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Study Highlights Value of Biocept's Blood-Based Diagnostic for Determining Hormonal Status in Patients With Metastatic Breast Cancer

SAN DIEGO, Feb. 23, 2015 (GLOBE NEWSWIRE) -- <u>Biocept</u>, Inc. (Nasdaq:BIOC), a molecular oncology diagnostics company specializing in biomarker analysis of cell-free circulating tumor DNA (ctDNA) and circulating tumor cells (CTCs), today announced that its blood-based diagnostic, OncoCEE-BR[™], was used to determine hormonal status of metastatic breast cancer patients in a prospective study performed at the Columbia University College of Physicians and Surgeons in New York City. Findings from the Columbia study were recently published in the peer-reviewed journal *Clinical and Translational Oncology*.

Breast cancer remains one of the most lethal forms of cancer despite advances in early detection and treatment. A patient's hormone receptor (HR) status, which includes estrogen receptor (ER) and progesterone receptor (PR) status, conveys both prognostic and predictive implications for patients with breast cancer. Up to 75 percent of breast tumors rely on ER signaling to grow. Targeting this pathway with anti-estrogen therapy has been shown in trials to have a clear clinical benefit in the treatment of this subset of breast cancer patients. Understanding HR status at the time of diagnosis, occurrence of metastasis and throughout the course of therapy can help inform patient treatment and, ultimately, has the potential to influence patient outcome.

The Columbia study used Biocept's proprietary CTC isolation platform to prospectively define hormonal status (ER/PR) using a simple blood sample in women with metastatic breast cancer. These blood samples were compared to the hormonal status results from their corresponding tumor biopsy tissue. The study reports a high concordance of results between testing of a patient's CTCs and testing of primary and metastatic tissue - results that indicate Biocept's blood-based diagnostic may be as effective in determining a patient's HR status as traditional tissue biopsy.

"We are encouraged that the results of this study further support the validity of Biocept's liquid biopsy in the continuous monitoring and treatment of breast cancer, and we are proud that an academic entity as prestigious as Columbia University Medical Center appreciates the utility of our diagnostic offering," said Veena Singh, M.D., Biocept Senior Vice President and Senior Medical Director.

"These findings could ultimately have significant implications in how we treat advanced stage breast cancer patients," said Kevin Kalinsky, M.D., Assistant Professor of Medicine at Columbia University Medical Center and first author of the paper. "Since it is not always feasible to obtain metastatic tissue from breast cancer patients, CTCs are an attractive alternative source of tumor material. CTCs provide real-time information about the HR status of a tumor that can be monitored more readily on an ongoing basis."

The ultimate goal of CTC evaluation is to assist physicians with making treatment decisions, such as the role of anti-estrogen therapy. The Columbia study shows that CTCs afford diagnostic results that are comparable to tumor tissue.

About Biocept, Inc.

Biocept, Inc., headquartered in San Diego, Calif., is a commercial-stage oncology diagnostics company focused on providing information on patients' tumors to physicians using its proprietary technology platform to help improve individual patient treatment. Biocept has developed proprietary technology platforms for capture and analysis of circulating tumor DNA, both in circulating tumor cells (CTCs) and in plasma (cell free tumor DNA). A standard blood sample is utilized to provide physicians with important prognostic and predictive information to enhance individual treatment of their patients with cancer. Biocept currently offers CLIA validated tests for breast, lung and gastric cancer and plans to offer additional assays for colorectal, prostate and other solid tumors based on its proprietary technology platforms in the future.

About Kevin Kalinsky, M.D., M.S.

Dr. Kalinsky received his undergraduate B.A. from Emory University. He received his M.D. from the Medical University of South Carolina and completed his Internal Medicine internship and residency at Tufts Medical Center. During his Hematology/Oncology fellowship at Tufts Medical Center, he received the Abby Shevitz Award for Young Physician's in Hematology/Oncology. In Boston, he also trained as a breast cancer clinical research fellow at Massachusetts General Hospital. In addition, he completed an advanced oncology fellowship in breast cancer at Memorial Sloan-Kettering Cancer Center.

Dr. Kalinsky cares for patients diagnosed with breast cancer and teaches on the Breast Oncology service. His research involves the development of early phase clinical trials to assess novel therapeutic agents in breast cancer. The goal of his research is to translate findings developed at the bench to clinical trials for study at the bedside. His work is funded by a number of sources, including the National Institute of Health and SWOG/The Hope Foundation.

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 Biocept's impact on diagnostic strategies, 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 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 <u>www.sec.gov</u>

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