diluent.

28. The aqueous formulation of claim 27, wherein the diluent is water or ½ normal saline.

29. The aqueous formulation of claim 27, wherein the diluent is normal saline.

30. The aqueous formulation of any one of claims 27-29, comprising (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereoisomer or mixture of stereoisomers, pharmaceutically acceptable salt, tautomer, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in an amount of 0.1 to 0.3 mg/mL.

31. The aqueous formulation of any one of claims 27-30, wherein the aqueous solution has a pH in a range from 3.0 to 3.6.

32. The aqueous formulation of any one of claims 27-30, wherein the aqueous solution has a pH in a range from 4.2 to 4.4.

33. The aqueous formulation of any one of claims 27-32, wherein the aqueous solution has an osmolality of 260-280 mOsm/kg.

34. The aqueous formulation of any one of claims 27-32, wherein the aqueous solution has an osmolality of 310-380 mOsm/kg.

35. Use of the formulation of any one of claims 1-26 or use of the aqueous formulation of any one of claims 27-34 in the manufacture of a medicament for treating a cancer in a mammal, wherein the medicament is to be administered to the mammal.

36. The use of claim 35, wherein the aqueous formulation of any one of claims 27-34 is to be administered intravenously.

37. The use of claim 35 or 36, wherein the cancer is leukemia.

38. The use of claim 37, wherein the leukemia is chronic lymphocytic leukemia, chronic myelocytic leukemia, acute lymphoblastic leukemia or acute myeloid leukemia.

39. The use of any one of claims 35-38, wherein the medicament is to be administered in combination with a therapeutically effective amount of another second active agent or a supportive care therapy to the mammal.

40. The use of claim 39, wherein the other second active agent is a therapeutic antibody that specifically binds to a cancer antigen, a hematopoietic growth factor, a cytokine, anti-cancer agent, an antibiotic, a cox-2 inhibitor, an immunomodulatory agent, an immunosuppressive agent or a corticosteroid.

41. The formulation of any one of claims 1-26 or the aqueous formulation of any one of claims 27-34 for use as a medicament.

42. The formulation of any one of claims 1-26 or the aqueous formulation of any one of claims 27-34 for use in a method of treating a cancer in a mammal.

43. The aqueous formulation for use of claim 42, wherein the aqueous formulation is to be administered intravenously.

44. The formulation for use of claim 42 or the aqueous formulation for use of claim 42 or 43, wherein the cancer is leukemia.

45. The formulation for use of claim 44 or the aqueous formulation for use of claim 44, wherein the leukemia is chronic lymphocytic leukemia, chronic myelocytic leukemia, acute lymphoblastic leukemia or acute myeloid leukemia.

46. The formulation for use of claims 41, 42 or 44 or the aqueous formulation for use of any one of claims 41-45, further comprising the formulation and the aqueous formulation to be administered in combination with a therapeutically effective amount of another second active agent or a supportive care therapy.

47. The formulation for use of claim 46 or the aqueous formulation for use of claim 46, wherein the other second active agent is a therapeutic antibody that specifically binds to a cancer antigen, hematopoietic growth factor, cytokine, anti-cancer agent, antibiotic, cox-2 inhibitor, immunomodulatory agent, immunosuppressive agent or corticosteroid.

48. A process of preparing the formulation of any one of claims 1-11 comprising: dissolving (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide) in formic acid to obtain a premix, dissolving hydroxypropyl β-cyclodextrin in water to obtain a solution, adding the premix to the solution to obtain a drug solution.

49. A process of preparing the formulation of any one of claims 12-26 comprising: dissolving hydroxypropyl β-cyclodextrin in a citrate buffer to obtain a buffer solution, dissolving (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide) in DMSO to obtain a premix, adding the premix to the buffer solution to obtain a solution.

50. The process of claim 49 further comprising lyophilizing the solution to produce a lyophilized formulation.

51. The process of claim 48 further comprising lyophilizing the solution to produce a lyophilized formulation.