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## **Biocept Presents Robust Analytical Validation Study Results for its PD-L1 Liquid Biopsy Test at the 17th IASLC World Conference on Lung Cancer**

**Results demonstrate high level of analytical sensitivity and specificity for the Company's non-invasive, clinically actionable biomarker test for immunotherapy**

SAN DIEGO, Dec. 7, 2016 /PRNewswire/ -- [Biocept, Inc.](#) (NASDAQ: BIOC), a leading commercial provider of clinically actionable liquid biopsy tests to improve the management of cancer patients, announces the analytical validation study results for its blood-based PD-L1 assay, which demonstrate the highly sensitive, specific, and reproducible performance of this immunotherapy biomarker test. The study results, "Validation of PD-L1 Expression on Circulating Tumor Cells in Lung Cancer," were presented today in a poster session at the IASLC World Conference on Lung Cancer in Vienna, Austria, in collaboration with David Rimm, M.D., Ph.D., Professor of Pathology and Medical Oncology at the Yale University School of Medicine and renowned PD-L1 diagnostics thought leader.



In the study, introduced cell lines derived from multiple cancers were tested with Biocept's PD-L1 assay using its proprietary Target Selector™ platform to capture and interrogate tumor cells for PD-L1 expression. Results yielded 100% concordance between PD-L1 expression of the tumor cells and their original PD-L1 status, whether positive or negative. Further clinical testing demonstrated the ability of Biocept's PD-L1 assay to successfully determine PD-L1 status on the circulating tumor cells (CTCs) of clinical samples.

"Assessing PD-L1 status of a cancer patient has become increasingly important, as immuno-oncology treatments such as Merck's Keytruda® and Bristol-Myers Squibb's Opdivo® target the immune checkpoint pathway and expression of this biomarker," stated Dr. Rimm. "These pilot results demonstrate the ability of Biocept's blood-based circulating tumor cell assay to identify the presence of PD-L1 on circulating tumor cells, which can have important implications in cases when a tissue biopsy is insufficient or not practical."

The human immune system can recognize and eliminate tumor cells through immunosurveillance, however, certain cancer cell types suppress immune function by expressing programmed cell death ligand 1 (PD-L1), which binds to its receptor, PD-1, on T cells to prevent their activation. As a result, high levels of PD-L1 expression are associated with poor patient prognosis. Immunotherapies such as Keytruda® and Opdivo® inhibit the PD-1/PD-L1 pathway and allow the body's natural defenses to combat the tumor. To determine which patients are suitable candidates for receiving immunotherapy, levels of PD-L1 expression are traditionally determined from tumor biopsies. However, the amount of tumor tissue or the variability in tumor tissue composition (tumor heterogeneity) can confound these results, creating the need for a non-invasive methodology for the identification and subsequent monitoring of tumor-associated PD-L1 expression.

"These data support the high sensitivity of our Target Selector™ platforms and our focus on providing clinically actionable information to oncologists and their patients based on a simple blood test," stated Lyle Arnold, Ph.D., Biocept's Chief Scientific Officer. "Our proprietary liquid biopsy technology offers the unique ability to analyze oncogene mutations, amplifications, fusions and tumor-associated proteins such as PD-L1, enabling an analysis of cancer-driving molecular alterations to improve patient care."

"The presentation of these study results at a major cancer conference significantly increases our visibility with lung cancer specialists and further supports the use of our high performance liquid biopsy platform," said Michael W. Nall, President and Chief Executive Officer of Biocept. "We remain focused on providing the most clinically relevant menu of cancer biomarkers in a liquid biopsy platform to provide oncologists with the actionable information they need to improve the care of their patients."

## **About the IASLC World Conference on Lung Cancer**

The IASLC World Conference on Lung Cancer is the world's largest meeting dedicated to lung cancer and other thoracic malignancies. More than 7,000 delegates come from more than 100 countries to discuss the latest developments in thoracic malignancy research. Attendees include surgeons, medical oncologists, radiation oncologists, pulmonologists, radiologists, pathologists, epidemiologists, research scientists, nurses and patients.

## **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 clinically actionable information for treating and monitoring patients diagnosed with cancer. The Company'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](http://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 management, diagnosis and treatment of cancer, the ability of our tests to provide clinically actionable information to oncologist and their patients, and our ability to expand the adoption of our tests, 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](http://www.sec.gov).

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