WHAT IS CLAIMED IS:

~~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.~~

8.1. A formulation comprising: 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, a citrate buffer, 30.00% to 90.00% human albumin, and 20.00% to 60.00% 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.

10.2. The formulation of claim 8 or 91 further comprising about 1% to 9% sodium chloride.

11.3. The formulation of any one of claims 8-10claim 1 or 2 further comprising about 0.5% to 2.5% sodium N acetyltryptophanate.

12.4. The formulation of any one of claims 8-111-3 further comprising about 0.3% to 1.2% sodium caprylate.

13.5. The formulation of any one of claims 8-121-4 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.

14.6. The formulation of any one of claims 8-131-5 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.~~7. A formulation comprising: 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, a citrate buffer, 40.00% to 55.00% human albumin, 10.00% to 25.00% trehalose and 15% to 30% mannitol.

~~16.~~8. The formulation of claim ~~15~~7 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.~~9. The formulation of claim ~~16~~8 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.~~10. The formulation of any one of claims ~~1-17~~1-9, 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.~~11. The formulation of any one of claims ~~8-14~~1-10, wherein the formulation is an aqueous formulation further comprising a diluent.

~~26.~~12. The formulation of claim ~~25~~11, 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.~~13. A vial comprising the formulation of any one of claims 1-12~~28~~.

~~30.~~14. Use of the formulation of any one of claims ~~1-28~~1-12 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.~~15. The use of claim ~~30~~14, wherein the aqueous formulation of ~~any one of claims 19 to 28~~ claim 11 or 12 is to be intravenously administered to the mammal.

~~32.~~16. The use of claim ~~30 or 31~~14 or 15, wherein the cancer is leukemia.

~~33.~~17. The use of claim ~~32~~16, wherein the leukemia is chronic lymphocytic leukemia, chronic myelocytic leukemia, acute lymphoblastic leukemia or acute myeloid leukemia.

~~34.~~18. The use of claim ~~32 or 33~~16 or 17, wherein the leukemia is an acute myeloid leukemia.

~~35.~~19. The use of any one of claims ~~32-34~~16-18, wherein the leukemia is relapsed, refractory or resistant.

~~36.~~20. The use of any one of claims ~~32-35~~16-19, the formulation is to be administered with a therapeutically effective amount of another second active agent or a supportive care therapy.

~~37.~~21. The use of claim ~~36~~20, 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.~~22. The use of claim ~~37~~21, 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.~~23. Use of the formulation of any one of claims ~~1-28~~1-12 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.~~24. The use of claim ~~39~~23, the formulation is to be administered with a ~~a~~ JAK inhibitor.

~~41.~~25. Use of the formulation of any one of claims ~~1-28~~1-12 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.~~26. The use of claim ~~41~~25 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.~~27. Use of the formulation of any one of claims ~~1-28~~1-12 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.~~28. The use of claim ~~43~~27, 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.~~29. The use of claim ~~43or 44~~26 or 28, wherein the leukemia is an acute myeloid leukemia characterized by the presence of a mutant allele of IDH2.

~~46.~~30. The use of any one of claims ~~43-45~~27-29, wherein the leukemia is relapsed, refractory or resistant.

~~47.~~31. The formulation of any one of claims ~~1-28~~1-12 for use as a medicament.

~~48.~~32. The formulation of any one of claims ~~1-28~~1-12 for use in a method of treating a cancer in a mammal.

~~49.~~33. The formulation for use of claim ~~48~~32, wherein he aqueous formulation of any one of claims 19 to 28 is to be administered to the mammal intravenously.

~~50.~~34. The formulation for use of claim ~~48 or 49~~32 or 33, wherein the cancer is leukemia.

~~51.~~35. The formulation for use of claim ~~50~~34, wherein the leukemia is chronic lymphocytic leukemia, chronic myelocytic leukemia, acute lymphoblastic leukemia or acute myeloid leukemia.

~~52.~~36. The formulation for use of any one of claims ~~48 to 51~~32 to 35, wherein the formulation is to be administered with a therapeutically effective amount of a second active agent or a supportive care therapy.

~~53.~~37. The formulation for use of claim ~~52~~36, 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.~~38. The formulation for use of claim ~~53~~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 to the mammal.

~~55.~~39. The formulation for use of claim ~~54~~38, 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.~~40. The formulation for use of claim ~~55~~39, wherein the second active agent is a JAK inhibitor.

~~57.~~41. The formulation for use of claim ~~56~~40, wherein the JAK inhibitor is selected from tofacitinib, momelotinib, filgotinib, decernotinib, barcitinib, ruxolitinib, fedratinib, NS-018 and pacritinib.

~~58.~~42. The formulation for use of claim ~~54~~38, wherein the second active agent is a FLT3 inhibitor.

~~59.~~43. The formulation for use of claim ~~58~~42, wherein the FLT3 inhibitor is selected from quizartinib, sunitinib, midostaurin, pexidartinib, lestaurtinib, tandutinib, and crenolanib.

~~60.~~44. The formulation for use of claim ~~59~~43, wherein the second active agent is everolimus.

~~61.~~45. The formulation for use of any one of claims ~~59-60~~43-44, wherein the leukemia is an acute myeloid leukemia.

~~62.~~46. The formulation for use of claim ~~61~~45, wherein the acute myeloid leukemia is relapsed, refractory or resistant.

~~63.~~47. The formulation of any one of claims ~~1-28~~1-12 for use in a method of treating a myeloproliferative neoplasm in a mammal,

~~64.~~48. The formulation for use of claim ~~63~~47, wherein the formulation is to be administered with a JAK inhibitor to the mammal.

~~65.~~49. The formulation for use of claim ~~64~~48, wherein the JAK inhibitor is selected from tofacitinib, momelotinib, filgotinib, decernotinib, barcitinib, ruxolitinib, fedratinib, NS-018 and pacritinib.

~~66.~~50. The formulation of any one of claims ~~1-28~~1-12 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.~~51. The formulation for use of claim ~~66~~50, wherein the second active agent is everolimus.

~~68.~~52. The formulation of any one of claims ~~1-28~~1-12 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.~~53. The formulation for use of claim ~~68~~52, 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.~~54. The formulation for use of claim ~~69~~53, wherein the leukemia is an acute myeloid leukemia characterized by the presence of a mutant a llele of IDH2.

~~71.~~55. The formulation for use of claim ~~70~~54, 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.~~56. A process for preparing the formulation of any one of claims ~~8-14~~1-6 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.~~57. The process of claim ~~74~~56 further comprising: filtering the drug solution to obtain a filtered solution, and lyophilizing the filtered solution to obtain a lyophilized formulation.

~~76.~~58. A process for preparing the formulation of any one of claims ~~15-17~~7-10 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.~~59. The process of claim ~~76~~58 further comprising: filtering the drug solution to obtain a filtered solution, and lyophilizing the filtered solution to obtain a lyophilized formulation.