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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in an amount of about 1 to 1.3%, citrate buffer in an amount of about 9 to 12% and mannitol in an amount of about 85 to 90 %, 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in an amount of about 1.0%, based on the total weight of the formulation.

3. The formulation of claim 1 or 2, comprising citrate buffer in an amount of about 10.63% based on the total weight of the formulation.

4. The formulation of any one of claims 1-3, wherein the citrate buffer comprises citric acid monohydrate and sodium citrate dihydrate.

5. The formulation of any one of claims 1-4, comprising mannitol in an amount of about 88% based on the total weight of the formulation.

6. The formulation of any one of claims 1-5, 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in the amount of about 1.0% citrate buffer in an amount of about 10.63% and mannitol in an amount of about 88%, based on the total weight of the formulation.

7. The formulation of claim 1 comprising 1 mg (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), 5.24 mg citric acid monohydrate, 4.4 mg sodium citrate dihydrate and 80 mg mannitol.

8. 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof, a citrate buffer, human albumin, and sucrose.

9. The formulation of claim 8, comprising about 0.03% to about 0.25% 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof, about 30.00% to 90.00% human albumin, about 20.00% to 60.00% sucrose, and about 1.00% to 8.00% citric acid.

10. The formulation of claim 8 or 9 further comprising about 1% to 9% sodium chloride.

11. The formulation of any one of claims 8-10 further comprising about 0.5% to 2.5% sodium N acetyltryptophanate.

12. The formulation of any one of claims 8-11 further comprising about 0.3% to 1.2% sodium caprylate.

13. The formulation of any one of claims 8-12 comprising about 0.03% to 0.05% 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof, about 38.00% to 47.00% human albumin, about 45.00% to 55.00% sucrose, and about 3.00% to 4.00% citric acid.

14. The formulation of any one of claims 8-13 comprising about 0.042% 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof, about 42.29% human albumin, about 50.75% sucrose, about 3.66% citric acid, about 1.79% sodium chloride, about 0.91% sodium N acetyltryptophanate and about 0.56% sodium caprylate.

15. 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof, a citrate buffer, human albumin, trehalose and mannitol.

16. The formulation of claim 15 comprising about 0.08% to 0.12% 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or

polymorph thereof, about 40.00% to 55.00% human albumin, about 10.00% to 25.00% trehalose, about 15% to 30% mannitol, about 3.00% to 4.50% citric acid, about 1.50% to 2.50% sodium chloride, about 0.80% to 1.50% sodium N-acetyltryptophanate, about 0.50% to 1.00% sodium caprylate, about 0.30% to 0.50% formic acid and about 0.20% to 0.60% acetic acid based on the total weight of the formulation.

17. The formulation of claim 16 comprising about 0.1% 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof, about 50.79% human albumin, about 20.32% trehalose, about 20.32% mannitol, about 3.90% citric acid, about 2.15% sodium chloride, about 1.09% sodium N-acetyltryptophanate, about 0.68% sodium caprylate, about 0.46% formic acid and about 0.20% acetic acid based on the total weight of the formulation.

18. The formulation of any one of claims 1-17, comprising (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide).

19. The formulation of any one of claims 1-6, wherein the formulation is an aqueous formulation further comprising a diluent.

20. The formulation of claim 19, wherein the diluent comprises PEG400, ethanol, and water for injection.

21. The formulation of claim 20, wherein the diluent comprises PEG400, ethanol, and water for injection in a volume ratio of 50:10:40.

22. The formulation of any one of claims 19-21, 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in an amount of about 0.1 mg/mL.

23. The formulation of any one of claims 19-22, 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, prodrug, isotopologue, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in an amount of about 0.1 mg/mL, mannitol in an amount of 8.0 mg/mL, citric acid monohydrate in an amount of about 0.52 mg/mL, and sodium citrate dihydrate in an amount of about 0.44 mg/mL.

24. The formulation of any one of claims 19-23, wherein the formulation has a pH in a range from about 4 to 5.

25. The formulation of any one of claims 8-14, wherein the formulation is an aqueous formulation further comprising a diluent.

26. The formulation of claim 25, wherein the diluent comprises water.

27. The formulation of any one of claims 15-17, wherein the formulation is an aqueous formulation further comprising a diluent.

28. The formulation of claim 27, wherein the diluent comprises water.

29. A vial comprising the formulation of any one of claims 1-28.

30. Use of the formulation of any one of claims 1-28 in the manufacture of a medicament for a method of treating a cancer in a mammal, wherein the formulation is to be administered to the mammal.

