Biocept Signs CNSide™ Licensing Agreement with Plus Therapeutics

Sep 8, 2023

SAN DIEGO--(BUSINESS WIRE)--Sep. 8, 2023-- Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products, and services, announces the signing of a non-exclusive licensing agreement for CNSide™ with Plus Therapeutics, Inc. (Nasdaq: PSTV) (Plus), which expands the comprehensive laboratory services agreement between the two companies that was announced in June 2022. Plus is using CNSide in a clinical trial with their targeted radiotherapeutic to treat patients with carcinomas and/or melanomas with suspected leptomeningeal metastases (LM), which is cancer in the membranes that surround the brain and spinal cord. CNSide is Biocept's proprietary cerebrospinal fluid (CSF)-based tumor cell capture and enumeration platform used in detecting, quantifying, and monitoring tumor status in LM.

This new agreement allows for Plus to perform CNSide testing during its clinical trials and commercially, subject to regulatory approval. Biocept will provide expertise, including consulting on equipment and materials sourcing, as well as providing the necessary technology and training to perform CNSide. Plus will pay Biocept an upfront fee of $150,000 in stock, plus $6,000 per CSF tumor cell enumeration analysis performed in Biocept's CLIA-certified and CAP-accredited laboratory prior to the completion of the technology transfer. Once the technology transfer is complete, Plus will pay Biocept $300,000 plus fees on a sliding scale starting at $2,800 for each CNSide test they perform. The license agreement also gives Plus the option to negotiate for third-party exclusivity with a $1,000,000 payment to Biocept.

"We are gratified that Plus continues to recognize the value of CNSide in leptomeningeal metastases disease management. We share their commitment to improving the lives of patients suffering from cancer of the central nervous system (CNS)," said Antonino Morales, Biocept President and CEO. "We view this agreement as further validation of the clinical utility of CNSide and the important role it plays in diagnosing and monitoring patients with LM. It also sets the stage for future agreements with other companies developing treatments for cancer of the CNS and provides Biocept with non-dilutive funding to support our goal of establishing CNSide as standard of care under the National Comprehensive Cancer Network® (NCCN®) guidelines.

"Importantly, Plus will reimburse Biocept for CNSide testing performed prior to completion of the technology transfer at $6,000 per enumeration," he added. "This amount more than covers our costs and potentially sets the stage for reimbursement at a similar level in future arrangements."

Plus is using CNSide in its ReSPECT-LM Phase 1/2a dose-escalation clinical trial of Rhenium 186 Obisbemeda for the treatment of patients with LM. Plus recently announced completion of Phase 1/Part A of the trial and presented favorable preliminary safety and efficacy results. Plus has received U.S. Food and Drug Administration (FDA) approval to move to Phase 1/Part B of the ReSPECT-LM clinical trial. For more information on Plus, please visit www.plustherapeutics.com.

"The CNSide test is the emerging gold standard for the definitive diagnosis and follow up of patients with LM," said Marc H. Hedrick, M.D., President and CEO of Plus Therapeutics. "The CNSide technology may, in the near future, supplement or replace existing diagnostic technology for cerebrospinal fluid malignancies. We view CNSide as an important complement to our novel radiotherapeutic technology, Rhenium 186 Obisbemeda, now in clinical development for leptomeningeal metastases in our actively enrolling ReSPECT-LM trial."

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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