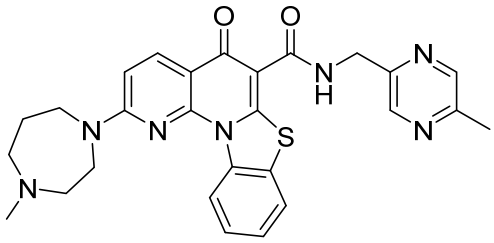
CLAIMS

What is Claimed:

1. ~~A method for treating cancer in a subject, comprising administering to a subject in need thereof a therapeutically effective amount~~ Use of Compound I, or a pharmaceutically acceptable salt or solvate thereof,



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in the manufacture of a medicament for the treatment of cancer in a subject, wherein the Compound I, or a pharmaceutically acceptable salt or solvate thereof is to be administered to the subject, and wherein~~,~~ the subject has a *PALB2* mutation and/or a *BRCA2* mutation.

2. The ~~method~~ use of claim 1, wherein the subject has a *PALB2* mutation.

3. The ~~method~~ use of claim 1, wherein the subject has a *BRCA2* mutation.

4. The ~~method~~ use of claim~~s~~ 1, wherein the subject has a *PALB2* mutation and a *BRCA2* mutation.

~~5. The method of any one of claims 1-4, wherein the subject has one or more additional gene mutations in the homologous recombination pathway.~~

~~6. The method of any one of claims 1-5, wherein the cancer is a solid tumor.~~

~~7.~~5. The use~~method~~ of any one of claims 1-~~6~~4, wherein the cancer is a hematologic malignancy, colorectal cancer, breast cancer, lung cancer, liver cancer, ovarian cancer, cervical cancer, Ewing's sarcoma, pancreatic cancer, cancer of the lymph nodes, colon cancer, prostate cancer, brain cancer, bone cancer, cancer of the head and neck, skin

cancer, kidney cancer, osteosarcoma, cancer of the heart, uterine cancer, gastrointestinal malignancies, or carcinomas of the larynx and oral cavity.

~~8.~~6. The ~~method~~ use of claim ~~7~~5, wherein the cancer is breast cancer, ovarian cancer, ~~or~~ pancreatic cancer, or prostate cancer.

~~9.~~7. The use~~method~~ of claim ~~7~~5, wherein the hematologic malignancy is selected from leukemia, lymphoma, myeloma, and multiple myeloma.

~~10. The method of any one of claims 1-6, wherein the cancer is a *PALB2*-mutated cancer.~~

~~11. The method of any one of claims 1-6, wherein the cancer is a *BRCA2*-mutated cancer.~~

~~12. The method of claims 10 or 11, wherein the cancer is breast cancer, ovarian cancer, pancreatic cancer, or prostate cancer.~~

~~13. The method of claim 10 or 11, wherein the cancer is breast cancer or prostate cancer.~~

~~14. The method of any one of claims 1-13, wherein the *PALB2* mutation is a loss-of-function mutation of the *PALB2* gene.~~

~~15. The method of any one of claims 1-14, wherein the *PALB2* mutation is a monoallelic loss-of-function mutation.~~

~~16. The method of any one of claims 1-14, wherein the *PALB2* mutation is a biallelic loss-of-function mutation.~~

~~17. The method of any one of claims 1-13, wherein the *BRCA2* mutation is a loss-of-function mutation of the *BRCA2* gene.~~

~~18.~~8. The use~~method~~ of any one of claims 1-~~1~~7, wherein ~~the subject is administered~~ the Compound I or a pharmaceutically acceptable salt thereof is to be administered at a dose ranging from about 50 mg to about 1,000 mg of the Compound I or a

pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).

