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Biocept Introduces New Test for Patients With Non-Small Cell Lung Cancer

Company launches blood-based 'liquid biopsy' to identify ROS1 rearrangement and better inform NSCLC treatment decisions

SAN DIEGO, Jan. 20, 2015 (GLOBE NEWSWIRE) -- [Biocept, Inc.](#) (Nasdaq:BIOC), a molecular oncology diagnostics company specializing in biomarker analysis of circulating tumor DNA (ctDNA) and Circulating Tumor Cells (CTCs), today announced the launch of ROS1 testing on CTCs, which will help physicians identify which of their patients may be receptive to certain drugs for the treatment of non-small cell lung cancer.

Biocept's new blood test identifies chromosomal rearrangements of the gene encoding ROS1 proto-oncogene receptor tyrosine kinase (ROS1), thereby defining a distinct molecular subgroup of NSCLCs. Patients with ROS1-positive tumors may be receptive to a number of therapeutic options that inhibit this target.

It can be difficult to obtain enough tissue material for molecular testing of biomarkers like ROS1 from lung cancer patients due to the small size of tissue biopsies. Occasionally, tissue biopsies are altogether impossible because of risks associated with a surgical procedure for these patients. Biocept's 'liquid biopsy' offers a method of determining the crucial genomic status of a tumor using a simple blood test.

The Company's CLIA-validated assay for ROS1 in patients with NSCLC can be used in conjunction with other molecular offerings for lung cancer such as the diagnostic for ALK chromosomal rearrangements which Biocept launched in late 2014. All of Biocept's assays, including the ALK and ROS1 tests for mutations in NSCLC, are performed at the Company's CLIA-certified and CAP-accredited laboratory.

"Findings published in the *New England Journal of Medicine* in the November 2014 issue demonstrated that treatment with the targeted therapy drug, Crizotinib, effectively halts the growth of lung tumors driven by rearrangements of the ROS1 gene," said Veena Singh M.D., Senior Medical Director of Biocept. "In published papers, an international research team reported that Crizotinib treatment led to significant tumor shrinkage in ROS1-positive patients."

While Crizotinib is currently only FDA-approved for the treatment of ALK-positive NSCLC patients, National Comprehensive Cancer Network (NCCN) guidelines recommend that patients with advanced lung cancer be considered for ROS1 testing and that Crizotinib should be used to treat patients that test positive for ROS1.

"By adding ALK and ROS1 assays to their diagnostic work up of patients with NSCLC, Biocept enables physicians to profile patients for two key biomarkers that have frequently not been evaluated due to limited availability of tissue biopsy material," said Raaj Trivedi, VP of Commercial Operations for Biocept. "We are excited to provide physicians with a growing number of actionable genomic tests for NSCLC patients utilizing a non-invasive liquid biopsy."

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 OncoCEE - GATM for Gastric Cancer and plans to introduce additional CLIA validated tests for breast, lung, colorectal, melanoma, 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 effectiveness of Biocept's offered tests and our 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 Securities and Exchange Commission, which can be accessed over the Internet at the SEC's website located at www.sec.gov.

Reference

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