



Biocept's CNSide Cerebrospinal Fluid Assay Identifies Actionable HER2 Mutations in Patients with Breast Cancer that has Metastasized to the Brain

December 9, 2021

Spotlight Presentation at SABCS showed that in 38% of patients the HER2 status of the metastatic cancer differed from the primary tumor, offering new information to aid treatment decisions

SAN DIEGO--(BUSINESS WIRE)--Dec. 9, 2021-- [Biocept, Inc.](#) (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, presented a study demonstrating the ability of its CNSide™ assay to identify HER2 and other actionable tumor alterations in the cerebrospinal fluid of patients with breast cancer and leptomeningeal disease (LMD). The [poster](#) was chosen for a Spotlight Presentation at the San Antonio Breast Cancer Symposium on Dec. 8, 2021.

LMD is a devastating complication in which cancer spreads to the membrane surrounding the brain and spinal cord. The current standard of care for diagnosing LMD is through clinical evaluation, imaging and cytology, which have limited sensitivity and are unable to identify important tumor biomarkers such as HER2. HER2-targeted treatment for patients with breast cancer and LMD may provide substantial survival advantages over the expected median survival of less than three months.

In this analysis, cerebrospinal fluid (CSF) of 63 patients with stage IV breast cancer and LMD was collected, and CSF tumor cells were captured and characterized using CNSide. HER2 amplification was detected in 56% of all patients. HER2 status differed between the primary tumor and LMD in 38% of cases, with more than 80% of those patients exhibiting a switch from a HER2-negative primary tumor to HER2-positive LMD.

"Knowing if a patient's tumor is HER2 positive or negative, and especially whether HER2 status has changed from primary tumor to LMD, allows us to more precisely treat those patients and achieve a better response," said Amir Azadi, M.D., a neuro-oncologist at Banner MD Anderson, who participated in a key opinion leader [webcast event](#) earlier this year discussing the advantages of CNSide in detecting central nervous system metastases. "Patients with brain metastases and leptomeningeal disease have a very poor prognosis. CNSide provides new information to help guide treatment decisions that may extend life expectancy and improve quality of life for these patients."

"Our CNSide assay can be used both to confirm the presence of tumors and to identify important biomarkers in LMD such as HER2," said Michael Dugan, M.D., Chief Medical Officer and Medical Director of Biocept. "Finding HER2 amplification in breast cancer tumor cells in the CSF is critical because anti-HER2 targeted therapy provides one of the best options for physicians treating patients with breast cancer who have developed the life-threatening complications of LMD."

The CNSide CSF assay is designed to help physicians better detect and manage treatment of metastatic cancers involving the central nervous system. It provides a timely and accurate method to help diagnose these tumors, identify actionable biomarkers and assess response to therapy, with the goal of improving patient survival and quality of life. The assay is based on Biocept's proprietary quantitative tumor cell capture and detection method, paired with assays to identify actionable molecular treatment targets. CNSide has the ability to answer key questions that may help inform treatment decisions: Is there involvement by tumor? Is there a target for treatment? Is there a trend with respect to treatment response?

The poster, titled, "Characterization of HER2 Amplification in the Cerebrospinal Fluid of Patients with Leptomeningeal Disease in Stage IV Patients with Breast Cancer," can be accessed [here](#).

About Biocept

Biocept, Inc. develops and commercializes molecular diagnostic assays that provide physicians with clinically actionable information to aid in the diagnosis, treatment and monitoring of patients with cancer. In addition to its broad portfolio of blood-based liquid biopsy tests, the company has developed the CNSide™ cerebrospinal fluid assay, designed to diagnose cancer that has metastasized to the central nervous system. Biocept also is leveraging its molecular diagnostic capabilities to offer nationwide RT-PCR-based COVID-19 testing and services to support public health efforts during this unprecedented pandemic. For more information, visit www.biocept.com. Follow Biocept on [Facebook](#), [LinkedIn](#) and [Twitter](#).

Forward-Looking Statements Disclaimer

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 Biocept believes that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, Biocept 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," "could," "expect," or "believe" 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 regarding the capabilities and potential benefits of Biocept's CNSide assay and the ability of Biocept's assays to provide physicians with clinically actionable information, 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 the risk that Biocept's products and services may not perform as expected. These and other risks 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, 2021, filed with the Securities and Exchange Commission (SEC) on November 15, 2021. The effects of such risks and uncertainties could cause Biocept's

actual results to differ materially from the forward-looking statements contained in this release. Biocept does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law. Readers are advised to review Biocept's filings with the SEC, which can be accessed over the Internet at the SEC's website located at www.sec.gov.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20211209005337/en/>

Media Contact:

Andrea Sampson, Sampson PR Group
asampson@sampsonprgroup.com, 562-304-0301

Investor Contact:

Jody Cain, LHA Investor Relations
Jcain@lhai.com, 310-691-7100

Source: Biocept, Inc.