~~19. The method of any one of claims 1-18, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt thereof at a dose ranging from about 50 mg to about 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~20. The method of any one of claims 1-19, wherein the dose ranges from about 150 mg to about 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~21. The method of any one of claims 1-19, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt and/or solvate thereof at a dose of about 50 mg, about 100 mg, about 150 mg, about 170 mg, about 325 mg, about 475 mg, or about 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~22. The method of any one of claim 1-18, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt and/or solvate thereof at a dose of at least 150 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~23. The method of any one of claim 1-18, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt and/or solvate thereof is to be administered at a dose ranging from about 150 mg to about 800 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~24. The method of claim 22 or 23, wherein the subject has a *BRCA2* mutation.~~

~~25. The usemethod of any one of claim 1-18, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt and/or solvate thereof at a dose of at~~

~~least 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~26. The method of any one of claim 1-18, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt and/or solvate thereof at a dose ranging from about 650 mg to about 800 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~27. The method of claim 25 or 26, wherein the subject has a *PALB2* mutation.~~

~~28. The method of any one of claims 1-27, wherein the Compound I or a pharmaceutically acceptable salt thereof is administered as a solid dosage form or a liquid dosage form.~~

~~29. The method of any one of claims 1-28, wherein the Compound I or a pharmaceutically acceptable salt thereof is in a lyophilized form.~~

~~30.~~9. The use~~method~~ of any one of claims 1-~~2~~8, wherein the Compound I or a pharmaceutically acceptable salt thereof is to be administered in a liquid dosage form prepared from a lyophilized form of the Compound I or a pharmaceutically acceptable salt thereof.

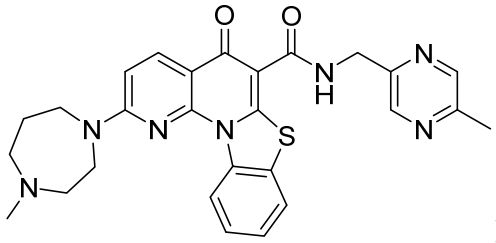
~~31. The method of any one of claims 1-28, wherein the Compound I or a pharmaceutically acceptable salt thereof is administered intravenously.~~

~~32.~~10. The use~~method~~ of any one of claims 1-~~3~~19, wherein the Compound I or a pharmaceutically acceptable salt thereof is to be administered in a 28-day cycle.

~~33.~~11. The use~~method~~ of claim~~s~~ ~~32~~10, wherein a dose of the Compound I or a pharmaceutically acceptable salt thereof is to be administered on day 1, day 8, and day 15 of the 28-day cycle.

~~34.~~12. The use~~method~~ of claim~~s~~ ~~32~~10, wherein a dose of the Compound I or a pharmaceutically acceptable salt thereof is to be administered on day 1 and day 8 of the 28-day cycle.

~~35.~~13. A pharmaceutical composition comprising Compound I, or a pharmaceutically acceptable salt and/or solvate thereof and a pharmaceutically acceptable carrier or excipient,



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wherein, the composition provides a plasma Compound I AUC_{∞} ranging from about 2,000 ng*hr/mL to about 110,000 ng*hr/mL after a single dose administration of the composition to a human subject at a dose of about 50 mg to about 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).

~~36. The pharmaceutical composition of claim 35, wherein the dose of Compound I, or a pharmaceutically acceptable salt or solvate thereof ranges from about 150 mg/m^2 to about 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~37. The pharmaceutical composition of claim 35 or 36, wherein the plasma Compound I AUC_{∞} ranges from about 5,000 ng*hr/mL to about 70,000 ng*hr/mL.~~

~~38.~~14. The pharmaceutical composition of ~~any one of claims 35-37~~claim 13, wherein the composition provides a plasma Compound I C_{max} ranging from about 200 ng/mL to about 6,000 ng/mL.

~~39. The pharmaceutical composition of any one of claims 35-37, wherein the composition provides a plasma Compound I C_{max} ranging from about 500 ng/mL to about 5,000 ng/mL.~~

~~40.~~15. The pharmaceutical composition of ~~any one of claims 35-39~~claim 13 or 14, wherein the composition provides a plasma Compound I T_{max} ranging from about 0.3 hour to about 2.0 hours.

41. The pharmaceutical composition of any one of claims 35-39, wherein the composition provides a plasma Compound I T_{max} ranging from about 0.4 hour to about 1.5 hour.

42. The pharmaceutical composition of claim 35, wherein the composition provides a plasma Compound I C_{max} ranging from about 200 ng/mL to about 6,000 ng/mL and wherein the composition provides a plasma Compound I T_{max} ranging from about 0.3 hour to about 2.0 hours.

43. The pharmaceutical composition of claim 35, wherein the composition provides a plasma Compound I C_{max} ranging from about 500 ng/mL to about 5,000 ng/mL and wherein the composition provides a plasma Compound I T_{max} ranging from about 0.4 hour to about 1.5 hour.

