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Biocept Launches Liquid Biopsy Immuno-Oncology PD-L1 Test

New test uses patient's blood sample to profile and monitor for PD-L1 expression, an important biomarker in immuno-oncology treatment decision making
Test developed in collaboration with renowned pathologist David Rimm, MD, PhD, of Yale University School of Medicine

SAN DIEGO, May 31, 2016 /PRNewswire/ -- Biocept, Inc. (NASDAQ: BIOC), a molecular diagnostics company commercializing and developing liquid biopsies to improve the diagnosis and treatment of cancer, announces the expansion of its liquid biopsy offering into immuno-oncology with the commercial launch of its PD-L1 protein expression test. The CLIA-validated test uses Biocept's proprietary, patented Target Selector™ platform with circulating tumor cells (CTCs) from a patient's blood sample and can be used to detect and monitor PD-L1 protein expression throughout the course of a patient's cancer therapy. The PD-L1 test was developed by Biocept's scientists in collaboration with David Rimm, MD, PhD, Professor of Pathology and Medicine at Yale University School of Medicine and a scientific advisor to Biocept.

Immuno-oncology therapy fights cancer by stimulating a patient's immune system to directly attack tumor cells or by enhancing anti-tumor responses to man-made immune system proteins. Patients with cancers expressing the PD-L1 protein are more likely to respond to certain immuno-oncology therapeutics and several PD-L1-related immuno-oncology therapies have received U.S. Food and Drug Administration (FDA) approval. Among the recent approvals include Keytruda® (pembrolizumab) for patients with advanced non-small cell lung cancer. Many additional immuno-oncology therapies are in clinical development.

"Immunotherapy is among today's most promising approaches to improving the outcomes of patients with cancer and shows even greater potential in the future as drugs currently in development come to market," said Michael Nall, Biocept's President and CEO. "We believe Biocept has one of the few, if not the only, commercial, CLIA-validated, blood-based test for detecting PD-L1 expression. Our test provides a new option for physicians to qualify patients for approved immuno-oncology therapies and for companies in developing these breakthrough therapies. With the commercial introduction of our PD-L1 test, we again demonstrate our ability to execute on a high priority business initiative to broaden our commercial liquid biopsy test offering and open a new market opportunity for Biocept."

"Determining PD-L1 status is required to qualify patients for certain immuno-oncology therapeutics and our test allows for the detection of this protein's expression through a simple blood test, rather than an invasive tissue biopsy," said Veena Singh, MD, Biocept's Senior Vice President and Senior Medical Director. "This test could be particularly compelling for patients with recurrent or progressive disease. It also has application in instances in which the tumor is heterogeneous in its PD-L1 expression. Our test, which is based on CTCs in blood, could show PD-L1 expression missed by multiple tissue samples from the same tumor."

"The Biocept team has completed an analytical validation on the Target Selector with the PD-L1 assay on CTCs and the data is solid," said Dr. Rimm. "Clinical validation is underway and we look forward to the future publication of these study results. We believe this test has the potential to track and monitor a patient's expression of PD-L1 on cancer cells without the need for invasive tissue sampling. This could provide critical information for use in patient management."

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

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 material in both CTCs and in plasma (ctDNA). After thousands of tests, the platform has shown effectiveness in identifying cancer mutations. Biocept plans to introduce additional CLIA-validated tests in the near term. 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 diagnosis and treatment of cancer, immunotherapy's ability to improve the outcomes of patients with cancer, our ability to broaden our commercial liquid biopsy test offering and open new market opportunities, the ability of our PD-L1 protein expression test to improve treatments for patients with recurrent or progressive disease, the ability of our PD-L1 protein expression test to show PD-L1 expression missed by multiple tissue samples, our ability to obtain clinical validation for our test and the publication of study results, the ability of our PD-L1 protein expression test to track and monitor a patient's expression of PD-L1 on cancer cells without the need for invasive tissue sampling, 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 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.

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