Biocept Announces Full Commercial Launch of CNSide™ Cerebrospinal Fluid Assay to Address Unmet Needs for Patients with Metastatic Brain Cancer

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Molecular assay provides highly sensitive, quantitative method to identify cancer involving the central nervous system, inform treatment decisions, and monitor therapy response

SAN DIEGO--(BUSINESS WIRE)--Apr. 21, 2021-- Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, has announced the full commercial launch of CNSide™, its cerebrospinal fluid (CSF) assay designed to better detect and manage treatment of metastatic cancers involving the central nervous system (CNS). The assay, initially introduced in January 2020, has the ability to offer a timely and accurate method to diagnose disease, identify actionable biomarkers, and assess response to therapy, potentially impacting life expectancy and quality of life.

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CNSide is based on Biocept's proprietary quantitative tumor cell capture and detection method paired with assays to identify actionable molecular treatment targets. The assay answers three key questions: Is there involvement by tumor? Is there a target for treatment? Is there a trend with respect to treatment response?

The CNSide assay addresses a high unmet clinical need, as the current standard of care, CSF cytology, has limited sensitivity for detecting brain metastasis and assessing therapy response, and does not provide quantitative results. Between 10% and 30% of patients with cancer, depending on cancer type, will develop brain or spinal cord metastasis. Overall survival expectancy is low, and many patients are not diagnosed early enough for therapeutic intervention. However, the use of newer targeted therapies for lung and breast cancer with intracranial metastasis can often extend survival for a year or more, resolving symptoms and substantially improving quality of life.

"Simply stated, patients diagnosed with advanced cancer and their physicians need better tools to diagnose brain metastasis earlier, more accurately, and to assess response to therapy in a timely, quantitative fashion so that patients can benefit from the remarkable advances in cancer therapies available today," said Michael Dugan, MD, Biocept's Senior Vice President, Chief Medical Officer and Medical Director. "These patients do not have time to waste on inaccurate or uncertain diagnostic tests."

"CNSide, with Target Selector ™ technology, provides information well beyond what we can obtain from current diagnostics—specifically, it provides insights to help us select the right treatment for our patients, as well as insights on duration of therapy," said Priya Kumthekar, MD, Associate Professor of Neurology and Oncology, Northwestern University Feinberg School of Medicine, during a recent key opinion leader webinar. "I see CNSide as a way to improve diagnosis and monitoring of CNS involvement in a patient population that represents a very high unmet need, and a population that appears to be growing."

"The full sales force launch of our CSF assay, along with new branding, is an exciting next step toward our goal of establishing CNSide as a new standard-of-care diagnostic test for cerebrospinal fluid," said Michael Nall, Biocept's President and CEO. "Initial acceptance by neuro-oncology early-adopters has been highly encouraging as physicians from nearly two dozen leading academic institutions have ordered CNSide—with many becoming repeat users. This represents a significant market opportunity that we estimate at more than $1 billion annually in the United States for breast and lung cancers that have metastasized to the central nervous system."

In 2020, Biocept presented highly favorable results from pilot studies with the assay at three major scientific meetings.[1-3] The studies showed that in approximately 80% of the cases of suspected CNS involvement, tumor cells were detected using the CNSide assay, compared with about 50% of cases examined by CSF cytology. The assay is currently validated to identify metastatic cancers originating in the lung and breast. Biocept plans to expand its CSF testing menu for additional tumor types and biomarkers in the future.

A recent webinar hosted by Biocept featured leading neuro-oncologists discussing the use of the CNSide assay for diagnosing and managing tumors that have metastasized to the CNS. The webinar can be viewed here.

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. In addition to its broad portfolio of blood-based liquid biopsy assays, Biocept has developed the CNSide™ cerebrospinal fluid assay that detects cancer that has metastasized to the central nervous system. Biocept's patented Target Selector™ technology captures and quantitatively analyzes CSF tumor cells for tumor-associated molecular markers, using technology first developed for use in blood. Biocept also is leveraging its molecular diagnostic capabilities to offer nationwide COVID-19 RT-PCR testing 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 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 "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 news release are not strictly historical, including, without limitation, statements as to the ability of CNSide to impact life expectancy and quality of life, our ability to establish CNSide as the new standard of care for the diagnosis of patients with suspected cancer metastasis to the CNS, our ability to expand our CSF testing menu for additional tumor types and biomarkers in the future, and our ability to provide physicians with clinically actionable information for treating and monitoring patients diagnosed with a variety of cancers, 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 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/.

1. Fenn K, Singh V, Lee S, et al. Diagnosis of leptomeningeal metastasis (LM) through identification of circulating tumor cells (CTCs) in cerebrospinal fluid (CSF). *J Clin Oncol*. 2020; 38(15): 3567.
2. Singh V, Fisher D, Berz D, et al. The next generation of cerebrospinal fluid (CSF)-based molecular diagnostics: Improving sensitivity and actionability in breast and lung cancer patients with CNS involvement. *J Clin Oncol*. 2020;38(15): e14502.
3. Berz D, Singh V, Camidge R, et al. Utility of Liquid Biopsy in Diagnosis and Treatment Response in EGFR Mutant NSCLC Patients with Leptomeningeal Involvement. IASLC Virtual Meeting. October 2020. Presentation available online.

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