Study Shows Biocept's Switch-Blocker Technology Enhances Performance of Conventional PCR-Based Liquid Biopsy Assays in Detecting Rare Cancer Mutations

November 9, 2021

Abstract published in the Journal of Molecular Diagnostics shows 200-1,000 times increase in assay sensitivity with the addition of Switch-Blocker technology

SAN DIEGO--(BUSINESS WIRE)--Nov. 9, 2021-- Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, today announced the publication of a study showing that the addition of Switch-Blocker™ technology to common PCR-based liquid biopsy assays significantly increased sensitivity in detecting rare cancer mutations. The abstract was published in the November 2021 issue of the *Journal of Molecular Diagnostics*.

Biocept's proprietary Switch-Blocker technology enriches oncogenic mutations of interest while suppressing wild-type (normal) DNA, resulting in ultra-high sensitivity, specificity and accuracy. In this study, Switch-Blockers were combined with conventional real-time PCR and droplet digital PCR (ddPCR) assays.

"Our quantitative Switch-Blocker technology demonstrates an unprecedented ability to find and distinguish extremely rare genetic events—even in blood that contains mostly DNA from normal white blood cells," said Michael Dugan, Chief Medical Officer and Medical Director of Biocept. "This can greatly enhance the clinical sensitivity of our cell-free tumor DNA assays and has broad application in the continued development of highly sensitive and quantitative molecular diagnostic assays used to evaluate cerebrospinal fluid or blood from patients with cancer. Switch-Blocker-based assays can help detect cancer biomarkers that otherwise might be missed, improving treatment selection. They can also be used to evaluate treatment-related changes, find minimal residual disease or identify early disease recurrence."

Results showed that the addition of Switch-Blockers increased the sensitivity of allele-specific primer assays by more than 200 times, from about 1% minor allele frequency (MAF) to better than 0.01%. The sensitivity of multiplex competitive allele-specific TaqMan assays, commonly used with PCR amplification, were increased greater than 1,000 times, from about 10% MAF to 0.01% or better. The ability to significantly increase the sensitivity of conventional mutation assays using Switch-Blocker technology is critical for helping to find rare genetic events in a wide range of applications, including solid tumor cancers, where a majority of biomarkers in blood occur at less than 1% MAF.

The abstract (#TT33), titled "The Use of Switch-Blocker Probes for the Ultra-High Sensitivity of Detection of Rare Genetic Events Using Conventional Real-Time and Droplet Digital PCR Assays," can be accessed here.

About Switch-Blocker Technology

Biocept's proprietary Switch-Blocker platform is the basis for the company's Target Selector™ assays and can be used with tissue, blood and cerebrospinal fluid (CSF) samples. The technology enables industry-leading sensitivity for the detection of mutations/variants from circulating tumor DNA (ctDNA). It has been validated to 0.05% minor allele frequency in blood, which provides significant advantages for identifying actionable cancer biomarkers and assessing therapeutic tumor response. Switch-Blockers enhance the performance and specificity of the PCR method, the most widely used amplification approach for clinical diagnostic applications and can be customized to aid in biopharmaceutical research for the development of targeted therapies for cancer. Switch-Blocker technology also has been validated and found to be highly sensitive, quantitative and reproducible in detecting the presence of the SARS-CoV-2 virus that causes COVID-19 infections.

About Biocept

Biocept, Inc., develops and commercializes molecular diagnostic assays that provide physicians with clinically actionable information to aid in the diagnosis, treatment and monitoring of patients with cancer. In addition to its broad portfolio of blood-based liquid biopsy tests, the company has developed the CNSide™ cerebrospinal fluid assay, designed to diagnose cancer that has metastasized to the central nervous systemBiocept also is leveraging its molecular diagnostic capabilities to offer nationwide RT-PCR-based COVID-19 testing and services to support public health efforts during this unprecedented pandemic. For more information, visit www.biocept.com. Follow Biocept on Facebook, LinkedIn and Twitter.

Forward-Looking Statements Disclaimer

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 Biocept believe that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, Biocept 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," "could," "expect," or "believe" 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 capabilities of Biocept's Switch-Blocker technology and the ability of Biocept's assays to provide physicians with clinically actional information, 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 Biocept's products and services may not perform as expected. These and other risks are described in greater detail under the "Risk Factors" heading of Biocept's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, filed

with the Securities and Exchange Commission (SEC) on August 16, 2021. The effects of such risks and uncertainties could cause Biocept's actual results to differ materially from the forward-looking statements contained in this release. Biocept does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law. Readers are advised to review Biocept's 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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