Biocept Announces CE IVD Marks and Availability of its CEE-Sure® Blood Collection Tube and Sample Collection Shipping Kit in Europe

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Patented Blood Collection Tube and Sample Collection Shipping Kit enable the safe transport at room temperature of patient specimens containing both circulating tumor DNA or RNA (ctDNA or ctRNA) and circulating tumor cells (CTCs)

SAN DIEGO, Nov. 7, 2019 /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 CE (Conformité Européene) IVD Marks and availability of its CEE-Sure® Blood Collection Tube and CEE-Sure® Sample Collection Shipping Kit in Europe. The CE Marks confirm that the Company's CEE-Sure® products, designed to collect and transport blood and other liquid biopsy specimens, meet the requirements of the European In-Vitro Diagnostic Devices Directive (98/79/EC), which now allows Biocept to commercialize its tubes and collection/shipping kits throughout the European Union and other CE Mark geographies.

"We are excited to announce this milestone, that our proprietary specimen collection tubes and shipping kits are now commercially available in Europe, consistent with our quest to brand Biocept globally as a leading technology provider in the liquid biopsy segment," stated Michael Nall, Biocept's President and CEO. "Our internally-developed and patented tube technology offers the ability to preserve and ship specimens containing CTCs, ctDNA, and ctRNA for use in oncology and prenatal diagnostics, as well as other molecular testing, throughout the world without refrigeration or special handling. We believe that these advantages will enable more patients to benefit from the use of liquid biopsy."

About Biocept's CEE-Sure® Blood Collection Tube

The CEE-Sure® Blood Collection Tube allows for the intact transport of liquid biopsy samples at room temperature from the clinic to central laboratories conducting molecular and cellular analyses. A unique feature is the ability to preserve CTCs, ctDNA or ctRNA collected from the patient in the same tube. The CEE-Sure® technology has a unique patented media that inhibits cell clumping, thus preventing clogging of microfluidics devices, which is a common problem with CTC analysis. It also can preserve high-quality circulating ctDNA or ctRNA for advanced molecular testing platforms like next generation sequencing (NGS), and applications such as non-invasive prenatal testing and detection of gene mutations in cancer. The CEE-Sure® Blood Collection Tube can be used to collect and transport many specimen types including blood, cerebrospinal fluid, sputum, and fluid obtained from pleural effusion. Use of these collection tubes does not require pre-shipment specimen processing, refrigeration during shipping, or centrifugation upon receipt, which can be barriers to the adoption of liquid biopsy. Study data demonstrating the ability to successfully collect and preserve patient blood samples for use with single gene tests and a broad liquid biopsy panel were presented in a poster at the 2017 American Association for Cancer Research (AACR) Annual Meeting.

About Biocept's CEE-Sure® Sample Collection and Shipping Kits

Biocept's CEE-Sure® Sample Collection and Shipping Kit contains Biocept's CEE-Sure® Blood Collection Tubes as well as components and instructions for collecting and shipping the blood samples.

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 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 CTCs and in plasma (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 enabling more patients to benefit from the use of liquid biopsy and the potential clinical utility of our proprietary technology platform, 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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