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Biocept Launches Lung Cancer Offering

Blood-Based Liquid Biopsy Testing Launched for NSCLC Indications

SAN DIEGO, Nov. 12, 2014 (GLOBE NEWSWIRE) -- Biocept, Inc. (Nasdaq:BIOC), a molecular oncology diagnostics company specializing in biomarker analysis of circulating tumor DNA and Circulating Tumor Cells (CTCs), today announced the launch of its lung cancer liquid biopsy testing that will be performed at the Company's CLIA-certified and CAP-accredited laboratory.

By launching blood-based biomarker testing for non-small cell lung cancer (NSCLC), along with the previously commercialized breast cancer offering, Biocept is providing options for health care providers and researchers when a tumor biopsy is not available, is unsafe to perform or when additional information is desired. For patients with recurrent or newly diagnosed metastatic lung cancer, accurate identification of genomic biomarker information is a key piece of information that clinicians need when making treatment decisions. A challenge for physicians has been availability of tissue from the surgical biopsy that is required to perform the biomarker testing. This limitation occurs as a result of tumor location or health of the patient. According to a recent study¹, when lung biopsies are attempted, there is a 19.3% risk of complication such as a collapsed lung or an infection. Managing these complications quadruples the cost of care. In comparison, the cost of a simple blood draw is nominal, and poses little risk for patients, and the Company believes it has the potential to simultaneously save cost and improve outcomes for the health care system.

The Company's first CLIA-validated assay for lung cancer will be testing for ALK fusions on CTCs captured in Biocept's patented device. ALK is incorporated into the testing guidelines utilized by oncologists when making treatment decisions in NSCLC patients. ALK positive patients now have targeted treatment options with two key drugs that have been approved by the FDA: the first is Pfizer's Xalkori (Crizotinib) and the second is Novartis's Zykadia (ceritinib), and others are in development.

"The evaluation of biomarker status is the standard-of-care in determining the course of therapy for patients with lung cancer," said Michael Nall, President and CEO of Biocept. "We are excited to be able to help physicians by providing actionable genomic information for lung cancer patients with a simple blood test."

"A liquid biopsy, or blood based genomic test, has the advantage of being far less invasive than a surgical biopsy, therefore being appropriate for diagnostic and importantly, monitoring purposes. This gives physicians insight into the molecular status of the patient in real time so that therapeutic changes can be made for better patient outcomes," says Lyle Arnold, SVP and Chief Scientific Officer of Biocept.

The Company currently plans to offer additional biomarkers for lung cancer that physicians use when making treatment decisions before the end of the year and during 2015, including EGFR mutations, Ros1 fusions, KRAS mutations, and EGFR and MET amplification. EGFR mutation status, like ALK, is a biomarker included in guidelines that oncologists follow to determine the best treatment plan for a patient. Patients who have EGFR mutations are eligible for Tyrosine Kinase Inhibitors such as Tarceva^R from Genentech or Iressa^R from AstraZeneca. In addition, the Company is validating important resistance markers for these targeted therapies that they expect to be used most often when physicians are monitoring patients.

Biocept expects that some of these biomarkers will be performed on CTCs while others will be performed on circulating cell free DNA, which, if successful, has the potential to make Biocept one of the first to offer genomic analysis both on intact cells and plasma.

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 its OncoCEE-BRTM test for breast cancer and OncoCEE-LUTM for non-small cell lung cancer and plans to introduce CLIA validated tests for colorectal, prostate and other solid tumors based on its proprietary technology platforms over the coming months.

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 cost savings, improvement of outcomes, our impact on diagnostic strategies and planned future offerings, 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 Securities and Exchange Commission, which can be accessed over the Internet at the SEC's website located at www.sec.gov.

¹Lokhandwala T, Dann R, Johnson M, et al. Costs of the Diagnostic Workup for Lung Cancer - A Medicare Claims Analysis. Presented at: 2014 Chicago Multidisciplinary Symposium in Thoracic Oncology; October 30-November 1, 2014; Chicago, Illinois. Presentation Number: 103.

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