Biocept Expands Commercial Offering of CNSide™ Assay to Most Cancers that Metastasize to the Central Nervous System

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The cerebrospinal fluid (CSF) assay is now validated for melanomas and carcinomas, providing information to help physicians improve treatment decisions for more patients with advanced cancers

SAN DIEGO--(BUSINESS WIRE)--Oct. 17, 2022-- Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products, and services, announces the expanded commercial availability of CNSide for patients with metastatic melanoma. Previously validated for lung, breast, and all other carcinomas, Biocept's CNSide is a proprietary CSF assay designed to better detect and inform treatment decisions for patients with metastatic cancers involving the central nervous system (CNS).

The new CNSide for melanoma assay uses a novel antibody cocktail optimized for the capture of melanoma cells based on unique cellular characteristics. This assay represents a significant development in the field of neuro-oncology related diagnostics. It is believed to be the first CLIA-validated assay designed for the quantitative identification of melanoma cells in CSF.

Melanoma is the third most common tumor type involved in CNS metastasis, with more than 60% of Stage IV melanoma patients developing CNS metastasis from their disease. Overall survival expectancy is low and patient management can be challenging due in part to diagnostic limitations. CNSide addresses a high unmet clinical need, as current standard of care approaches—CSF cytology and MRI imaging—have limited sensitivity for detecting CNS metastasis and are not adequate to assess the response to therapy. CNSide can also help identify molecular biomarkers considered targets for novel therapy approaches. Combined, these features help clinicians answer three key questions for patients with CNS metastasis: Is there tumor? Is there a target for treatment? Is there a trend or favorable response to treatment?

"Our early development experience evaluating patients with melanoma with CNSide is similar to what we have seen in carcinomas, supporting the expanded clinical use of this CLIA laboratory developed test," said Michael Dugan, M.D., Biocept's Chief Medical Officer and Medical Director. "Physicians are finding CNSide valuable for managing patients with CNS metastasis, particularly to assess treatment response. Declining CSF tumor cell counts have correlated well with successful response to therapy and symptom resolution, while better illustrating residual, recurrent or resistant disease. CSF can also be more frequently and easily evaluated while the patient is in the clinic, compared to follow-up radiologic imaging that might occur weeks later."

"We are pleased to expand the commercial use of CNSide for physicians treating patients with metastatic melanoma," said Samuel D. Riccitelli, Biocept's Chairman, and interim President and CEO. "This is another step toward our goal of establishing CNSide as a new standard-of-care diagnostic test for patients with metastatic cancer that has spread to the CNS; patients who have no time to waste."

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 CNS, 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 our ability to establish CNSide as the new standard-of-care diagnostic test for patients with metastatic cancer that has spread to the central nervous systems, and the ability of our products, including CNSide, 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 risks and uncertainties, including risks and uncertainties associated with the ability of our products to compete successfully with competitive products or treatments; our ability to obtain and maintain adequate reimbursement for our products; 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 March 31, 2022, filed with the SEC on May 23, 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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