44. The pharmaceutical composition of any one of claims 35-43, wherein the plasma Compound I AUC_{∞} ranges from about 11,000 ng*hr/mL to about 52,000 ng*hr/mL after a single dose administration of the composition to a human subject at a dose of about 475 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).

45. The pharmaceutical composition of any one of claims 35-43, wherein the plasma Compound I AUC_{∞} ranges from about 30,000 ng*hr/mL to about 40,000 ng*hr/mL after a single dose administration of the composition to a human subject at a dose of about 475 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).

46. The pharmaceutical composition of any one of claims 35-45, wherein the plasma Compound I C_{max} ranges from about 900 ng/mL to about 2,600 ng/mL after a single dose administration of the composition to a human subject at a dose of about 475 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).

47. The pharmaceutical composition of any one of claims 35-45, wherein the plasma Compound I C_{max} ranges from about 1,200 ng/mL to about 2,300 ng/mL after a single

~~dose administration of the composition to a human subject at a dose of about 475 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~48. The pharmaceutical composition of any one of claims 35-47, wherein the plasma Compound I T_{max} ranges from about 1.0 hour to about 1.4 hour after a single dose administration of the composition to a human subject at a dose of about 475 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~49. The pharmaceutical composition of any one of claims 35-48, wherein the composition is a solid composition or a liquid composition.~~

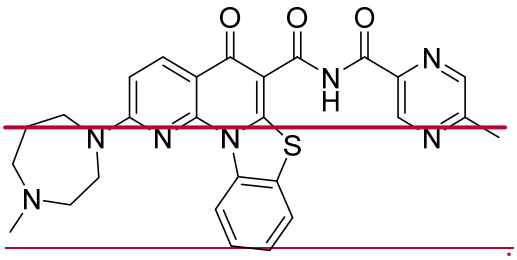
~~50. The pharmaceutical composition of any one of claims 35-49, wherein the composition comprises a lyophilized form of Compound I or a pharmaceutically acceptable salt and/or solvate thereof.~~

~~51.~~16. The pharmaceutical composition of any one of claims ~~35-49~~13-15, wherein the composition ~~comprises~~ is a liquid composition prepared with a lyophilized form of Compound I or a pharmaceutically acceptable salt and/or solvate thereof.

~~52. The pharmaceutical composition of any one of claims 35-51, wherein the composition is for an intravenous administration.~~

~~53. The pharmaceutical composition of any one of claims 35-52, wherein the composition comprises less than about 1% impurities.~~

~~54. The pharmaceutical composition of any one of claims 35-53, wherein the composition comprises less than 0.1% of~~



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~~55. The pharmaceutical composition of any one of claims 35-54, wherein the pharmaceutically acceptable excipient is a bulking agent.~~

~~56. The pharmaceutical composition of claim 55, wherein the bulking agent is sucrose, mannitol, or trehalose.~~

~~57.~~17. ~~A method for treating or ameliorating cell proliferation disorder in a subject, comprising administering to the subject in need thereof~~Use of a therapeutically effective amount of a pharmaceutical composition of any one of claims ~~35-56~~13-16 in the manufacture of a medicament for the treatment or amelioration of cell proliferation disorder in a subject in need thereof, wherein the pharmaceutical composition is administered to the subject.

~~58. The use~~method of claim 57, wherein the cell proliferation disorder is a cancer.

~~59. The use~~method of claim 58, wherein the cancer is a solid tumor.

~~60.~~18. The use~~method~~ of claim ~~58~~17, wherein the cell proliferation disorder ~~the cancer~~ is a hematologic malignancy, colorectal cancer, breast cancer, lung cancer, liver cancer, ovarian cancer, cervical cancer, Ewing's sarcoma, pancreatic cancer, cancer of the lymph nodes, colon cancer, prostate cancer, brain cancer, bone cancer, cancer of the head and neck, skin cancer, kidney cancer, osteosarcoma, cancer of the heart, uterine cancer, gastrointestinal malignancies, or carcinomas of the larynx and oral cavity.

~~61.~~19. The ~~method~~ use of claim ~~58~~18, wherein the cancer is breast cancer, ovarian cancer, ~~or~~ pancreatic cancer, or prostate cancer.

62.20. The usemethod of claim 5818, wherein the hematologic malignancy is selected from leukemia, lymphoma, myeloma, and multiple myeloma.

