**BACKGROUND**

- Treatment of locally advanced breast cancer (LABC) with neoadjuvant chemotherapy measures the in vivo response to chemotherapy, assesses long-term clinical outcomes associated with that response, and enables some patients to undergo breast-conservation therapy due to therapeutic down-staging of the tumor.
- Patients with LABC and possible axillary treated with neoadjuvant chemotherapy prior to definitive surgery achieve a pCR of the tumor and axillae.
- 25–27% of patients with a pCR following neoadjuvant chemotherapy have a survival advantage of 85%, which is double the expected survival of those without a pCR.
- Sentinel lymph node (SLN) staging before treatment can optimize post-treatment prognostic stratification in clinically node-negative patients.
- If patients who are likely to show a pCR could be identified prior to initiation of therapy, it would enable more informed treatment decisions.
- Recurrence genetics testing has the potential to provide information on the likelihood of a patient with LABC responding to neoadjuvant chemotherapy.
- In the current study, the chemosensitivity predictiveness of MammaPrint and BluePrint will be assessed in patients receiving neoadjuvant chemotherapy in the clinical diagnostic setting.

**OBJECTIVES**

1. To determine the predictive power of MammaPrint and BluePrint for sensitivity to neoadjuvant chemotherapy, as measured by pCR.
2. To compare TargetPrint single-gene read-out of ER, PR, and HER2 with conventional IHC-based subtype classification.
3. To determine possible correlations between the TheraPrint research gene panel and response to neoadjuvant chemotherapy.
4. To identify possible gene expression profiles of clinical response or resistance to neoadjuvant chemotherapy.
5. To compare the three BluePrint molecular subtype categories with IHC-based subtype classification.

**TREATMENTAL DESIGN**

- **MINT 1 (NCT01044767):** prospective study to test the ability of molecular profiling and traditional pathologic/clinical prognostic factors to predict resistance to neoadjuvant chemotherapy in patients with LABC (Figure 1).

**OBJECTIVES**

1. To identify possible correlations between the TheraPrint research gene panel and response to neoadjuvant chemotherapy.
2. To compare TargetPrint single-gene read-out of ER, PR, and HER2 with conventional IHC-based subtype classification.
3. To determine possible correlations between the BluePrint three molecular subtypes and clinical response or resistance to neoadjuvant chemotherapy.
4. To compare the three BluePrint molecular subtype categories with IHC-based subtype classification.

**TRIAL DESIGN**

- **Eligible patients will receive neoadjuvant chemotherapy** in patients with LABC (Figure 1).
- **Neoadjuvant chemotherapy regimens**
  - **THR: Doxorubicin 75 mg/m² iv + cyclophosphamide 500 mg/m² iv day 1 Followed by:**
    - Carboplatin ADJ lasting 1 to 21 days
    - Trastuzumab initial dose 4 mg/kg iv for one dose, followed by:
      - 1 mg/kg 30-minute iv infusion Weekly for 12 weeks
      - Trastuzumab initial dose 4 mg/kg iv for one dose, followed by:
      - 6 mg/kg 30–90-minute iv infusion Every 3 weeks for 52 weeks
  - **THC: Doxorubicin 75 mg/m² iv day 1 Followed by:**
    - Paclitaxel 100 mg/m² iv day 1 Followed by:
      - Cisplatin 50 mg/m² iv day 1
      - Paclitaxel 200 mg/m² iv days 1 and 8 + epirubicin 50 mg/m² iv day 1 + cyclophosphamide 500 mg/m² iv day 1 Every 21 days for 4 cycles
  - **TC: Doxorubicin 75 mg/m² iv + cyclophosphamide 500 mg/m² iv day 1** followed by:
    - Paclitaxel 100 mg/m² iv day 1 Every 21 days for 4 cycles

**EXCLUSION CRITERIA**

- Patients with inflammatory breast cancer

**INCLUSION CRITERIA**

- Women ≥ 18 years
- Histologically proven invasive breast cancer T2 (≤ 5 cm) or T3, N0 Mo or T3, N1Mo
- Ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS) are allowed in addition to invasive cancer at T1 or T3 level
- Adequate bone marrow reserves and adequate renal and hepatic function
- Signed informed consent

**REFERENCES**

9. As of November 19, 2012 (cut-off date for this poster), 40 patients have been enrolled at 5 centers (Figure 3).
10. For further information, please contact Jessica Gibson at jessica.gibson@agenda.com

**FURTHER INFORMATION**

- For further information, please contact Jessica Gibson at jessica.gibson@agenda.com

**ACCURR**

- A total of 226 eligible patients are expected to be enrolled from up to 10 institutions between October 2011 and October 2014.
- As of November 19, 2012 (cut-off date for this poster), 40 patients have been enrolled at 5 centers (Figure 3).

**Figure 3. Study centers to date**

- TX
- FL
- CA
- OH
- IL
- CA
- TX
- FL
- TX
- CA
- TX
- FL
- TX
- CA
- TX
- FL