

## Biocept and UT Southwestern Medical Center Announce Clinical Study to Profile and Monitor Non-Small Cell Lung Cancer Patients with ALK Rearrangements

Leading clinical investigator to utilize Biocept's liquid biopsy tests for the detection of ALK rearrangements at baseline and to monitor treatment response and resistance mechanisms over time

SAN DIEGO, Aug. 17, 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 cancer patients, announces it has entered into a clinical study agreement with the University of Texas Southwestern Medical Center (UT Southwestern Medical Center). Led by recognized oncologist and *ALK* mutation researcher Dr. Saad Khan, the study is designed to evaluate the clinical utility of Biocept's Target Selector<sup>TM</sup> platform for patients diagnosed with *ALK*-positive non-small cell lung cancer and treated with *ALK*-inhibitor therapy. A second arm of the study will evaluate patients with rare cancers such as anaplastic thyroid cancer to determine if driver mutations such as *ALK* rearrangements can be identified and treated with targeted therapy to improve patient outcomes.



"Identifying *ALK* rearrangements in patients with lung cancer has become important as new targeted therapies are available to help manage disease in patients harboring this type of alteration," said Saad Khan, MD, Medical Oncologist and Assistant Professor of Internal Medicine at UT Southwestern Medical Center. "We have designed this study to demonstrate the ability to rapidly identify *ALK* rearrangements, and to provide further evidence that patients with both non-small cell lung cancer and rare cancers harboring *ALK* alterations can benefit from targeted therapy and serial monitoring of *ALK* and other key alterations."

"Demonstrating the clinical utility of our Target Selector™ platform in studies conducted by top researchers like Dr. Khan is important to expand the clinical adoption of our liquid biopsy offering in oncology," 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 *ALK* fusions and other alterations with our assays can help guide treatment decisions resulting in improved patient outcomes. Our Target Selector™ tests can be used to help physicians rapidly obtain the actionable information they need to design personalized treatment plans for their cancer patients."

## About ALK Rearrangements in Lung Cancer

The ALK gene encodes the anaplastic lymphoma kinase (ALK) protein, which belongs to a family of receptor tyrosine kinases involved in transmitting cell surface signals to the inside of the cell. In approximately 5% of non-small cell lung cancer patients, a portion of the ALK gene is abnormally rearranged when DNA is replicated during cell division. Fusion of ALK DNA sequences to another gene results in the disruption of normal ALK protein function, causing uncontrolled cell growth as is characteristic in cancer. Various ALK gene arrangements, or translocations, have been observed in NSCLC; the majority of variants involve gene fusions between the ALK and EML4 genes. Biocept's Target Selector<sup>TM</sup> platform is able to identify ALK translocations in circulating tumor cells (CTCs) using fluorescence in situ hybridization (FISH) probes that are also commonly used for molecular profiling in tissue. Non-small cell lung cancer patients who test positive for an ALK fusion are likely to respond to ALK inhibitor therapy such as Xalkori® (crizotinib). Biocept's liquid biopsy testing may be used to identify ALK translocations to quide treatment decisions and selection of an appropriate targeted therapy.

## **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<sup>TM</sup> 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 <a href="https://www.biocept.com">www.biocept.com</a>.

## **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 cancer patients, the success of the UT Southwestern 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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