**Patient Population**

See Section 3.0 for Complete Eligibility Details

- Age ≥ 18 years (all genders), ECOG PS 0-2
- Must have histologically confirmed HER2+ primary invasive breast carcinoma by ASCO/CAP guidelines (determined by local testing)
- Must have known ER/PR status by local testing (ASCO/CAP guidelines); patients with hormone receptor-positive or hormone receptor-negative HER2+ breast cancer are eligible
- Must be Stage IIa-IIIc (AJCC 8th ed.):
  - Patients without nodal involvement (cN0) are eligible if T size > 2.0cm (T2-4)
  - Patients with nodal involvement (cN1-3) are eligible if T2-4
  - Patients with clinical T4d are not eligible
- Patients with bilateral HER2+ invasive breast cancers or multiple ipsilateral invasive tumors can be eligible; see protocol for details
- Must not have had any prior treatment for the current breast cancer (surgery, chemo, hormonal therapy, radiation, or experimental therapy)
- Must plan to start a standard neoadjuvant pertuzumab (or other biosimilar)-based regimen
- Patients with a prior/concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety/efficacy of this imaging intervention are eligible
- Patients with HIV are permitted per protocol
- Must not be pregnant/breast-feeding
- Must not have any contraindication to FDG-PET/CT imaging (i.e., routine glucose values > 200 mg/dL, severe claustrophobia)
- Must be participating at a site that agreed to perform the imaging research studies, completed the EA-defined PET/CT scanner qualification and received EA approval (see protocol for details)

**Treatment Plan**

See Section 5.0 for Complete Study Plan Details

- Patients will undergo FDG-PET/CT imaging at baseline (T0) and on day 15 (+ 7 days) of cycle 1 (T1) of the selected neoadjuvant pertuzumab-based systemic regimen
  - T0 PET/CT scan can be done prior to or after registration and both must meet the parameters of the EA1211 Imaging Manual and Section 7.5
  - After: must be completed within 21 days of registration, prior to initiating the systemic treatment, which must start within 21 days of T0 scan (note: if T0 is M1/stage IV, patient will come off study)
  - Before: systemic treatment must start after registration and within 21 days of T0 scan
- T1 (cycle 1 day 15 [+ 7 days]) FDG-PET/CT scan must be completed prior to start of day 1 cycle 2 treatment
  - Patients must not use long-acting colony stimulating factors within 14 days prior to completing T0 and T1 FDG-PET/CT scans
  - The use of daily filgrastim is discouraged and must be completed within 72 hours prior to T1 FDG-PET/CT
- Standard of care (SOC) neoadjuvant therapy options (as recommended by the treating physician):
  - Docetaxel or paclitaxel, herceptin, pertuzumab (THP) x 12 weeks
  - Docetaxel or paclitaxel, carboplatin, herceptin, pertuzumab (TCHP) x 18 weeks
  - Note: if a paclitaxel/docetaxel allergy is experienced, or the patient needs to avoid steroid medications, nab-paclitaxel can be substituted
  - In patients with evidence of disease progression during neoadjuvant therapy, additional pre-surgical therapy should be given at the discretion of the treating oncologist
- After neoadjuvant therapy, patient will undergo SOC surgery per treating physician

**Study Chair:**
Heather Jacene, MD

**Study Co-Chair:**
Roisin Connolly, MD

**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!