**The BEACON Study (BrEaSt Cancer Outcomes With NKTR-102): A Phase 3 Open-Label, Randomized, Multicenter Study of Eliotinotecan Pegol (NKTR-102) Versus Treatment of Physician’s Choice (TCP) in Patients With Locally Metastatic Breast Cancer Previously Treated With Antracycline, Taxane, and Capecitabine**

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**Introduction**

The BEACON study (BrEaSt Cancer Outcomes With NKTR-102) is a phase 3 randomized, open-label, international study of eliotinotecan pegol (ETG) in patients with MBC that will evaluate single agent eliotinotecan pegol in patients who have previously received at least 1 prior line of systemic therapy for MBC (100% prior taxane, 89% anthracycline; 26% with prior ATC).

**Background**

- Nektar Therapeutics is a biopharmaceutical company developing a pipeline of drug candidates that utilize its advanced polymer conjugate technology to improve the benefits of drugs for patients.
- Eliotinotecan pegol (NKTR-102) is in clinical trials for patients with adenocarcinoma of the breast, including breast cancer, ovarian cancer, and colorectal cancer.
- Eliotinotecan pegol is a next-generation topoisomerase I inhibitor with a unique Pharmacokinetic (PK) profile that provides a continuous concentration of active drug with reduced peak concentrations (PK).
- Eliotinotecan pegol has demonstrated better efficacy as measured both by tumor growth delay and regression compared to etirinotecan against a wide range of human xenograft tumors, including a breast tumor model (figure 2).

**The BEACON Study**

- The BEACON study (BrEaSt Cancer Outcomes With NKTR-102) is a phase 3 randomized, open-label, international study of eliotinotecan pegol (ETG) in patients with MBC that will evaluate single agent eliotinotecan pegol in patients who have previously received at least 1 prior line of systemic therapy for MBC (100% prior taxane, 89% anthracycline; 26% with prior ATC).

**Key Patient Entry Criteria**

- Adult females with histologically or cytologically confirmed carcinoma of the breast.
- Patients: metastatic breast cancer is a primary or metastatic cancer of the breast.
- Patients with brain metastases may be eligible, provided local control of lesions is achieved and lesions are not life-threatening.

**Study Design**

- **This study will randomize approximately 940 patients using a 1:1 randomization ratio.** Prior to randomization of a patient, the Investigator must determine which TCP will be offered to the patient as the primary regimen of the informed consent and entry into the study.
- **Randomization will be stratified by geographic region, prior use of other anticancer therapy, and Prior use of systemic therapy for MBC.**
- **Central laboratory for safety tests (in addition to local laboratories).**
- **Central imaging will not be used in this trial.**
- **Healthcare utilization: every 4 weeks.**
- **In a subset of patients:**
  - **Biomarkers in a subset of patients.**
  - **Central laboratory for safety tests (in addition to local laboratories).**

**Exploratory Biomarkers**

- **Exploratory biomarkers in BEACON study:**
  - **Nektar will work with ApoCell, a leader in the field for capturing and storing single tumor cells.**
  - **Nektar will work with ApoCell to capture single tumor cells.**
  - **An independent data monitoring committee (DMC) will review the safety of eliotinotecan pegol treatment in the study.**
  - **Clinical benefit rate will be compared between treatment groups using a stratified log-rank test.**
  - **OS will be compared between treatment groups using a stratified log-rank test.**
  - **CPTC will be compared between treatment groups using a stratified log-rank test.**
  - **Quantify CTCs, assess biomarkers of DNA damage, topoisomerase IIalpha and IIbeta (figure 5).**

**Statistical Plan and Methods**

- Approximately 940 patients (420 patients per treatment group) will be required for sufficient events to occur in the planned phases of the study.

**Protocol Procedures**

- **Investigator determination of response and progression by RECIST v1.1.**
- **Patients will be evaluated every 4 weeks.**
- **In a subset of patients:**
  - **Biomarkers in a subset of patients.**
  - **Central laboratory for safety tests (in addition to local laboratories).**

**Accrual**

- BEACON is open for enrollment and enrollment is expected to be completed by December 2013.
- Regions: Approximately 190 sites in North America, Europe and Asia.

**Contact Information**

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**Copies of this poster may be obtained by contacting the corresponding author.**

**References**