Biocept Announces Participation in an Investigator-Initiated Study to Better Understand the Development and Progression of Metastatic Breast Cancer to the Central Nervous System

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Conducted by leading breast oncologists from UCSF under a grant from the California Breast Cancer Research Program and the University of California, San Francisco Brain Spore, the study will analyze results from cerebrospinal fluid using Biocept's CNSide™ assay with results from blood samples

SAN DIEGO--(BUSINESS WIRE)--Nov. 16, 2022-- Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, announces a collaboration agreement to participate in an investigator-initiated, non-therapeutic pilot study to evaluate the cerebrospinal fluid tumor and immune cell microenvironment in patients with metastatic breast cancer and brain metastases and/or leptomeningeal disease. The study is designed to identify biomarkers associated with central nervous system (CNS) metastasis, enabling a better understanding of treatment response, prognosis, and treatment resistance that may improve the management of CNS disease in patients with metastatic breast cancer.

The study is being conducted by breast oncologists Michelle E. Melisko, M.D. and Laura A. Huppert, M.D. at the University of California, San Francisco (UCSF) under a grant from the California Breast Cancer Research Program and the UCSF Brain Spore. Results from cerebrospinal fluid using Biocept's CNSide assay and matched patient blood samples will be analyzed and compared to detect and characterize cancer in the cerebrospinal fluid with the goal of identifying new targets and to guide therapeutic decisions. In addition, Drs. Huppert and Melisko will work with Dr. Chris Im in the laboratory of Dr. Max Krummel at UCSF to examine the immune-cell microenvironment in a companion study, and the results will be analyzed together.

"We hypothesize that patients with metastatic breast cancer and brain metastases and/or leptomeningeal disease will have tumor cells and cell-free tumor DNA (ctDNA) that can be detected in cerebrospinal fluid, and that higher concentrations of cerebrospinal fluid tumor cells and ctDNA will correlate with progression of brain metastases and/or development of leptomeningeal disease," said Dr. Melisko. "The ability to identify cancer biomarkers that predict an elevated risk of CNS disease progression will have prognostic and therapeutic implications in treating these patients."

"This collaborative study is designed to provide important information derived from cerebrospinal fluid samples that will better inform physicians treating patients with metastatic breast cancer involving the CNS, in particular those with leptomeningeal disease, who have a very poor prognosis if untreated," said Michael Dugan, M.D., Biocept's Chief Medical Officer and Medical Director. "CNSide will help these physicians determine the extent of involvement, potential targets for treatment and help them evaluate the response to treatment."

"This study will also evaluate and compare the information derived from cerebrospinal fluid versus that of matched blood samples, where—based on our early experience—we believe cerebrospinal fluid could be more informative of intracranial response to treatment than related blood-based tests or radiologic changes routinely assessed by MRI," he added.

The pilot study will collect cerebrospinal fluid and blood samples from 20 patients with metastatic breast cancer and brain metastases and/or leptomeningeal disease. The samples will be analyzed for the presence, quantity and mutational profile of cerebrospinal fluid ctDNA and cerebrospinal fluid tumor cells, which will be paired with results from peripheral blood mononuclear cell samples. Exploratory analysis of changes in cerebrospinal fluid ctDNA, tumor cell, and immune cell characteristics will be performed over time in a limited number of serial samples. The cerebrospinal fluid findings will then be correlated with clinical outcomes, including CNS disease progression and survival.

The Rationale for the Study

One of the most devastating complications of metastatic breast cancer is the development of CNS disease, including brain metastases and/or leptomeningeal disease. Among patients with metastatic breast cancer, approximately 15-45% develop brain metastases and approximately 5-10% develop leptomeningeal disease during the course of their disease, resulting in significant morbidity and mortality. As patient outcomes improve with better systemic treatment options, control of CNS disease has become increasingly important to reduce morbidity and prolong survival.

Patients with leptomeningeal disease are often excluded from clinical trials and there are few effective treatments. In order to develop better tools for the diagnosis and treatment of metastatic breast cancer with CNS disease, it is critical to better understand the biology of this condition. Specifically, the profiling of the cerebrospinal fluid tumor and immune microenvironment in patients with brain metastases and/or leptomeningeal disease will enable a better understanding of the characteristics that may contribute to the development and progression of CNS disease.

About the California Breast Cancer Research Program

The mission of the California Breast Cancer Research Program (CBCRP) is to prevent and eliminate breast cancer by leading innovation in research, communication, and collaboration in the California scientific and lay communities. CBCRP is the largest state-funded breast cancer research effort in the nation and is administered by the Research Grants Program Office within the University of California Office of the President. The CBCRP funds California investigators to solve questions in basic breast cancer biology, causes and prevention of breast cancer, innovative treatments and ways to live well following a breast cancer diagnosis, and involves advocates and scientists in every aspect of CBCRP decision-making, including program planning and grant application review. Since 1994 the CBCRP has awarded more than $280 million in research funds to institutions across California, with 95% of its revenue going directly to funding research and education efforts.

About CNSide

CNSide is 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 central nervous system, the evaluation of cerebrospinal fluid with CNSide provides a unique opportunity to identify biomarkers such as HER2 and EGFR 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, Inc. develops and commercializes molecular diagnostic assays that provide physicians with clinically actionable information for treating and monitoring patients diagnosed with a variety of cancers. For more information, visit www.biocept.com. Follow Biocept on Facebook, LinkedIn, Twitter, and Instagram.

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 study design and its potential results, benefits and other outcomes, our hypotheses, the prognostic and therapeutic implications of the ability to identify biomarkers that predict an elevated risk of CNS disease progression, and the ability of CNSide to detect, characterize and monitor disease progression in patients with leptomeningeal disease, 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 with the risk that the study described in this press release does not provide clinically meaningful data, does not confirm our hypothesis or otherwise does not demonstrate the clinical value of our CNSide assay for the diagnosis and treatment of the patients in the study, 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 June 30, 2022, filed with the SEC on November 10, 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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