Biocept Expands its Menu of Molecular Assay Kit Offering with Release of its Target Selector™ BRAF Kit for Clients' Use in Their Own Laboratories

May 14, 2020

Target Selector™ molecular assay kits are research-use-only (RUO) and offer superior sensitivity compared to NGS-based biomarker analysis for the detection of key actionable oncogene mutations

SAN DIEGO, May 14, 2020 /PRNewswire/ -- Biocept, Inc. (NASDAQ: BIOC), a leading commercial provider of molecular technologies designed to provide physicians with clinically actionable information to improve the outcomes of patients diagnosed with cancer, announces the availability of a Target Selector™ molecular assay research-use-only (RUO) kit for the detection of BRAF mutations. Biocept's molecular assay kits offer superior sensitivity compared with next generation sequencing (NGS) panels for the detection of biomarkers of key oncogene mutations from a blood sample.

Biocept's Target Selector™ molecular assay kits detect key oncogene mutations through the analysis of both Formalin-Fixed Paraffin-Embedded (FFPE) tissue gained from surgical biopsies as well as circulating tumor DNA (ctDNA) gained from blood-based liquid biopsies. The BRAF molecular assay kit is designed for the BRAF mutation, which is among the most frequently evaluated biomarkers across many solid tumor cancers, including lung cancer and melanoma. Biocept previously launched its molecular assay kit for the detection of EGFR mutations and plans to release additional Target Selector™ molecular assay kits in the future.

Biocept's Target Selector™ platform utilizes the Company's patented Switch-Blocker technology to enrich the specimen for mutations of interest, resulting in ultra-high assay sensitivity and specificity compared to other methods currently used in most laboratories such as standard RT-PCR or NGS. Biocept's Target Selector™ assay technology is patent protected in the United States, seven countries in Europe and five international territories.

"In NGS and many other molecular technology platforms, most of the cost of running an assay is due to analyzing the non-mutated gene of interest, so called 'wild type' or normal DNA," said Michael Nall, President and CEO of Biocept. "Our patented Switch-Blocker technology provides the unique ability to block the normal DNA and only analyze the target area of interest. Eliminating the cost related to analyzing the wild type DNA makes running a Switch-Blocker-based assay significantly more cost effective. In the case of NGS panels the costs related to analysis of wild type DNA is compounded, because in these panels approximately 70% or more of the genes are not currently clinically actionable.

"In international healthcare systems, access to advanced molecular testing for cancer patients can be limited because of cost issues, especially in developing countries," he added. "Therefore, we believe that Target Selector™ molecular assay kits, which offer the combination of a focus on clinically actionable genes, are cost-efficient to run and provide high analytical performance, will be an especially competitive offering."

About Biocept's Target Selector™ ctDNA Assay Kits

Biocept's Target Selector™ molecular assay kits can enable molecular laboratories around the world to detect key oncogene mutations through the analysis of both Formalin-Fixed Paraffin-Embedded (FFPE) tissue gained from surgical biopsies as well as ctDNA gained from blood-based liquid biopsies.

Target Selector™ molecular assay kits utilize Biocept's proprietary and patented Switch-Blocker technology to enable industry-leading sensitivity for the detection of mutations/variants of interest in ctDNA (one mutant copy in 10,000 wildtype DNA).

Due to its industry-leading sensitivity and the ability to block DNA amplification from normal cells, we believe Target Selector™ should allow laboratories to eliminate macro-dissection of tumor blocks, which can result in major workflow improvements and cost savings in the pathology laboratory. Target Selector™ assays can also provide results with small DNA inputs, compared to most tissue-based assays, thus allowing the laboratory to get results even with small amounts of tissue.

The 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 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.

For more information on Biocept's Target Selector™ liquid biopsy kits, or to order Assay Kits, please contact Biocept Customer Service at (888) 332-7729 or go to customerservice@biocept.com.

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 clinically actionable 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 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 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, our ability to launch additional RUO test kits for other oncogene mutations in the future, the market opportunity for our Target Selector™ kits, the ability of our Target Selector™ kits to offer research laboratories a number of efficiencies and cost savings, the ability of our Target Selector™ kits to provide a result when other FFPE assays may be unable to do so, and our ability to provide physicians with clinically actionable information for treating and monitoring 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 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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