63.21. The usemethod of any one of claims 58-6218-20, wherein the cancer is a *PALB2*-mutated cancer.

64.22. The usemethod of any one of claims 58-6318-21, wherein the cancer is a *BRCA2*-mutated cancer.

65. The method of claims 63 or 64, wherein the cancer is breast cancer, ovarian cancer, pancreatic cancer, or prostate cancer.

66. The method of claim 63 or 64, wherein the cancer is breast cancer or prostate cancer.

67. The method of claim 63, wherein the *PALB2* mutation is a loss-of-function mutation of the *PALB2* gene.

68. The method of claim 63, wherein the *PALB2* mutation is a monoallelic loss-of-function mutation.

69. The method of claim 63, wherein the *PALB2* mutation is a biallelic loss-of-function mutation.

70. The method of claim 64, wherein the *BRCA2* mutation is a loss-of-function mutation of the *BRCA2* gene.

71.23. The usemethod of any one of claims 57-7017-22 wherein the subject is to be administered the Compound I or a pharmaceutically acceptable salt thereof at a dose ranging from about 50 mg to about 1,000 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).

72. The method of any one of claims 57-71 wherein the subject is administered the Compound I or a pharmaceutically acceptable salt thereof at a dose ranging from about

~~50 mg to about 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~73. The method of any one of claims 57-72, wherein the dose ranges from about 150 mg to about 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~74. The method of any one of claims 57-73, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt and/or solvate thereof at a dose of about 50 mg, about 100 mg, about 150 mg, about 170 mg, about 325 mg, about 475 mg, or about 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~75. The usemethod of any one of claim 57-71, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt and/or solvate thereof is to be administered at a dose of at least 150 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~76. The usemethod of any one of claim 57-71, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt and/or solvate thereof is to be administered at a dose ranging from about 150 mg to about 800 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~77. The usemethod of claim 75 or 77, wherein the subject has a *BRCA2* mutation.~~

~~78. The usemethod of any one of claim 57-71, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt and/or solvate thereof is to be administered at a dose of at least 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~79. The usemethod of any one of claim 57-71, wherein the subject is administered the Compound I or a pharmaceutically acceptable salt and/or solvate thereof is to be administered at a dose ranging from about 650 mg to about 800 mg of the Compound I~~

~~or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).~~

~~80. The usemethod of claim 78 or 79, wherein the subject has a *PALB2* mutation.~~

~~81. The method of any one of claims 57-80, wherein the Compound I or a pharmaceutically acceptable salt thereof is to be administered intravenously.~~

~~82.~~24. The use~~pharmaceutical composition~~ of any one of claims ~~57-81~~17-23, wherein the composition is to be administered in a 28-day cycle.

~~83.~~25. The use~~pharmaceutical composition~~ of claim~~s~~ ~~82~~24, wherein a dose of the Compound I or a pharmaceutically acceptable salt thereof is to be administered on day 1, day 8, and day 15 of the 28-day cycle.

~~84.~~26. The use~~pharmaceutical composition~~ of claim~~s~~ ~~82~~24, wherein a dose of the Compound I or a pharmaceutically acceptable salt thereof is to be administered on day 1 and day 8 of the 28-day cycle.

~~85.~~27. ~~A method of inhibiting Pol I transcription in a subject, comprising administering to a subject in need thereof~~ Use of a therapeutically effective amount of a pharmaceutical composition of any one of claims ~~35-56~~13-16 in the manufacture of a medicament for the inhibition of Pol I transcription in a subject in need thereof, wherein the pharmaceutical composition is administered to the subject~~.~~.

~~86. The method of claim 85, wherein the inhibition ofinhibiting Pol I transcription is in peripheral blood mononuclear cells.~~

~~87.~~28. ~~A method of stabilizing G-quadruplexes (G4s) in a subject, comprising administering to a subject in need thereof~~Use of a therapeutically effective amount of a pharmaceutical composition of any one of claims ~~35-56~~13-16 in the manufacture of a medicament for the stabilization of G-quadruplexes (G4s) -in a subject in need thereof, wherein the pharmaceutical composition is administered to the subject.

~~88. The method of claim 87, wherein the stabilization ofstabilizing G4s is in peripheral blood mononuclear cells.~~