Biocept and Protean BioDiagnostics Establish Research Collaboration to Demonstrate Advantages of Biocept's Target Selector™ Assay Kit for Non-Small Cell Lung Cancer Patients

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Target Selector™ EGFR assays offer ultra-high sensitivity and require less tumor sample than most commercial assays

SAN DIEGO--(BUSINESS WIRE)--Feb. 23, 2021-- Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, will collaborate with Protean BioDiagnostics Inc. to research the ability of Biocept's Target Selector™ molecular assay to determine EGFR status in non-small cell lung cancer (NSCLC) patients. The research will be conducted in an independent pathology laboratory setting.

Protean BioDiagnostics also expects to validate the analytical performance of a laboratory developed test (LDT) based on Biocept's EGFR assay test kit in accordance with the requirements of the College of American Pathologists (CAP) validation process.

Biocept's novel molecular assay kit, available for research-use-only and with CE-IVD mark, enables molecular laboratories around the world to utilize its Target Selector platform to analyze both formalin-fixed paraffin-embedded (FFPE) tissue samples and circulating tumor DNA (ctDNA) from biological fluids. Target Selector leverages patented Switch-Blocker technology to enrich specimens for mutations of interest and block DNA amplification from normal cells, requiring less tumor sample and resulting in higher assay sensitivity than most commercial assays. Biocept's molecular assays have been validated for the detection of frequent oncogenic mutations EGFR, KRAS and BRAF, which are among the most frequently evaluated biomarkers for lung cancer and melanoma.

"We are pleased to collaborate with Biocept to demonstrate the potential of its assay in determining EGFR status," said Anthony M. Magliocco, MD, President and CEO of Protean BioDiagnostics. "Obtaining adequate tissue sample for genomic profiling continues to be a challenge in first-line therapy selection for patients with NSCLC. Target Selector EGFR assays require 50% less tumor input sample than most commercial assays, making it a potentially powerful tool in helping qualify more patients for targeted tyrosine kinase inhibitor, or TKI, therapy. This potential advantage is coupled with previous studies demonstrating Target Selector assays' best-in-class low-end limit of detection of mutations in both FFPE and liquid biopsy samples."

"Protean BioDiagnostics is the ideal partner for this collaboration, as we share a joint commitment to advancing the best possible care for patients with cancer," said Michael Nall, Biocept President and CEO. "Protean has extensive experience working with some of the world's leading biotechnology companies. Together, our goal is to demonstrate how Target Selector assays can help physicians create more personalized, responsive treatment plans for their patients."

About Target Selector™ Molecular Assay Kits
Target Selector molecular assay kits are marketed for research-use-only (RUO) in the U.S. and CE-IVD in the European Union and other CE Mark geographies, offering industry-leading sensitivity for the detection of mutations/variants of interest in both FFPE and ctDNA. Target Selector assays with Switch-Blocker technology can also provide results with smaller DNA inputs (minimum 4.6 ng) than most tissue-based assays, allowing laboratories to get results even with small amounts of tissue. These capabilities should allow laboratories to eliminate macro-dissection of tumor blocks, potentially resulting in major workflow improvements and cost savings.

Target Selector assays can be used in combination with a variety of low-cost analytical platforms including qPCR, Sanger sequencing, microarrays, and mass-spectrometry, in addition to next generation sequencing. Target Selector kits (RUO and CE-IVD) offer high content per assay, which can reduce costs by selectively amplifying multiple mutations/variants in hot-spot regions of interest in a single reaction. All Target Selector assays are quantitative.

Target Selector molecular assay kits (RUO and CE-IVD) are currently available for EGFR and BRAF mutations. Additional test kits for other oncogene mutations are planned for launch in the future. For more information on Biocept's Target Selector molecular assay kits, contact Biocept Customer Service at (888) 332-7729 or customerservice@biocept.com.

About Protean BioDiagnostics
Protean BioDiagnostics Inc is a disruptive biotechnology company developing and commercializing novel cancer diagnostics supporting precision oncology. Protean has created Oncology MAPS™ - a unique and innovative, fully integrated diagnostic system for oncologists. This easy-to-deploy system enables rapid access to precision diagnostics for underserved community-based cancer doctors and their patients wherever they practice. Oncology MAPS™ includes comprehensive support and access to the latest genetic, molecular and cancer blood monitoring tests as well as educational and telemedicine support.

Protean is transforming cancer practice using a big data approach which integrates digital pathology, multi-omics, and artificial intelligence. Protean also provides support for contract research, clinical trials, and novel biomarker development using its CAP-accredited, CLIA-certified laboratories and through its extensive client networks.

Companion diagnostics can be quickly evaluated and deployed leveraging Protean's extensive laboratory capabilities, expertise, and extensive global research networks.

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
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 regarding the ability of our assays to improve the outcomes of patients diagnosed with cancer, the ability of our Target Selector molecular assay to determine EGFR status in NSCLC patients, the potential validation of the analytical performance of an LDT based on our EGFR assay test kit, the potential of our assay to determine EGFR status, the ability of our Target Selector assays to help physicians create more personalized, responsive treatment plans for their patients, the ability of our Target Selector assay to allow laboratories to eliminate macro-dissection of tumor blocks and improve workflow and cost savings, our future launch of test kits for additional oncogene mutations and the speed with which companion diagnostics can be evaluated and deployed, 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 and the risk that we will not be able to enter into additional services agreements. These and other risks are described in greater detail 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.

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