[0005] Most early breast cancers are treated with multi-modality therapy (surgery +/- radiotherapy + chemotherapy). Multiple large randomized trials have demonstrated identical outcomes may be obtained irrespective of the order of surgery and chemotherapy. Thus neoadjuvant (chemotherapy followed by surgery) and adjuvant (surgery followed by chemotherapy) treatment regimens are considered equivalent. One advantage of neoadjuvant therapy is that tumor responses to chemotherapy can be measured, unlike in the adjuvant setting where all known tumor is surgically removed prior to chemotherapy. The tumor response to neoadjuvant chemotherapy provides significant prognostic information. Those patients that achieve complete pathological tumor responses (no living cancer cells can be identified in the surgical specimen) have significantly better prognoses than those that do not.

[0006] It has been discovered that the PARP inhibitor veliparib, 2-[(2R)-2-methylpyrrolidin-2-yl]-1H-benzimidazole-4-carboxamide, acts synergistically in combination with the DNA-damaging agent carboplatin to increase the efficacy of the current standard-of-care treatment for early triple negative breast cancer. Adding veliparib and carboplatin to the standard of care increases the number of women that achieve pCR status in a neoadjuvant setting. This is estimated to translate into additional treated women remaining free of disease at 5 years. This is also expected increase the number of patients who would become eligible for less extensive surgery (fewer mastectomies, more breast-conserving surgery).

BRIEF SUMMARY OF THE INVENTION

[0007] The present invention relates to a method for the treatment of ER-negative, PR-negative, and HER-2 negative cancer of the breast in a subject, comprising administering to the subject 50 mg of 2-[(2R)-2-methylpyrrolidin-2-yl]-1H-benzimidazole-4-carboxamide twice a day continuously for twelve weeks; 80 mg/m^2 paclitaxel on day 1 of twelve 7-day cycles; and AUC 6 mg/mL/min carboplatin on day 1 of four 21-day cycles.

1. **[0007a]** In one aspect, there is provided the use of

(a) 50 mg of 2-[(2R)-2-methylpyrrolidin-2-yl]-1H-benzimidazole-4-carboxamide twice a day continuously for twelve weeks;

(b) 80 mg/m^2 paclitaxel on day 1 of twelve 7-day cycles; and

(c) AUC 6 mg/mL/min carboplatin on day 1 of four 21-day cycles, in the manufacture of a medicament for the treatment of ER-negative, PR-negative, and HER-2 negative cancer of the breast in a subject.

DETAILED DESCRIPTION OF THE INVENTION

[0008] Definitions

[0009] The terms "treat", "treating" and "treatment" refer to a method of alleviating or abrogating a disease and/or its attendant symptoms.

WHAT IS CLAIMED IS

1. ~~A method for the treatment of ER-negative, PR-negative, and HER-2 negative cancer of the breast in a subject, comprising administering to the subject~~Use of

   (a) 50 mg of 2-[(2R)-2-methylpyrrolidin-2-yl]-1H-benzimidazole-4-carboxamide twice a day continuously for twelve weeks;

   (b) 80 mg/m^2 paclitaxel on day 1 of twelve 7-day cycles; and

   (c) AUC 6 mg/mL/min carboplatin on day 1 of four 21-day cycles, in the manufacture of a medicament for the treatment of ER-negative, PR-negative, and HER-2 negative cancer of the breast in a subject.~~:~~

2. The ~~method~~ use of claim 1, followed by a second chemotherapy segment comprising administering to the subject

   (a) 60 mg/m^2 doxorubicin on day 1 of four 14-day cycles; and

   (b) 600 mg/m^2 cyclophosphamide on day 1 of four 14-day cycles.

3. The ~~method~~ use of claim 1, followed by a second chemotherapy segment comprising administering to the subject

   (a) 60 mg/m^2 doxorubicin on day 1 of four 21-day cycles; and

   (b) 600 mg/m^2 cyclophosphamide on day 1 of four 21-day cycles.

4. The ~~method~~ use of any of claims 1-3, wherein the subject has early-stage breast cancer.

5. The ~~method~~ use of any of claims 1-4, wherein the subject is a candidate for surgery.

6. The ~~method~~ use of claim 5, wherein the subject has surgery approximately 4-8 weeks after the last chemotherapy treatment.

7. The ~~method~~ use of claim 6, wherein the subject has a mastectomy.

8. The ~~method~~ use of claim 6, wherein the subject has breast conservation surgery.

9. The ~~method~~ use of any of claims 1-8, wherein the ER-negative, PR-negative, and HER-2 negative cancer of the breast has a BRCA1 mutation.

10. The ~~method~~ use of any of claims 1-8, wherein the ER-negative, PR-negative, and HER-2 negative cancer of the breast has a BRCA2 mutation.