**The BEACON Study (BrEast Cancer Outcomes With NKTR-102): A Phase 3 Open-Label, Randomized, Multicenter Study of Etiromotecan Pegol (NKTR-102) Versus Treatment of Physician’s Choice (TPC) in Patients With Locally Recurrent or Metastatic Breast Cancer (MBC) Previously Treated With An Anthracycline, a Taxane, and Capecitabine (ATC)**

**Background**

- NektarTherapeutics is a biopharmaceutical company developing a pipeline of drug candidates that utilizes its advanced polymer conjugate technology to improve the benefits of drugs for patients.
- Distinctive peg-irinotecan (NKTR-102) is in clinical trials for patients with solid tumors and hematological malignancies.
- Distinctive peg-irinotecan is a novel topoisomerase I inhibitor with a unique pharmacokinetic (PK) profile that provides a continuous and extended exposure compared to SN-38 without increased toxicity.
- Distinctive peg-irinotecan is a next-generation topoisomerase I inhibitor with a unique pharmacokinetic (PK) profile that provides a continuous and extended exposure compared to SN-38. It is currently in clinical trials for both solid tumors and hematological malignancies.
- Etiromotecan pegol (NKTR-102) is in clinical trials for patients with solid tumors and hematological malignancies.

**Introduction**

- There is currently a topoisomerase inhibitors landscape approved by the FDA to treat breast cancer. Nektar is currently evaluating the potential of etromotecan pegol as an alternative to these agents.

**Topoisomerase Inhibition with Irinotecan in MBC**

- A previous phase 2 study looked at etinotecan schedules (q1 and q2) for patients with metastatic Breast Cancer (MBC) refractory to or not suitable for an anthracycline, a taxane, or a cytokine.

**Table 1: Doses of SN-38 T1/2: Clinical Schedules of MBC**

| Sn38 Cmax | Time (weeks) After irinotecan: SN-38 T1/2 ~ 1-2 days; ETI ~ 7 days; CPT ~ 30 days; IRI ~ 3-7 days; CAPE = 1-2 days. ETI = Etiromotecan pegol; CAPE = Capecitabine.

**Key Patient Entry Criteria**

- Adult females with histologically or cytologically confirmed cancers of the breast:
  - Patients were measurable or non-measurable disease in RECIST, locally recurrent or metastatic disease.
  - Prior therapy (administered in the neoadjuvant, adjuvant, or metastatic setting) must include an anthracycline and a taxane and not be medically contraindicated for the patient, aetiology, and皿 and visceral (capacitabine).

**Procedures**

- An independent data monitoring committee (DMC) will review the safety of patients in the study and will assess interim efficacy data.
- Data will be collected on subsequent anticancer therapies in both treatment arms.
- Accrual to the study will continue until the planned follow-up time.

**Statistical Plan and Methods**

- Approximately 1440 patients (1000 patients) are treatment group will be required for sufficient events to occur in the planned follow-up time.

**Clinicaltrials.gov**

- Regions: Approximately 160 sites in North America, Europe and Asia.

**Accrual**

- BEACON is open for enrollment and enrollment is expected to be completed by December 2011.

**Conclusions**

- Accrual to the study will continue until the planned follow-up time.

**References**