31. The use of claim 30, wherein the aqueous formulation of any one of claims 19 to 28 is to be intravenously administered to the mammal.

32. The use of claim 30 or 31, wherein the cancer is leukemia.

33. The use of claim 32, wherein the leukemia is chronic lymphocytic leukemia, chronic myelocytic leukemia, acute lymphoblastic leukemia or acute myeloid leukemia.

34. The use of claim 32 or 33, wherein the leukemia is an acute myeloid leukemia.

35. The use of any one of claims 32-34, wherein the leukemia is relapsed, refractory or resistant.

36. The use of any one of claims 32-35, the formulation is to be administered with a therapeutically effective amount of another second active agent or a supportive care therapy.

37. The use of claim 36, 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, a corticosteroid or a pharmacologically active mutant or derivative thereof.

38. The use of claim 37, wherein the second active agent is selected from a glucocorticoid receptor agonist, an IL-1β receptor antagonist, an interleukin-1β blocker, a JAK inhibitor, a FLT3 inhibitor, an mTOR inhibitor, a spiceosome inhibitor, an ERK inhibitor, an LSD1 inhibitor, an SMG1 inhibitor, a BH3 mimetic, and a topoisomerase inhibitor.

39. Use of the formulation of any one of claims 1-28 in the manufacture of a medicament for a method of treating a myeloproliferative neoplasm in a mammal, wherein the formulation is to be administered to the mammal.

40. The use of claim 39, the formulation is to be administered with a a JAK inhibitor.

41. Use of the formulation of any one of claims 1-28 in the manufacture of a medicament for a method of treating a cancer selected from breast cancer, neuroendocrine tumor, and renal cell carcinoma in a mammal, wherein the formulation is to be administered to the mammal.

42. The use of claim 41 wherein the formulation is to be administered with a second agent selected from everolimus, temsirolimus, 1-ethyl-7-(2-methyl-6-(1H-1,2,4-triazol-3-yl)pyridin-3-yl)-3,4-dihydropyrazino[2,3-b]pyrazin-2(1H)-one and 7-(6-(2-hydroxypropan-2-yl)pyridin-3-yl)-1-((trans)-4-methoxycyclohexyl)-3,4-dihydropyrazino[2,3-b]pyrazin-2(1H)-one to the mammal.

43. Use of the formulation of any one of claims 1-28 in the manufacture of a medicaments fora method of treating a leukemia in a mammal, wherein the formulation is to be administered in combination with an IDH2 inhibitor to the mammal, wherein the leukemia is characterized by the presence of a mutant allele of IDH2.

44. The use of claim 43, wherein the IDH2 inhibitor is enasidenib or 6-(6-(trifluoromethyl)pyridin-2-yl)-N^2-(2-(trifluoromethyl)pyridin-4-yl)-1,3,5-triazine-2,4-diamine.

45. The use of claim 43or 44, wherein the leukemia is an acute myeloid leukemia characterized by the presence of a mutant allele of IDH2.

46. The use of any one of claims 43-45, wherein the leukemia is relapsed, refractory or resistant.

47. The formulation of any one of claims 1-28 for use as a medicament.

48. The formulation of any one of claims 1-28 for use in a method of treating a cancer in a mammal.

49. The formulation for use of claim 48, wherein he aqueous formulation of any one of claims 19 to 28 is to be administered to the mammal intravenously.

50. The formulation for use of claim 48 or 49, wherein the cancer is leukemia.

51. The formulation for use of claim 50, wherein the leukemia is chronic lymphocytic leukemia, chronic myelocytic leukemia, acute lymphoblastic leukemia or acute myeloid leukemia.

52. The formulation for use of any one of claims 48 to 51, wherein the formulation is to be administered with a therapeutically effective amount of a second active agent or a supportive care therapy.

53. The formulation for use of claim 52, wherein the 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, corticosteroid or a pharmacologically active mutant or derivative thereof.

54. The formulation for use of claim 53, wherein the second active agent is selected from a glucocorticoid receptor agonist, an IL-1β receptor antagonist, an interleukin-1β blocker, a JAK inhibitor, a FLT3 inhibitor, an mTOR inhibitor, a spiceosome inhibitor, an ERK inhibitor, an LSD1 inhibitor, an SMG1 inhibitor, a BH3 mimetic, and a topoisomerase inhibitor to the mammal.

