Enrollment Completed in the Feasibility Phase of the FORESEE Clinical Trial with Biocept's CNSide™ Assay to Evaluate Patients with Leptomeningeal Metastases

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SAN DIEGO--(BUSINESS WIRE)--Sep. 21, 2023-- Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, announces the full enrollment of 40 subjects with breast or non-small cell lung cancer (NSCLC) who have suspicious or confirmed leptomeningeal metastases (LM) in the feasibility phase of its prospective FORESEE clinical trial (NCT0414123). This trial is evaluating the performance of Biocept's proprietary CNSide assay in monitoring the response to therapy of LM, a cancer in the membranes that surround the brain and spinal cord, and assessing its impact on treatment decisions made by physicians.

"Completing enrollment in this first phase of our FORESEE trial, and doing so ahead of our internal timeline, is significant as we work toward establishing CNSide as standard of care under the National Comprehensive Cancer Network®, or NCCN®, guidelines," said Antonino Morales, Biocept President and CEO. "We believe obtaining standard-of-care status is the best path forward to support further physician adoption and to set reimbursement at a rate that reflects the value of our test in the clinical decision making process. The FORESEE trial is specifically designed to measure the impact of CNSide on physicians' clinical decisions to generate the data needed to help us reach this goal.

"Our CNSide assay is the first commercially available method that has the potential to objectively measure the presence of tumor in the central nervous system (CNS), as well as help guide and monitor therapy, an area of critical need for these terminally ill patients," he added. "Early adoption and reorder rates are encouraging and suggest that neuro-oncologists are finding the information generated by CNSide as useful in managing patients with this devastating cancer."

FORESEE is a two-part prospective clinical trial designed to follow subjects and collect data from each enrollee at four key time points in their treatment, as well as to compare CNSide cell detection in the cerebrospinal fluid to that of conventional cytology. CNSide has notable advantages over current standards of care, such as cytology, clinical evaluation and MRI, which have limited sensitivity and specificity. In retrospective pilot studies, CNSide demonstrated 92% sensitivity and 95% specificity in detecting LM. Additionally, CNSide is both qualitative and quantitative, which are key to monitoring treatment response and improving the ability of physicians to make or change treatment decisions.

"The current standards of care can present a significant obstacle in patient care due to the limitations in the detection and monitoring of LM. In addition to the current methods, there is a need for a reliable tool to diagnose and to monitor response to treatments in patients with LM," said Jonathan Yang, MD, PhD at the University of Washington and principal investigator at this site of the FORESEE trial. "In my practice I've found that CNSide provides important information that augments the detection and monitoring of LM, which is becoming increasingly important as patients with LM are living longer with improved quality of life due to improvement in treatments."

Biocept expects to have results from the feasibility phase of the FORESEE trial in the first half of 2024 and to then begin enrolling between 40 and 100 subjects in the trial's validation phase. Enrollment is currently open at four clinical sites with two additional sites expected to join the FORESEE trial in the near term.

About CNSide

CNSide is a laboratory developed test (LDT) based on Biocept's proprietary quantitative tumor cell capture and detection method, paired with assays to identify actionable molecular treatment targets. Given the genetic changes that can occur as metastatic cancer spreads to the CNS, the evaluation of cerebrospinal fluid with CNSide provides a unique opportunity to identify biomarkers in patients with metastatic carcinoma or melanoma to help guide physicians in therapy selection. In addition, the quantitative tumor cell count assay can be used in a serial fashion to monitor the response to therapy more effectively than other current methods.

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 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, please visit www.biocept.com.

Forward-Looking Statements Disclaimer Statement

This news 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 "will," "expect," "goal," "objective," "believe" or "intend" or the negative of these words or other variations on these words or comparable terminology. To the extent that statements in this news release are not strictly historical, including, without limitation, statements regarding CNSide's clinical utility to support drug development, any exclusivity payment, future agreements with biotech and biopharmaceutical companies, monitoring patients on cancer therapies, adoption into clinical care guidelines, and support reimbursements, our plan to provide further

evidence of CNSide's clinical utility through our FORESEE clinical trial, publications in peer-reviewed medical journals, additional manuscripts to be submitted for peer review, our cash runway, and other statements that are not historical fact, 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 that the results of the FORESEE clinical trial may not support the inclusion of CNSide in clinical care guidelines; Medicare and private payors may not provide coverage and reimbursement or may breach, rescind or modify their contracts or reimbursement policies or delay payments; risks related to 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 in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the Securities and Exchange Commission (SEC) on May 10, 2023, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 14, 2023. The effects of such risks and uncertainties could cause actual results to differ materially from the forward-looking statements contained in this news 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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