All subjects who have a Final Visit < 30 days after the last dose of study drug will have a Follow-up Visit approximately 30 days after the Final Visit.

Survival and post treatment therapy information will be collected every two months (unless requested by sponsor more frequently to support data analysis) beginning on the date the subject is registered off study until the endpoint of death, until the subject has become lost to follow-up, or until study termination by AbbVie.

Optional Veliparib Crossover Treatment

Subjects who discontinue study treatment because of disease progression may be eligible to receive veliparib monotherapy treatment starting at 300 mg BID upon unblinding and confirmation that they were receiving placebo. Disease progression must be documented based upon central imaging review or by discussion with the AbbVie Medical Monitor. If the subject tolerates 300 mg BID for 2 weeks, veliparib may be increased to 400 mg BID at the investigator's discretion. Treatment with veliparib monotherapy should continue until a second disease progression event or unacceptable toxicity occurs. Subjects who enter crossover treatment with veliparib monotherapy should follow the schedule of assessments as outline in Table 3, starting with Cycle 1 Day 1.

5.2 Selection of Study Population

5.2.1 Inclusion Criteria

Subjects will be adult men and women with HER2-negative metastatic or locally advanced unresectable breast cancer and a documented deleterious or suspected deleterious *BRCA1* or *BRCA2* germline mutation.

Subjects must meet all of the following inclusion criteria to be eligible:

1. ≥ 18 years of age.
2. Histologically or cytologically confirmed breast cancer that is either locally advanced or metastatic. Locally advanced breast cancer must not be amenable to surgical resection or radiation with curative intent.

3. Suspected deleterious or deleterious *BRCA1* or *BRCA2* germline mutation.

   The investigator should ensure that the testing is consistent with local guidelines, and clinical practice, and that the test uses either 1) direct DNA sequencing/multiplex ligation-dependent probe amplification (MLPA) or 2) a well-characterized methodology previously validated by sequencing, such as that used to assess founder mutations. If testing has been performed prior to Study M12-914, subjects may be enrolled but must be re-tested by the Sponsor core laboratory for documentation of *BRCA1* or *BRCA2* germline mutations.

4. Breast cancer must be HER2-negative defined as IHC 0 – 1+ OR HER2-neu negative according to ASCO-CAP[40] guideline recommendations (Appendix G).

5. Measurable or non-measurable (but radiologically evaluable) disease per RECIST (version 1.1) on CT scan (within 28 days of randomization) with at least one lesion outside previously irradiated areas.

6. ECOG performance status of 0 to 2.

7. Subject is able to swallow and retain oral medication and does not have uncontrolled emesis.

8. Adequate hematologic, renal, and hepatic function as follows (within 28 days of randomization):

   - Bone Marrow: Absolute neutrophil count (ANC) $\geq 1500/mm^3$ ($1.5 \times 10^9/L$); Platelets $\geq 100{,}000/mm^3$ ($100 \times 10^9/L$); Hemoglobin ≥ 9.5 g/dL (1.4 mmol/L);
   - Renal Function: Serum creatinine $\leq 1.5 \times$ upper limit of normal (ULN) range **OR** creatinine clearance ≥ 50 mL/min/1.73 m^2 (according to local assessment method) for subjects with creatinine levels above institutional normal;
   - Hepatic Function: AST $\leq 2.5 \times$ upper limit of normal; ALT $\leq 2.5 \times$ upper limit of normal, bilirubin $\leq 1.5 \times$ the ULN range. For subjects with liver metastases, AST $< 5 \times$ ULN range; ALT $< 5 \times$ ULN range. Subjects with Gilbert's syndrome may have a bilirubin $\geq 1.5 \times$ the ULN range, if no evidence of biliary obstruction exists;

- Activated Partial Thromboplastin Time (APTT) must be ≤ 1.5 × the ULN range and INR < 1.5. Subjects on anticoagulant therapy will have an appropriate APTT and INR as determined by the investigator.

9. Women of childbearing potential and men must agree to use adequate contraception (one of the following listed below) prior to study entry, for the duration of study participation, and for 90 days following completion of therapy. Women of childbearing potential must have a negative serum pregnancy test within 7 days prior to initiation of treatment. To be considered of non-childbearing potential, postmenopausal women must be amenorrheic for at least 12 months or subjects must be surgically sterile.

   - Total abstinence from sexual intercourse (for minimum of one complete menstrual cycle prior to study drug administration);
   - Vasectomized male subjects or vasectomized partner of female subjects;
   - Double-barrier method (condoms, contraceptive sponge, diaphragm, or vaginal ring with spermicidal jellies or cream); or
   - Intra-Uterine Device (IUD).
   - Additionally, male subjects (including those who are vasectomized) whose partners are pregnant or might be pregnant must agree to use condoms and refrain from sperm donation for the duration of the study and for 90 days following completion of therapy.
   - Male and female patients of childbearing potential and/or their partners must each use a contraception method for at least 6 months after treatment with paclitaxel as specified in the SmPC of the paclitaxel marketing authorization in each country.

