We claim:

1. Use of a therapeutically effective amount of gedatolisib, or a pharmaceutically acceptable salt, solvate, or ester thereof, in the manufacture of a medicament for treating cancer in a human subject in need thereof, wherein:

the medicament is to be repeatedly administered for at least two cycles, wherein in each cycle: the medicament is to be administered at least once a week for a period of three weeks;

the medicament is to be discontinued for a period of one week; and thereafter

the medicament is to be resumed for at least once a week.

2. The use of claim 1, wherein:

a CDK 4/6 inhibitor is to be repeatedly administered to the human subject for at least two cycles, wherein in each cycle:

the CDK 4/6 inhibitor is to be administered to the human subject at least once a week for a period of three weeks;

the CDK 4/6 inhibitor is to be discontinued for a period of one week; and thereafter

the CDK 4/6 inhibitor is to be resumed for at least one week.

3. The use of claim 1 or 2, wherein the CDK 4/6 inhibitor and the medicament are to be administered during concurrent weeks.

4. Use of a therapeutically effective amount of gedatolisib, or a pharmaceutically acceptable salt, solvate, or ester thereof, and a CDK 4/6 inhibitor in the manufacture of a medicament for treating cancer in a human subject in need thereof, wherein:

the medicament is to be repeatedly administered for at least two cycles, wherein in each cycle:

the medicament is to be administered at least once a week for a period of three weeks;

the medicament is to be discontinued for a period of one week; and thereafter

the medicament is to be resumed for at least once a week.

5. The use of any one of claims 1 to 4, wherein the medicament is to be resumed for at least once a week for a period of three weeks.

6. The use of any one of claims 1 to 5, wherein the medicament is to be repeatedly administered for at least 3 cycles, at least 4 cycles, at least 5 cycles, at least 6 cycles, at least 7 cycles, at least 8 cycles, or at least 9 cycles.

7. The use of any one of claims 1 to 6, wherein gedatolisib, or pharmaceutically acceptable salt, solvate, or ester thereof, is to be administered at a dose of 180mg once a week.

8. The use of any one of claims 2-7, wherein the CDK 4/6 inhibitor is selected from the group consisting of palbociclib, ribociclib, abemaciclib, trilaciclib, dalpiciclib, riviciclib, and combinations thereof, preferably wherein the CDK 4/6 inhibitor is palbociclib, preferably wherein the palbociclib is to be administered at a dose of 125 mg per day.

9. The use of any one of claims 1-8, wherein an estrogen receptor antagonist is to be administered to the human subject.

10. The use of claim 9, wherein the estrogen receptor antagonist is fulvestrant, preferably wherein the fulvestrant is to be administered at a dose of 500mg every two weeks or every four weeks.

11. The use of any one of the preceding claims, wherein the cancer is a solid cancer.

12. The use of claim 11, wherein the solid cancer is selected from the group consisting of breast cancer, vaginal cancer, vulvar cancer, cervical cancer, uterine cancer, ovarian cancer, endometrial cancer, cancer of the Fallopian tubes, prostate cancer, testicular cancer, penile cancer, lung cancer, colorectal cancer, melanomas, bladder cancer, brain/CNS cancer, esophageal cancer, gastric cancer, head/neck cancer, kidney cancer, liver cancer, pancreatic cancer, and sarcomas.

13. The use of claim 11 or 12, wherein the solid cancer is a hormone-dependent cancer.

14. The use of claim 13, wherein the hormone-dependent cancer is selected from the group consisting of breast cancer, vaginal cancer, vulvar cancer, cervical cancer, uterine cancer, ovarian cancer, endometrial cancer, cancer of the Fallopian tubes, prostate cancer, testicular cancer, and penile cancer, preferably breast cancer.

15. The use of claim 14, wherein the breast cancer is metastatic, hormone resistant, estrogen receptor positive, estrogen receptor negative, progesterone receptor negative, progesterone receptor positive, triple negative, HER2 positive, or HER2 negative breast cancer.

16. The use of claim 14 or 15, wherein the breast cancer is Basal or Luminal subtype.

17. The use of any one of claims 1-16 wherein the human subject is a pre-menopausal or post-menopausal female patient.

18. The use of any of claims 1-17, wherein the human subject has failed a prior treatment for cancer in a period of less than twelve months, or less than six months.

19. The use of any of claims 1-18, wherein the human subject has failed two or more prior treatments for cancer.

20. The use of claim 18 or 19, wherein the failed prior treatment is an endocrine treatment for cancer.