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Biocept Launches Proprietary Liquid Biopsy Test to Detect RET Fusions in Patients with Lung Cancer

Detecting RET fusions can identify patients who may benefit from targeted therapy with tyrosine kinase inhibitors

SAN DIEGO, May 19, 2016 /PRNewswire/ -- Biocept, Inc. (NASDAQ: BIOC), a leading molecular diagnostics company with liquid biopsy technology for cancer profiling and monitoring, announces the launch of its test to detect RET oncogene fusions from a simple blood draw. Positive identification of patients with the RET gene provides important information in determining therapy options including targeted tyrosine kinase inhibitors.

Biocept Completing the Answer[™]

Genetic alterations RET and ROS1 genes were identified in patients with non-small cell lung cancer (NSCLC). In initial screening studies using a variety of genotyping techniques, RET and ROS1 rearrangements were each reported in 1-2% of patients with NSCLC. Patients with either RET or ROS1 rearrangements appear to have unique clinical and pathologic features that may facilitate identification and enrichment strategies. These features may in turn expedite enrollment in clinical trials evaluating genotype-directed therapies, such as tyrosine kinase inhibitors, in these rare patient populations. In 2015, Biocept launched a blood-based test to detect the ROS1 biomarker.

"The discovery of RET and ROS1 chromosomal rearrangements involving specific genes in patients with NSCLC has stimulated interest in developing therapies that specifically target these oncogenic fusions," said Veena Singh, M.D., Senior Vice President Senior Medical Director of Biocept. "Genetic alterations in the RET gene involve chromosomal rearrangements that result in the formation of chimeric fusion kinases capable of driving oncogenic transformation and hence offer a potential viable therapeutic target."

"Just like ALK fusions are targeted by Crizotinib, leading to improvements in patients with ALK+ lung cancer, information on RET fusions can provide similar benefits to RET targeted agents," said Michael W. Nall, President and Chief Executive Officer of Biocept. "Many of these emerging biomarkers are not easy to test for in patients with lung cancer due to limited access to tissue biopsies, this is where Biocept's liquid biopsy can make an important contribution to the treatment of patients with cancer."

More than 220,000 new cases of lung cancer are reported year in the U.S. and lung cancer is the leading cause of cancerrelated mortality. The five-year survival rate for Americans lung cancer is 18%, according to the Centers for Disease Control.

About Biocept

Biocept, Inc. is a molecular diagnostics company with commercial tests targeting lung, breast, gastric, colorectal and prostate cancers and melanoma. The company uses its proprietary liquid biopsy technology to provide physicians with more precise information for treating and monitoring patients with cancer. The company's patented Target Selector[™] liquid biopsy technology platform captures and analyzes circulating tumor DNA in both circulating tumor cells (CTCs) and in plasma (ctDNA). After thousands of tests, the platform has proven to be effective in identifying cancer mutations. Biocept plans to introduce additional CLIA-validated tests in the near term. For additional information, please visit <u>www.biocept.com</u>.

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 detection and treatment of cancer, the role of androgen receptor expression in personalized medicine and its prognostic and predictive value, our impact on diagnostic strategies, our ability to enhance individual cancer treatments 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 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 <u>www.sec.gov</u>.

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