# Biocept Announces CE-IVD Mark and Availability of its Target Selector™ EGFR Molecular Assay Kit in Europe

April 28, 2020

**Target Selector™ assay kits enable assay developers to leverage Biocept's patented, high-sensitivity technology for the detection of key actional oncogene mutations from both tissue biopsies and blood for liquid biopsy uses**

SAN DIEGO, April 28, 2020 /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 patients diagnosed with cancer, announces the award of CE (Conformité Européene)-IVD Mark for its Target Selector™ molecular assay EGFR Kit. The CE Mark confirms that the Company's Target Selector™ kit products meet the requirements of the European In-Vitro Diagnostic Devices Directive (98/79/EC) and allows Biocept to commercialize its kits throughout the European Union and other CE Mark geographies.

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 EGFR pathway can include mutations that are among the most frequently evaluated biomarkers for lung cancer. The Biocept assay kit is designed to test for highly informative EGFR mutations, including those necessary for treatment decisions such as Del19, L858R and T790M. Biocept's future plans include submission of additional biomarker Target Selector™ molecular assay kits for CE-IVD Mark.

Biocept's Target Selector™ ctDNA platform also utilizes the Company's patented Switch-Blocker technology which enriches the specimen for mutations of interest, resulting in ultra-high assay sensitivity and specificity compared to other methods currently used in other laboratories. Biocept's Target Selector™ assay technology is patent protected in the United States, seven countries in Europe and five international territories.

"Obtaining the CE-IVD Mark expands the market opportunity for our Target Selector™ molecular assay kits in the EU and other major international markets where we are seeing an acceleration in adoption of liquid biopsy-based testing," said Michael Nall, President and CEO of Biocept. "We believe our Target Selector™ molecular assay kits offer features that uniquely meet the needs of the EU and other international markets through the highly sensitive detection of key actional mutations and while being extremely cost effective.

"Previously we announced CEE-IVD mark for our CEE-Sure™ ambient temperature blood collection tube and ship kit. We are excited to now offer laboratories in the EU and other international markets a complete solution from sample acquisition to shipping and on through molecular assay reporting for tissue or liquid biopsy-based testing," he added.

**About Biocept's Target Selector™ Molecular 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, the market opportunity for our Target Selector™ kits, the ability of our Target Selector™ kits to uniquely meet the needs of the EU and other international markets, 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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