



July 28, 2011

Biocept, Inc. announces availability of its new breast cancer test, OncoCEE-BR™ utilizing circulating tumor cells (CTCs)

- Capture, detection and enumeration
- Determination of HER2/neu status

Biocept, Inc., an advanced diagnostic CLIA-certified service laboratory developing novel tests for the oncology community, today announced the availability of OncoCEE-BR™ for breast cancer, a test designed to detect circulating tumor cells (CTCs) found in the blood of patients with this disease, and to assess their HER2/neu status by fluorescence in situ hybridization (FISH) performed on the CTCs detected in the blood. HER2/neu status is diagnostic of a potential response to targeted cancer therapies like Herceptin® and Tykerb®.

OncoCEE-BR™ is intended as an adjunct to current standard testing methods for breast cancer, and may be especially useful in clinical settings where it may not be possible to obtain a tissue biopsy. CTC analysis, including biomarker analysis such as HER2 gene amplification, may provide very important information for the physician in the treatment of a patient's cancer.

The OncoCEE-BR™ test includes: 1) the enumeration of CTCs (their actual number, per an 8 ml blood sample), and 2) the determination of the HER2/neu status of the detected CTCs by FISH. Clinical studies have demonstrated a poor prognosis for patients with elevated or increasing numbers of CTCs. The detection of HER2/neu amplification in tissue biopsy samples indicates a patient's eligibility for HER2-targeted therapies like trastuzumab (e.g., Herceptin®). In the future Biocept intends to add ER/PR status determination to the test, and potentially other biomarkers. OncoCEE-BR™ is the only commercially available test that combines CTC enumeration with cytogenetic characterization. It requires a proprietary blood draw tube and sample shipping container, which are provided by Biocept.

The results from an OncoCEE-BR™ test may provide oncologists, pathologists and their patients with a greater understanding of the status and aggressiveness of a patient's disease, and help guide clinical management of that patient. OncoCEE-BR™ provides real-time information on a tumor via a simple blood test to evaluate CTCs as compared to a surgical biopsy. This means that a tumor can be monitored and analyzed utilizing CTC analysis on an ongoing basis during therapy which may permit the early identification of emerging treatment resistance. In addition, expression of HER2 has been detected in CTCs in metastatic breast cancer patients whose primary tumors from surgery or biopsy were HER2 negative [Munzone, et al, Clin. Cancer Res. 2011]. In fact, preliminary reports suggest that breast cancer patients who were CTC HER2-positive and primary tumor HER2-negative responded to Herceptin® therapy [Meng et al, PNAS 2004]; larger prospective clinical studies are in process.

More than 200,000 new cases of breast cancer will be reported in the US in 2011. Approximately 20% of breast cancer patients are HER2 positive by primary tissue diagnosis, and thus candidates for HER2-targeted therapy. Due primarily to tumor heterogeneity, the false-negative rate for the HER2 test, particularly by immunohistochemistry (IHC), is estimated to be 10-15% or higher; the HER2 FISH test, which Biocept performs on CTCs, is considered a "gold standard".

"We believe that OncoCEE-BR™ may be an important tool for clinicians in the assessment of a breast cancer patient's prognosis and treatment options," said Executive Chairman David F. Hale. "It can complement tumor tissue analysis, offering the opportunity to "cross-check" those results. In situations where tissue is not available, for example at time of recurrence, or when monitoring therapy to determine its effectiveness, it can provide a real-time evaluation of the cancer at the cellular level." Mr. Hale continued, "Clinical studies are being conducted to examine the effects of HER2 targeted therapies in patients with HER2 positive CTCs, but HER2 negative tissue analysis. We believe that a positive HER2 FISH result in CTCs is very compelling. We feel that OncoCEE-BR™ offers clinicians with important information about their patients' tumors, which will enhance the treatment they provide, and potentially the outcomes their patients will experience."