10. Capable of understanding and complying with parameters as outlined in the protocol and able to sign and date the informed consent, approved by an IEC/IRB, prior to initiation of any screening or study-specific procedures.

Rationale for Inclusion Criteria

(1 – 7) To select the appropriate subject population with sufficient disease severity for evaluation.

(8) For the safety of the subjects.

(9) The impact of veliparib, carboplatin, and paclitaxel on the unborn fetus is unknown; therefore, these criteria ensure that adequate precautions are taken to avoid pregnancy.

(10) In accordance with harmonized Good Clinical Practice (GCP).

5.2.2 Exclusion Criteria

Subjects must not meet any of the following exclusion criteria to be eligible.

1. Received anticancer agent(s) or an investigational agent within 21 days prior to C1D-2 or radiotherapy within 28 days prior to C1D-2.
   - Prior treatment with palliative local breast or bone lesion radiation (other than pelvis) can occur, if administered at least 14 days prior to C1D-2.
   - Anticancer hormonal therapy must be stopped 7 days before starting C1D-2. Subjects receiving biophosphonates or denosumab are eligible.
2. More than 2 prior lines of cytotoxic chemotherapy (e.g., gemcitabine, doxorubicin, capecitabine) for metastatic disease.*
   - Regimens received in the adjuvant/neoadjuvant setting or for locally advanced breast cancer within the past 6 months will also be considered toward the maximum of 2 prior lines of therapy. Adjuvant/neoadjuvant chemotherapy for one cancer event will count as one prior line of therapy, if received within the past 6 months.
   - Previous treatments with hormonal therapy (tamoxifen, aromatase inhibitors) and signal transduction agents (e.g., erlotinib, gefitinib, everolimus, bevacizumab) are allowed and are not counted towards the prior line of therapy if not given in combination with cytotoxic chemotherapy.

3. More than one prior line of platinum therapy for breast cancer. Subjects who have progressed on platinum therapy or recurred within 12 months of platinum therapy will be excluded.
4. Subjects experiencing a significant adverse effect or toxicity (Grade 3 or Grade 4), causally attributed to previous anticancer treatment that has not recovered to at least Grade 2 are excluded.
5. Prior therapy with PARP inhibitors.*
6. Prior taxane therapy administered for the treatment of metastatic breast cancer with the below exceptions.*
   - Prior taxane therapy for metastatic breast cancer is allowed if the patient received ≤ 1 full cycle (i.e., therapy discontinued within 4 weeks for subjects receiving weekly paclitaxel or Abraxane; therapy discontinued within 3 weeks for subjects receiving paclitaxel or docetaxel every 3 weeks) in the absence of progression or if taxane therapy for metastatic disease was > 12 months prior to C1D-2.
   - Use of taxanes as adjuvant therapy or to treat locally advanced disease is permitted, if given more than 6 months prior to C1D-2.
7. Subjects with active brain metastases or leptomeningeal disease.
   - Subjects should have a brain MRI within 28 days of randomization to confirm the absence of CNS metastases. Contrast CT is acceptable for subjects who are unable to undergo a brain MRI.
   - Subjects with known brain metastases must have clinically controlled neurologic symptoms and have received previous adequate treatment, defined as surgical excision and/or radiation therapy with stable neurologic function and no evidence of Central Nervous System (CNS) disease progression as determined by comparing a computed tomography (CT) scan or magnetic resonance imaging (MRI) scan performed during screening to a prior scan performed at least 4 weeks earlier and provided that the subject is asymptomatic, has no evidence of cavitation or hemorrhage, and does not require corticosteroids (must have discontinued steroids at least 3 months prior to study drug administration).

8. A history of uncontrolled seizure disorder, including focal or generalized seizure within the past year.
9. Pre-existing neuropathy from any cause in excess of Grade 1 (except focal neuropathy such as brachial plexopathy or carpel tunnel syndrome).
10. Major surgery within 3 weeks of randomization.
11. Known history of allergic reaction to cremophor/paclitaxel, or carbolplatin or known contraindications to either drug.
12. Clinically significant uncontrolled condition(s) including, but not limited to:
    - Active infection;
    - Symptomatic congestive heart failure;
    - Unstable angina pectoris or cardiac arrhythmia;
    - Myocardial infarction within last 6 months;
    - Known active hepatitis B or hepatitis C with abnormal liver function tests or organ dysfunction;
    - Uncontrolled hypertension despite optimal medical management;
    - Psychiatric illness/social situations that would limit compliance with study requirements; or
    - Any medical condition that, in the opinion of the investigator, places the subject at an unacceptably high risk for toxicities.
13. A previous or concurrent cancer that is distinct in primary site or histology from breast cancer, except cervical carcinoma in situ, non-melanoma carcinoma of the skin, or in situ carcinoma of the bladder. Any cancer curatively treated more than 3 years prior to entry is permitted. For these subjects, metastases must be histologically or cytologically confirmed to be breast cancer.
14. Pregnant or breastfeeding.

* Note: For prior chemotherapy, treatment for 1 full cycle or less will not be considered as prior therapy unless the patient experienced progression of disease while on that therapy.