**EA1181/CompassHER2 pCR**

**For Patients with HER2 positive Breast Cancer**

**EA1181 Available Through ECOG-ACRIN Cancer Research Group**

Preoperative THP & Postoperative HP in Patients who Achieve a Pathologic Complete Response

Part I Component of: The CompassHER2 Trials (COMprehensive use of Pathologic response ASSessment to optimize therapy in HER2 positive breast cancer)

### Patient Population

See Section 3.0 for Complete Eligibility Details

- Age ≥ 18 years, ECOG PS 0-1, and adequate lab values
- Must have histologically confirmed HER2 positive primary invasive breast carcinoma (2018 ASCO/CAP) and determined by local testing
- ER and PR status must be known/determined by local testing; patients with hormone receptor positive or hormone receptor negative HER2 positive breast cancer are eligible
- Must have clinical stage II and IIIa (T2-3/N0-2/M0; see protocol for details)
- Must have no contraindication to standard adjuvant therapy, consisting of HER2 directed therapy, radiation (if indicated) and endocrine therapy (if ER+) if achieving pCR at surgery
- Patients with two separate invasive breast cancers, or with multifocal/multicentric disease are eligible per protocol
- Must not have impaired decision making capacity
- Must not have prior invasive breast cancer, or ipsilateral DCIS (see protocol for details/exceptions)
- No prior treatment for the current breast cancer
- LVEF within normal institutional parameters
- No > grade 1 peripheral neuropathy (any etiology)
- Must have bilateral mammogram and diagnostic breast ultrasound performed at screening; baseline imaging of the ipsilateral axilla is mandatory (subjects with axillary lymph nodes suspicious must be willing to have a needle aspiration or core biopsy)
- Must not have a concurrent serious medical condition that would preclude completion of study therapy (see protocol for examples)
- Women must not be pregnant/breast feeding
- HIV, HBV, and HCV patients are permitted per protocol

### Treatment Plan

See Section 5.0 for Complete Treatment Details

1 cycle = 21 days; treatment to be administered +/- 3 days

**Pre-Operative/Neoadjuvant THP:**

- Choice of taxane therapy- per the treating oncologist:
  - Option 1: Paclitaxel, Trastuzumab (or FDA approved biosimilar), Pertuzumab, x 4 cycles
  - Option 2: Docetaxel, Trastuzumab (or FDA approved biosimilar), Pertuzumab, x 4 cycles
  - Prophylactic growth factor support is required
  - Option 3: Nab-paclitaxel, Trastuzumab (or FDA approved biosimilar), Pertuzumab, x 4 cycles

- If surgery occurs later than 21 days after the 4th cycle of THP, a 5th cycle of HP (without taxane) must be administered before surgery. Patients who progressed during THP should get additional pre-surgical therapy (per the treating oncologist; followed per Arm B)

**Post-Operative/Adjuvant Therapy:**

- Arm A: pCR (no invasive disease); Trastuzumab, Pertuzumab for 13 cycles, radiation therapy and endocrine therapy if appropriate
- Arm B: SOC for patients who do NOT achieve pCR

**Notes:**

- Doses are based on actual body weight; one 3 week dose of docetaxel = 3 weekly doses of paclitaxel
- A clip must be placed in the breast primary tumor
- See protocol for pre-treatment tumor evaluation (imaging/staging/surgical assessment/axillary assessment pre-therapy); and neoadjuvant tumor evaluation (imaging/physical exam evidence of residual disease)
- Follow institutional guidelines for the order of infusions, and preparation/administration/pre-medications for paclitaxel/nab-paclitaxel

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**Patient Enrollment**

All Sites: Oncology Patient Enrollment Network (OPEN) [https://open.ctsu.org](https://open.ctsu.org)

**Protocol Information**

ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!
NOTE: Upcoming Addendum #1 (not yet released to sites) will feature this version of the schema, which includes the Pertuzumab Treatment and footnote #9. This information is correct in protocol section 5, but was missing in the schema for protocol version 12/20/19.