Case Report in Journal of Thoracic Oncology Demonstrates the Clinical Utility of Biocept's Liquid Biopsy Test for Patient Diagnosed with Non-Small Cell Lung Cancer

May 1, 2018

Letter to the editor highlights capability of Target Selector™ test to detect ROS1, a lung cancer biomarker used to qualify patients for targeted therapies that can improve treatment outcomes

SAN DIEGO, May 1, 2018 /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 the publication of a "letter to the editor" in a prominent lung cancer journal highlighting the clinical utility of its Target Selector™ *ROS1* gene rearrangement test. Biocept's circulating tumor cell (CTC)-based assay confirmed detection of a *ROS1* gene translocation in a patient diagnosed with non-small cell lung cancer who had previously received chemotherapy and was progressing. Detection of the *ROS1* rearrangement by Target Selector™ was concordant with tissue-based molecular profiling. In contrast, Biocept's CTC analysis was able to identify the genetic alteration where plasma testing by an alternate liquid biopsy technology did not detect the ROS1 translocation. The patient received sequential ALK inhibitor therapies, which are also used to treat patients harboring *ROS1* alterations, and has remained alive for 40 months on these targeted agents. The article, "ROS1 in Liquid Biopsies," was published in the May 2018 issue of the *Journal of Thoracic Oncology*.

"This case report showed that Biocept's Target Selector™ test identified a ROS1 gene rearrangement and was able to confirm results of a prior tissue biopsy, while another liquid biopsy method failed to find this important cancer biomarker," said Luis E. Raez, MD, FACP, FCCP, Chief of Hematology/Oncology & Medical Director, Memorial Cancer Institute, Memorial Health Care System. "Identifying an actionable biomarker was crucial for the treatment of this patient, and the Target Selector™ CTC test was able to provide this information using a non-invasive blood sample."

"The letter to the editor represents another important case study in which our Target Selector™ liquid biopsy platform has demonstrated the ability to inform physicians on the molecular information driving a patient's cancer, so that optimum therapy can be selected for treatment," said Biocept's President and CEO Michael Nall. "We continue to expand the body of evidence supporting the use of our industry-leading liquid biopsy platform, and are working on additional case reports for potential publication throughout the remainder of the year. Importantly, the *Journal of Thoracic Oncology* is the official journal of the International Association for the study of Lung Cancer (IASLC), which along with the College of American Pathologists (CAP) and the Association of Molecular Pathologists (AMP), recently updated molecular treatment guidelines to include liquid biopsy."

About the Journal of Thoracic Oncology

The *Journal of Thoracic Oncology (JTO)*, the official journal of the International Association for the Study of Lung Cancer, is the primary educational and informational publication for topics relevant to the prevention, detection, diagnosis, and treatment of all thoracic malignancies. JTO emphasizes a multidisciplinary approach and includes original research reviews and opinion pieces. The audience includes epidemiologists, medical oncologists, radiation oncologists, thoracic surgeons, pulmonologists, radiologists, pathologists, nuclear medicine physicians, and research scientists with a special interest in thoracic oncology.

About Biocept's Target Selector™ *ROS1* test

The *ROS1* gene is structurally similar to *ALK*, and *ROS1* gene rearrangements are found in 1–2% of non-small cell lung cancer (NSCLC) cases. Pre-clinical and early clinical evidence suggest that tumors associated with a *ROS1* rearrangement may be sensitive to dual ALK/MET inhibitors. The small molecule tyrosine kinase inhibitor, crizotinib (**Xalkori®**), was approved for the treatment of patients with metastatic NSCLC whose tumors are *ROS1*-positive. Biocept's Target Selector™ methodology identifies *ROS1* gene translocations in circulating tumor cells (CTCs) by fluorescence *in situ* hybridization (FISH) with the ROS1 (6q22) Break Apart FISH Probe Kit from Biocare Medical (Pacheco, California, USA); this FISH kit is used routinely by major reference laboratories for qualitative detection of *ROS1* gene rearrangements in formalin-fixed paraffin-embedded (FFPE) tissue. Biocept's Target Selector™ liquid biopsy platform has the ability to identify *ALK* gene translocations in patients using a simple blood sample.

For more information on Biocept's *ROS1* test or to order a test from Biocept please go to www.Biocept.com or click on the following link: https://biocept.com/technology/biomarker-index/#ros1

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 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 plasma (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 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 outcomes of patients diagnosed with cancer, the further adoption of our Target Selector™ assays, and whether additional clinical case studies will be published this year supporting the use of our liquid biopsy platform, 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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