Now Enrolling: CompassHER2 pCR (EA1181) – Testing the Ability to Decrease Chemotherapy in Patients with HER2 Positive Breast Cancer Who Have No Remaining Cancer at Surgery after Limited Pre-Operative Chemotherapy and HER2 Targeted Therapy

This study is a neoadjuvant trial for patients with clinical stage II or III HER2 positive breast cancer. It is asking if adjuvant therapy after surgery can safely be omitted for patients with pathologic complete response (pCR) after 12 weeks of pre-operative THP (single agent taxane plus trastuzumab and pertuzumab). The primary endpoint of the study for patients with pCR is 3-year recurrence-free survival.

Neoadjuvant therapy is now standard for newly diagnosed HER2 positive disease above Stage I. It offers the potential to optimize systemic therapy by decreasing unnecessary chemotherapy (and toxicities) in those with pCR. A more intensive HER2 targeted regimen with the antibody-drug conjugate T-DM1, and possibly more chemotherapy, is then reserved for patients with residual disease (RD).

Eligible patients with stage II-IIIa (T2-3; N0-2) HER2 positive breast cancer will receive 4 cycles (12 weeks) of neoadjuvant THP (physician's choice of weekly paclitaxel or every 3-week docetaxel) then surgery. If pCR, patients go on to complete a year of trastuzumab and pertuzumab, plus hormonal therapy and radiation if indicated. If RD, patients will receive standard post-operative adjuvant therapy and may enroll on other clinical trials, such as the upcoming companion trial A011801 (CompassHER2 RD), that Alliance will activate in mid-2020 to test the addition of tucatinib to standard T-DM1. Blood samples for the correlative aims will be collected at 5 time points (before, during, and after treatment), and tumor samples will be collected from the clinical biopsy and surgical specimen. Correlative objectives will assess whether any biomarkers can predict which patients are most likely to attain pCR with this approach. All patients will be followed for recurrence and survival.

The ECOG-ACRIN Breast Committee and Study Chair Dr. Nadine Tung (pictured above) are looking forward to ECOG-ACRIN membership participation in this important study! Additional information can be obtained from the EA1181 Study Team, the ECOG-ACRIN website, the CTSU and ClinicalTrials.gov (NCT04266249).