55. The formulation for use of claim 54, wherein the second active agent is selected from pladienolide B, chloro-N,N-diethyl-5-((4-(2-(4-(3-methylureido)phenyl)pyridin-4-yl)pyrimidin-2-yl)amino)benzenesulfonamide (compound Ii), venetoclax, topotecan and everolimus.

56. The formulation for use of claim 55, wherein the second active agent is a JAK inhibitor.

57. The formulation for use of claim 56, wherein the JAK inhibitor is selected from tofacitinib, momelotinib, filgotinib, decernotinib, barcitinib, ruxolitinib, fedratinib, NS-018 and pacritinib.

58. The formulation for use of claim 54, wherein the second active agent is a FLT3 inhibitor.

59. The formulation for use of claim 58, wherein the FLT3 inhibitor is selected from quizartinib, sunitinib, midostaurin, pexidartinib, lestaurtinib, tandutinib, and crenolanib.

60. The formulation for use of claim 59, wherein the second active agent is everolimus.

61. The formulation for use of any one of claims 59-60, wherein the leukemia is an acute myeloid leukemia.

62. The formulation for use of claim 61, wherein the acute myeloid leukemia is relapsed, refractory or resistant.

63. The formulation of any one of claims 1-28 for use in a method of treating a myeloproliferative neoplasm in a mammal,

64. The formulation for use of claim 63, wherein the formulation is to be administered with a JAK inhibitor to the mammal.

65. The formulation for use of claim 64, wherein the JAK inhibitor is selected from tofacitinib, momelotinib, filgotinib, decernotinib, barcitinib, ruxolitinib, fedratinib, NS-018 and pacritinib.

66. The formulation of any one of claims 1-28 for use in a method of treating a cancer selected from breast cancer, neuroendocrine tumor, and renal cell carcinoma in a mammal, wherein the formulation is to be administered with a second active agent selected from everolimus, temsirolimus, 1-ethyl-7-(2-methyl-6-(1H-1,2,4-triazol-3-yl)pyridin-3-yl)-3,4-dihydropyrazino[2,3-b]pyrazin-2(1H)-one and 7-(6-(2-hydroxypropan-2-yl)pyridin-3-yl)-1-((trans)-4-methoxycyclohexyl)-3,4-dihydropyrazino[2,3-b]pyrazin-2(1H)-one to the mammal.

67. The formulation for use of claim 66, wherein the second active agent is everolimus.

68. The formulation of any one of claims 1-28 for use in a method of treating a leukemia in a mammal, wherein the formulation is to be administered with an IDH2 inhibitor to the mammal and wherein the leukemia is characterized by the presence of a mutant allele of IDH2.

69. The formulation for use of claim 68, wherein the IDH2 inhibitor is enasidenib or 6-(6-(trifluoromethyl)pyridin-2-yl)-N^2-(2-(trifluoromethyl)pyridin-4-yl)-1,3,5-triazine-2,4-diamine.

70. The formulation for use of claim 69, wherein the leukemia is an acute myeloid leukemia characterized by the presence of a mutant a llele of IDH2.

71. The formulation for use of claim 70, wherein the leukemia is relapsed, refractory or resistant.

72. A process for preparing the formulation of any one of claims 1-7 comprising: dissolving mannitol in tert-butyl alcohol and citrate buffer to obtain a buffer solution, and dissolving (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide) in the buffer solution to a drug solution.

73. The process of claim 72 further comprising lyophilizing the drug solution to obtain a lyophilized formulation.

74. A process for preparing the formulation of any one of claims 8-14 comprising: (i) adding a mixture of sucrose and 20% human albumin to a citrate buffer in water to obtain

a sucrose/human albumin solution, and (ii) adding a solution of Compound 1 in formic acid to the sucrose/human albumin solution to obtain a drug solution.

75. The process of claim 74 further comprising: filtering the drug solution to obtain a filtered solution, and lyophilizing the filtered solution to obtain a lyophilized formulation.

76. A process for preparing the formulation of any one of claims 15-17 comprising: (i) adding a mixture of trehalose, mannitol and 20% human albumin to a citrate buffer in water to obtain a trehalose/mannitol/human albumin solution, and (ii) adding a solution of Compound 1 in formic acid to the trehalose/mannitol/human albumin solution to obtain a mixture, and (iii) adding acetic acid to the mixture to obtain a drug solution.

77. The process of claim 76 further comprising: filtering the drug solution to obtain a filtered solution, and lyophilizing the filtered solution to obtain a lyophilized formulation.