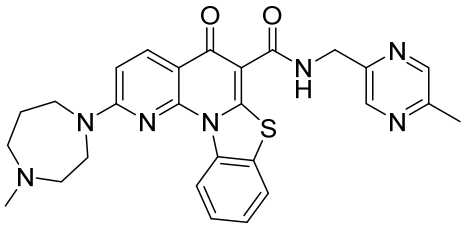
CLAIMS

What is Claimed:

1. Use of Compound I, or a pharmaceutically acceptable salt or solvate thereof,



,

I

in the manufacture of a medicament for the treatment of cancer in a human 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 the *PALB2* mutation is a germline and/or somatic mutation.

2. The use of claim 1, wherein the subject additionally has a *BRCA2* mutation, and the BRCA2 mutation is a germline and/or somatic mutation.

3. The use of claim 1 or 2, 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.

4. The use of claim 3, wherein the cancer is breast cancer, ovarian cancer, pancreatic cancer, or prostate cancer.

5. The use of claim 3, wherein the hematologic malignancy is selected from leukemia, lymphoma, myeloma, and multiple myeloma.

6. The use of any one of claims 1-5, wherein the Compound I or a pharmaceutically acceptable salt thereof is to be administered at a dose ranging from 50 mg to 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2).

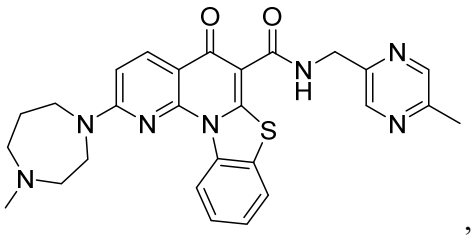
7. The use of any one of claims 1-6, wherein the Compound I or a pharmaceutically acceptable salt thereof is to be administered in a liquid dosage form prepared from a lyophilized form of the Compound I or a pharmaceutically acceptable salt thereof.

8. The use of any one of claims 1-7, wherein the Compound I or a pharmaceutically acceptable salt thereof is to be administered in a 28-day cycle.

9. The use of claim 8, 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.

10. The use of claim 8, 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.

11. Use of Compound I, or a pharmaceutically acceptable salt or solvate thereof,



,

I

in the manufacture of a medicament for the treatment of cancer in a human subject, wherein the Compound I, or a pharmaceutically acceptable salt or solvate thereof is to be administered to the subject in a pharmaceutical composition, wherein the composition provides a plasma Compound I AUC_∞ ranging from 2,000 ng*hr/mL to 110,000 ng*hr/mL after a single dose administration of the composition to a human subject at a dose of 50 mg to 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2), and wherein the cancer is a *PALB2*-mutated cancer.

12. The use of claim 11, wherein the composition provides a plasma Compound I C_{max} ranging from 200 ng/mL to 6,000 ng/mL.

13. The use of claim 11 or 12, wherein the composition provides a plasma Compound I T_{max} ranging from 0.3 hour to 2.0 hours.

14. The use of any one of claims 11-13, wherein the composition is a liquid composition prepared with a lyophilized form of Compound I or a pharmaceutically acceptable salt and/or solvate thereof.

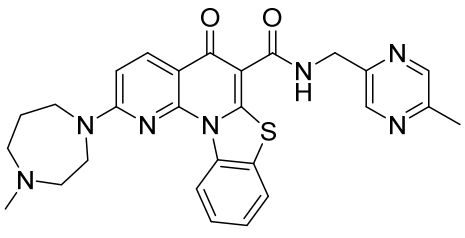
15. The use of claim 11, wherein the cancer is a hematologic malignancy, colorectal cancer, breast cancer, lung cancer, liver cancer, ovarian cancer, cervical cancer, Ewing's sarcoma, pancreatic cancer, cancer of the lymph nodes, colon cancer, prostate cancer, brain cancer, bone cancer, cancer of the head and neck, skin cancer, kidney cancer, osteosarcoma, cancer of the heart, uterine cancer, gastrointestinal malignancies, or carcinomas of the larynx and oral cavity.

16. The use of claim 15, wherein the cancer is breast cancer, ovarian cancer, pancreatic cancer, or prostate cancer.

17. The use of claim 15, wherein the hematologic malignancy is selected from leukemia, lymphoma, myeloma, and multiple myeloma.

18. The use of any one of claims 11-17, wherein the cancer additionally comprises a *BRCA2*-mutated cancer.

19. Use of Compound I, or a pharmaceutically acceptable salt or solvate thereof,



,

I

in the manufacture of a medicament for the treatment of cancer in a human subject, wherein the Compound I, or a pharmaceutically acceptable salt or solvate thereof is to be administered to the subject in a pharmaceutical composition, wherein the composition provides a plasma Compound I AUC_{∞} ranging from 2,000 ng*hr/mL to 110,000 ng*hr/mL after a single dose administration of the composition to a human subject at a dose of 50 mg to 650 mg of the Compound I or a pharmaceutically acceptable salt and/or solvate thereof, per body surface area of the subject (m^2), 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 a 28-day cycle.

20. The use of claim 19, wherein a dose of Compound I or a pharmaceutically acceptable salt thereof is to be administered on day 1 and day 8 of a 28-day cycle.

21. The use of claim 6, wherein the subject is to be administered the Compound I or a pharmaceutically acceptable salt thereof at a dose of 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 use of claim 19 or 20, 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.

23. The use of claim 22, wherein the cancer is breast cancer, ovarian cancer, pancreatic cancer, or prostate cancer.

24. The use of claim 22, wherein the hematologic malignancy is selected from leukemia, lymphoma, myeloma, and multiple myeloma.