Weekly Paclitaxel (WP): 80 mg/m² IV weekly for 12 doses.

It is expected that approximately 270 patients will need to be prescreened in order to enroll 54 patients (26 ER+/HER2- and 28 ER-/HER2-) who have abnormal HER2 signaling activity.

Agents targeting HER2, such as trastuzumab, lapatinib, and pertuzumab, have been shown to delay disease progression, metastasis and a poorer prognosis 

Pretreatment research core biopsy (2 cores) of primary tumor to procure tumor tissue for submission to Celcuity for assessment of HER2 signaling function.

TRIAL DESIGN

This is a prospective, single arm, open label, Phase II clinical trial designed to evaluate the efficacy of neoadjuvant chemotherapy plus trastuzumab and pertuzumab in a group of HER2-negative breast cancer patients with abnormal HER2 signaling activity, determined by a novel HER2 signaling test.

Patients will be required to have a pretreatment research core biopsy to confirm that the tumor consists solely of breast cancer cells. Patients with breast cancer that is not solely breast cancer cells and patients that are not autopsied post mortem will be excluded from the study.

The HER2-driven activity was determined (Δ) to be most reproducible (Δ) and to be significantly higher (Δ) in patients with HER2-negative breast cancer with abnormal HER2 signaling activity.

Table 2. Summary of Cell Line Characterizations

Table 3. Comparison of inhibition of HER2-driven breast cancer cell growth by Trastuzumab (3×) or Pertuzumab Alone in Combination

Confirmation

The findings suggest that both HER2-directed drug signaling status does not preclude breast cancer patients from benefitting from HER2-directed therapies. These findings positioning novel HER2-directed breast cancer patients with abnormal HER2 signaling may require trials in HER2-poor.