

# Triple negative breast cancer drug one step closer to approval

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On Friday, sanofi-aventis announced that the FDA has granted fast track approval to their investigational PARP1 inhibitor, BSI-201, and that accruals for their phase 3 clinical trial is on schedule and meeting expectations on patient accrual and trial site coverage in the United States. Investigators have enrolled 214 of their target number of 420 patients.

The "fast rack" process is designed to expedite the review of drugs being developed for serious diseases with the potential to address an unmet medical need.

BSI-201 entered a phase 3 clinical trial in the United States in July 2009 and is being evaluated in combination with chemotherapy in patients with metastatic triple-negative breast cancer (mTNBC), a condition defined by tumors lacking expression of estrogen, progesterone receptors and without overexpression of HER2. BSI-201 is a novel investigational targeted therapy that inhibits poly (ADP-ribose) polymerase (PARP1), an enzyme involved in DNA damage repair.

The decision to commence with the phase 3 study in July was based on the encouraging phase 2 study results presented at ASCO on May 31, 2009. In the phase 2 clinical trial, women with mTNBC were randomly assigned to receive gemcitabine and carboplatin (GC) in combination with the investigational agent BSI-201 or GC alone. Updated phase 2 data including overall survival were presented on Friday at a poster session during the San Antonio Breast Cancer Symposium.

The addition of BSI-201 to GC improved median overall survival from 7.7 months to 12.2 months. BSI-201 did not add to the frequency or severity of adverse events associated with chemotherapy. This is not a final analysis of the phase 2 data, but an updated analysis of overall survival. Median survival hasn't yet been reached in the BSI-201 arm, therefore the data cut-off period for the phase 2 trial was from September to November.

"The updated analysis from the phase 2 program, including data on overall survival, are consistent with the positive results presented earlier this year at ASCO," declared Marc Cluzel, executive vice president, R&D, sanofi-aventis. "We are very encouraged by the fast recruitment of patients in phase 3 trial. We hope the findings will lead to emerging strategy that may help women with metastatic triple negative breast cancer."