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# Biocept and UC San Diego Medical Center Announce Clinical Study Collaboration to Demonstrate Utility of Biocept's Liquid Biopsy Test in Immunotherapy

## Clinical validation of Biocept's novel PD-L1 test using multiple antibody clones has potential to improve detection, treatment selection, and patient monitoring with cancer immunotherapy

SAN DIEGO, Nov. 28, 2017 /PRNewswire/ -- Biocept, Inc. (NASDAQ: BIOC), a leading commercial provider of liquid biopsy tests designed to provide physicians with clinically actionable information to improve the outcomes of patients diagnosed with cancer, announces entering into a clinical study agreement with the University of California San Diego (UCSD) Medical Center. Led by recognized immune-oncology and precision medicine specialist Sandip Patel, M.D., Assistant Professor at UCSD School of Medicine, the 100-patient study is designed to clinically validate Biocept's Target Selector™ PD-L1 assay for patients diagnosed with non-small cell lung cancer (NSCLC). Importantly, Biocept's assay for PD-L1 will be evaluated using the two common antibody clones for PD-L1 detection, 28-8 and 22C3, which have the potential to offer high biomarker detection rates using liquid biopsy. The study's primary endpoint is concordance between tissue biopsy and liquid biopsy for the detection of PD-L1 protein expression. Correlation between treatment response and PD-L1 status as detected using liquid biopsy will be examined as a secondary endpoint in the study.

"Liquid biopsies have revolutionized oncology and precision medicine with the ability to obtain important biomarker information to identify patients for targeted therapy," said Dr. Patel. "In particular, identification of key driver mutations such as EGFR, ALK, and ROS1, among others, are crucial in advanced NSCLC, and liquid biopsy plays an important role in assessing for these targetable pathways. Equally important is PD-L1 staining in front-line NSCLC to assess for a 50% tumor-proportion score, which is key for the utilization of immunotherapy. To date, primarily tissue testing has been available to assess PD-L1 status, and this study attempts to broaden the use of liquid biopsies to encompass PD-L1 scoring, which is crucial in determining whether immunotherapy may be appropriate for a patient in a given disease setting."

"Immunotherapy has become an important treatment strategy for patients diagnosed with cancer and we believe that our unique liquid biopsy assay for PD-L1 offers a solution for rapid and non-invasive detection of this critical biomarker," said Biocept's President and Chief Executive Officer Michael Nall. "We continue to evaluate our Target Selector™ platform in clinical studies in which the identification of clinically actionable biomarkers, like PD-L1 protein expression, can help guide treatment decisions resulting in improved patient outcomes. We are excited to initiate this study with Dr. Patel and the UCSD Medical Center."

**About PD-L1 Biomarker Expression Using Liquid Biopsy**
PD-L1 immunohistochemistry (IHC) on tumor tissue is an important predictive biomarker for anti-PD-1/anti-PD-L1 cancer immunotherapy. PD-L1 IHC is a companion diagnostic for the utilization of anti-PD-1 directed therapies in non-small cell lung cancer (NSCLC) and bladder cancer, and can predict response to immune checkpoint blockade. However, tissue biopsy is not always available or may be insufficient to accurately test for PD-L1 expression and biopsy samples may not reflect the actual PD-L1 expression of the tumor due to tumor heterogeneity. Given this heterogeneity and the risks inherent with tissue biopsy, the ability to detect tumor PD-L1 status with a simple blood draw would be a major advance in this field. In addition to minimizing patient risk from a tissue biopsy, a circulating biomarker assay can avoid biopsy selection bias and provide a snapshot of the dynamic tumor landscape. Biocept has developed proprietary, minimally-invasive blood-based assays for the analysis of biomarkers on tumor-derived cells and cell-free DNA with the purpose of detecting predictive genomic and protein expression markers such as PD-L1 to aid in therapeutic selection.

**About Biocept**
Biocept, Inc. is a molecular diagnostics company with commercialized assays for lung, breast, gastric, colorectal and

prostate cancers, and melanoma. The Company leverages its proprietary liquid biopsy technology to provide physicians with clinically actionable information for treating and monitoring patients diagnosed with cancer. Biocept's patented Target Selector™ liquid biopsy technology platform captures and analyzes tumor-associated molecular markers in both circulating tumor cells (CTCs) and in circulating tumor DNA (ctDNA). With thousands of tests performed, the platform has demonstrated the ability to identify cancer mutations and alterations to inform physicians about a patient's disease and therapeutic options. For additional information, please visit www.biocept.com.

**Forward-Looking Statements Disclaimer Statement**

This news 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 be 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 news release are not strictly historical, including, without limitation, statements as to our ability to improve the outcomes of patients diagnosed with cancer, the success of the UC San Diego Medical Center study and its ability to meet its objectives, our ability to further validate our liquid biopsy technology, and our ability to increase the clinical adoption of our testing services, 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 news 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 at www.sec.gov

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