December 27, 2016

Columbia University Medical Center Sponsors Clinical Study Using Biocept's Liquid Biopsy Platform to Evaluate Cerebrospinal Fluid of Breast Cancer Patients for Metastatic Biomarkers

Study designed to address the significant medical need for rapidly and accurately diagnosing brain metastases in breast cancer patients to enable better treatment decisions

SAN DIEGO, Dec. 27, 2016 /PRNewswire/ -- Biocept, Inc. (NASDAQ: BIOC), a leading commercial provider of clinically actionable liquid biopsy tests designed to improve the outcomes of cancer patients, announces that Columbia University Medical Center will conduct a study to evaluate the clinical utility of the Company's Target Selector™ platform to diagnose leptomeningeal metastases (LM) in patients with breast cancer. LM occurs when tumor cells gain access to cerebrospinal fluid (CSF) pathways and regrow in distant sites within the spinal cord and brain leading to neurological complications. Biocept's liquid biopsy platform will be used to test the CSF of breast cancer patients and will be compared to standard methods for confirming the diagnosis of LM.

"Diagnosing LM in patients with breast cancer can be challenging given the low diagnostic sensitivity of traditional methods such as cytologic analysis," stated Kevin Kalinsky, MD, MS, Assistant Professor of Medicine, Columbia University Medical Center and the study's principal investigator. "We will be using Biocept's Target Selector™ technology to evaluate oncologic biomarkers in the CSF of breast cancer patients, with the potential to provide a rapid and accurate solution to confirm diagnosis and enable patients to begin treatment for LM earlier. This clinical study addresses a significant medical need, given the devastating nature of LM involvement in breast cancer patients."

The clinical trial is expected to enroll 46 patients with breast cancer who are undergoing lumbar puncture to detect the presence of LM. The primary study objective is to determine whether Biocept's Target Selector™ circulating tumor cell (CTC) technology has higher sensitivity for the detection of LM, as compared to standard cytopathological analysis. Secondary study objectives include the following:

- Comparing each patient's CTCs and cfDNA collected in CSF with blood samples.
- Comparing the performance of Biocept's Target Selector™ CTC platform to standard cytopathology in diagnosing LM within 2 subgroups: patients with LM confirmed by MRI and those with suspicious LM findings from MRI.
- Exploring CTC and cfDNA levels from the CSF of patients with an initial negative LM finding using standard cytopathologic and CTC analysis.
- Assessing the feasibility of determining estrogen, progesterone and HER2 receptor status on CTCs collected from CSF samples using Biocept's Target Selector™ technology.
- Assessing concordance between the receptor status of the primary and/or metastatic tumor and that of the LM cells collected using Biocept's Target Selector™ technology.

"We are very pleased to again collaborate with Dr. Kalinsky and Columbia University Medical Center in this study designed to further validate the clinical utility of our Target Selector™ platform in order to improve the diagnosis and treatment of LM," said Michael W. Nall, Biocept's President and CEO. "Among the significant advantages of our technology is its versatility, which enables applications in a variety of clinical situations and for use with multiple biofluids, potentially opening up future markets and expanded commercial opportunities."

About Leptomeningeal Disease in Breast Cancer

Leptomeningeal metastasis (LM) is a condition in which cancer cells seed the meninges (nerve tissue in the spine and brain) and may go on to invade the brain, spinal cord, cranial nerves or peripheral nerves. It is a devastating complication of breast cancer, and is often considered in the differential diagnosis when patients with breast cancer present with new neurological symptoms. It was previously thought to be a rare occurrence, but autopsy series have shown the true overall incidence to be up to 8%. In fact, while the incidence of meningeal metastasis in other cancers has decreased, the opposite is true of breast cancer, in which the clinical evidence suggests an increasing incidence. Diagnosing LM can be difficult. The diagnosis is traditionally based on CSF cytologic analysis, but more recently, MRIs of the brain and spine are being used as first-line diagnostics because of their noninvasive nature. However, MRI findings can be ambiguous, and confirmatory findings may be difficult with cytopathologic analysis. CSF cytopathologic analysis is used to provide diagnostic confirmation of LM, but is associated with relatively low sensitivity (~50% on the first lumbar puncture) and is highly examiner dependent. Repeat multi-site and high volume lumbar punctures are often required, which may increase sensitivity up to 90%, but are associated with patient discomfort, treatment delays, and complications.

About Biocept

Biocept, Inc. is a molecular diagnostics company with commercialized assays for lung, breast, gastric, colorectal and prostate cancers, and melanoma. The Company uses its proprietary liquid biopsy technology to provide physicians with clinically actionable information for treating and monitoring patients diagnosed with cancer. The Company's patented Target Selector™ liquid biopsy technology platform captures and analyzes tumor-associated molecular markers in both circulating tumor cells (CTCs) and in circulating tumor DNA (ctDNA). With thousands of tests performed, the platform has demonstrated the ability to identify cancer mutations and alterations to inform physicians about a patient's disease and therapeutic options. For additional information, please visit www.biocept.com.

Forward-Looking Statements Disclaimer Statement

This release contains forward-looking statements that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although we believe that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, we can give no assurance that such expectations and assumptions will prove to have been correct. Forward-looking statements are generally identifiable by the use of words like "may," "will," "should," "could," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. To the extent that statements in this release are not strictly historical, including without limitation statements as to our ability to improve the outcome of cancer patients, the clinical utility of our liquid biopsy technology to improve the diagnosis and treatment of LM, and the future market opportunities and commercial expansion of our liquid biopsy technology, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous risk factors as set forth in our Securities and Exchange Commission (SEC) filings. The effects of such risks and uncertainties could cause actual results to differ materially from the forward-looking statements contained in this release. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law. Readers are advised to review our filings with the SEC, which can be accessed over the Internet at the SEC's website located at www.sec.gov.