Significant Antitumor Activity in a Randomized Phase 2 Study Comparing Two Schedules of NKTR-102 in Patients With Pre-Treated Metastatic Breast Cancer


Institutes: Institut Jean Bertet, Belgium; Institute Universitaire de Saint-Marin, Liège, Belgium; Hospitais de la Pitie-Salpetriere, Paris, France; The Royal Marsden Hospital, London, UK; Cancer and Leukemia Group B; Baskent University Hospital, Ankara, Turkey; Memorial Hermann Hospital, Houston, TX; Cedars-Sinai Medical Center, Los Angeles, CA; Mayo Clinic, Jacksonville, FL, and the NKTR-102 Study Group.

Background

NKTR-102 is a PEGylated irinotecan cytotoxic conjugate that is stable and non-toxic in the circulation and demonstrates prolonged exposure to SN38, a critical metabolite and cytotoxic agent of irinotecan.

NKTR-102 has superior efficacy (measured both by tumor growth delay and regression compared to irinotecan) against a wide range of human xenograft tumors.

NKTR-102 showed high antitumor activity in a range of human in vivo models including a panel of 13 primary breast cancer xenograft models.

Study Design & Objectives

Study Design: Randomized Simon Two-Stage

Key Eligibility Criteria

- Male or female patients with advanced breast cancer following taxane therapy (adjuvant or neoadjuvant)
- Measurable disease as defined by RECIST version 1.0
- Patients may also have received prior anthracycline or capecitabine
- No known or suspected CNS metastases
- ECOG PS 0-2
- A/T/C combination agent. Phase 3 planning is underway in ovarian and breast cancers.

Study Demographics

- 71 patients (10 per schedule) randomized from February 2008 through May 2010 (median follow-up, 8 months)

Results

Objective Tumor Response Rate by RECIST (Investigator Assessment)

Response Rate by Prior Therapy

Response Rate by Tumor Characteristics

Study Drug Administration and Discontinuation Due to AE

Safety

Conclusions

- High confirmed objective response rate observed with single-agent NKTR-102 in patients with advanced breast cancer previously treated with taxane +/- chemotherapy (25% confirmed objective response rate, 28% objective response rate)
- Median PFS: 4.6 months in 2nd/3rd line, 6.0 months in 1st-line or metastatic
- Superiority seen in patients with triple negative disease
- NKTR-102 is being studied in multiple indications as a single- and combination agent. Phase 3 planning is underway in breast and ovarian cancers.

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