

Enrollment Begins in FORESEE Clinical Trial Using Biocept's CNSide™ to Evaluate Patients with Leptomeningeal Metastases

March 24, 2023

SAN DIEGO--(BUSINESS WIRE)--Mar. 24, 2023-- Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, announces enrollment of the first patient in the FORESEE clinical trial with the Company's proprietary cerebrospinal fluid assay CNSide (NCT05414123). This first patient was seen at the UT Southwestern Medical Center, one of the largest and most respected hospitals in the nation.

The FORESEE trial is a multicenter, prospective clinical trial expected to enroll 40 patients with breast or non-small cell lung cancer (NSCLC) who have suspicious or confirmed leptomeningeal metastases (LM). The goal of the FORESEE trial is to evaluate the performance of CNSide in monitoring the LM's response to treatment and to assess the impact of CNSide on treatment decisions made by physicians.

Standard-of-care methods to diagnose or assess the treatment response of LM (i.e., clinical evaluation, MRI and cytology) have limited sensitivity and specificity. This creates challenges for physicians to manage LM or determine the best course of treatment. CNSide is a Laboratory Developed Test (LDT) that is used commercially at the physician's discretion, with samples processed in Biocept's CLIA-certified, CAP-accredited laboratory.

"The enrollment of the first patient in the FORESEE clinical study is a major milestone for the management of patients with leptomeningeal disease," said Michael Youssef, MD, Assistant Professor in the Department of Neurology and the Department of Hematology and Oncology at UT Southwestern Medical Center. "We are excited to be at the forefront of this innovation, which will greatly benefit patients."

Priya Kumthekar, MD, Associate Professor of Neurology and Medicine (hematology and oncology) at the Feinberg School of Medicine at Northwestern University and Principal Investigator of the FORESEE trial, said, "I am impressed by the ease of use and the versatility of the CNSide technology, and how it can facilitate disease diagnosis and management for our leptomeningeal patients who are truly in need of improved diagnostics and therapeutics."

"The FORESEE trial evaluates the medical and clinical utility, when compared to standard of care, of the CNSide laboratory test, a revolutionary technology designed to detect cells in the cerebral spinal fluid of central nervous system brain metastasis patients," said Sam Riccitelli, Chairman and interim President and CEO of Biocept. "The test can be used to detect the presence of tumor, as well as guide and monitor therapy, an area of critical need for these terminally ill patients."

Dr. Kumthekar is a consultant to Biocept and Dr. Youssef has no financial interest in Biocept.

About CNSide

Using our proprietary CNSide[™] assay to analyze and interrogate CSF-TCs and cfDNA for certain biomarkers, physicians can be better informed about the actionable molecular information associated with a patient's metastatic cancer and develop a personalized cancer treatment plan. Through CNSide[™], Biocept's test menu focuses on cancer biomarkers that are clinically actionable based on clinical treatment guidelines listed by the National Comprehensive Cancer Network® (NCCN®). For more information, please visit https://biocept.com/technology/.

About Biocept

Biocept is a molecular diagnostics company with commercialized assays for patients with carcinomas or melanomas. Our experts have spent years working to change the way physicians look at cerebrospinal fluid (CSF) in cancer patients. Biocept has developed a unique, patented methodology to isolate cancer material that is shed from the primary tumor, such as CSF tumor cells (CSF-TCs) and cell-free DNA (cfDNA). As such, Biocept is a leading commercial provider of testing services designed to enable clinicians to rapidly detect and monitor cancer biomarkers from a cerebrospinal fluid sample. For more information visit https://www.biocept.com.

Forward-Looking Statements Disclaimer

This press 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 be correct. Forward-looking statements are generally identifiable by the use of words like "may," "will," "should," "could," "expect," "anticipate," "estimate," "believe," "intend," "goal," or "project," or the negative of these words or other variations on these words or comparable terminology. To the extent that statements in this press release are not strictly historical, including, without limitation, statements regarding the potential strategic alternatives the company is exploring and any potential enhancement of shareholder value or other benefit to the company's shareholders; the company's projected year-end cash position; the potential preservation or extension of the company's cash runway; the potential of CNSide; opportunities for CNSide; and other statements that are not historical fact, 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 risks related to preliminary financial results as described above, risks related to the company's business, market risks, our need for additional capital, and the risk that our products and services may not perform as expected. These and other factors are described in greater detail under the "Risk Factors" heading of Biocept's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed with the

Securities and Exchange Commission (SEC) on November 21, 2022. The effects of such risks and uncertainties could cause actual results to differ materially from the forward-looking statements contained in this press 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 at http://www.sec.gov/.

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