Study Shows Biocept's Target Selector™ Detects Mutations in "Quantity Not Sufficient" Specimens in Non-Small Cell Lung Cancer Patients

February 16, 2021

Data to be presented at Molecular Med Tri-Con Virtual Conference

SAN DIEGO--(BUSINESS WIRE)--Feb. 16, 2021-- Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, will present data showing that its Target Selector™ molecular assay kit detects mutations in up to 50% of tissue biopsy specimens, from patients diagnosed with non-small cell lung cancer, that were deemed quantity not sufficient (QNS). The study will be presented at the Molecular Med Tri-Con Virtual Conference, Feb. 16-18, 2021.

Molecular testing of biopsy specimens is critical to identify genetic mutations and guide potential treatment with targeted therapies. However, in up to 40% of cases, specimens lack sufficient tissue to perform testing[1] and are deemed insufficient. The presence of non-tumor cells can also be an obstacle in detecting specific mutations. As a result, QNS specimens are a significant issue in molecular diagnostic testing and a key challenge faced by oncologists and pathologists in managing cancer patients.

The pilot study utilized Biocept's Target Selector molecular assay with Switch-Blocker technology, which offers ultra-high sensitivity and requires less tumor sample than most commercial assays. The assay was used to evaluate the presence of several key EGFR and KRAS mutations in formalin-fixed paraformaldehyde embedded (FFPE) tissue slides, supplied by NeoGenomics Laboratories, Inc. that were deemed QNS for next generation sequencing (NGS) analysis. Results showed that EGFR mutations were detected in 50% (3/6) of patient samples, and KRAS mutations in 17% (1/6) of samples.

"We're looking for rare mutations from a very small tissue sample in a large background of non-tumor cells to help us guide treatment decisions for patients," said Michael C. Dugan, M.D., Senior Vice President, Chief Medical Officer and Medical Director of Biocept. "This collaboration with NeoGenomics confirms that our Target Selector assay used with FFPE samples has the potential to provide molecular results when other common platforms can't, offering actionable information for physicians to help identify potential targeted therapy options."

Biocept's Target Selector assay kits, available for research-use-only and CE-IVD, detect mutations in DNA derived from FFPE or blood plasma to give insight into a patient's cancer characteristics and provide tumor biomarker status. Target Selector utilizes patented Switch-Blocker technology to enrich specimens for mutations of interest and block DNA amplification from normal cells, resulting in ultra-high assay sensitivity and specificity compared to other methods currently used in laboratories. The kits allow molecular laboratories around the world to use Target Selector assays to detect key oncogene mutations through the analysis of both FFPE tissue from surgical biopsies and ctDNA from blood-based liquid biopsies. Biocept also offers Target Selector ctDNA-based tests in its CLIA-certified, CAP-accredited laboratory.

Biocept's virtual exhibit at the Tri-Con conference will offer information about the company's molecular assay technologies that assist clinicians and researchers in understanding the genomic basis of cancer. Also at the conference, Dr. Dugan will participate in a roundtable discussion on understanding the value and analytical requirements of circulating tumor cell (CTC) analysis as part of a comprehensive liquid biopsy analysis. The panel, titled "Introducing CTC Assays to Service Laboratories," will be held Wednesday, Feb. 17, at 12:55 p.m. ET. More information about the roundtable can be found here.

The poster, titled "Detection of EGFR Mutations in Quantity Insufficient Tissue Slides by High Sensitivity Assay Target Selector in Patients with Non-Small Cell Lung Cancer," can be accessed here.

About Biocept

Biocept, Inc. is a molecular diagnostics company developing and commercializing assays for lung, breast, gastric, colorectal and prostate cancers, and melanoma. The Company uses its proprietary technology to provide physicians with clinically actionable information for treating and monitoring patients diagnosed with cancer. The Company's patented Target Selector™ molecular diagnostic 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. Additionally, Biocept is offering nationwide COVID-19 polymerase chain reaction (PCR) testing to support public health efforts during this unprecedented pandemic. For additional information, please visit www.biocept.com. Follow Biocept on Facebook, LinkedIn and Twitter.

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. To the extent that statements in this release are not strictly historical, including without limitation statements regarding the ability of our assays to improve the outcomes of patients diagnosed with cancer, 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 risks and uncertainties, including the risk that our products and services may not perform as expected. These and other risks are described

in greater detail in our filings with the Securities and Exchange Commission (SEC), including under the "Risk Factors" heading of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020. 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.

1. Harada S, Agosto-Arroyo E, Levesque JA, et al. Poor cell block adequacy rate for molecular testing improved with the addition of Diff-Quik-stained smears: Need for better cell block processing. Cancer Cytopathol. 2015; 123(8):480-7.

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