Plus Therapeutics Provides Business Update on CNSide Diagnostics Subsidiary

June 26, 2025

U.S. commercial rollout of novel diagnostic platform to begin second half 2025

Underserved CNS cancer diagnostic U.S. market opportunity estimated to be in excess of $6 billion

Management to host a conference call today at 9am ET

HOUSTON, June 26, 2025 (GLOBE NEWSWIRE) -- Plus Therapeutics, Inc. (Nasdaq: PSTV) (the "Company"), a clinical-stage pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system (CNS) cancers, will provide a business update for its wholly-owned subsidiary, CNSide Diagnostics, LLC ("CNSide"). The proprietary CNSide Cerebrospinal Fluid (CSF) Assay Platform is designed and intended for patients suspected of having central nervous system cancer metastases (CNS Mets). The first test to be commercialized, CNSide CSF Tumor Cell Enumeration (TCE), has a total addressable market estimated to be $6 billion in the U.S.[1]

"The developer of the CNSide technology invested over $300 million in this core technology and after a year of detailed analysis and preparation by our team and key consultants, our enthusiasm regarding the unmet clinical need and the inherent value of CNSide has only grown," said Marc H. Hedrick, M.D., Plus Therapeutics' President and Chief Executive Officer. "CNSide, as a laboratory-developed test widely adopted under a prior commercial program, will begin to hit the market this year under our full commercial access strategy, providing Plus with an expedited path to both revenue and corporate profitability while allowing us to continue the progress in our core CNS radiotherapeutics clinical development pipeline."

CNSide is a Comprehensive Diagnostic Platform Addressing an Underserved Patient Population
CNS Mets are an epidemic affecting as many as 30% of adult cancer patients and affect the highly protected CNS space. Once the CNS is affected, diagnosis and treatment are difficult and as a result, approximately half of patients with CSF metastases instead receive just palliative care or hospice. The current standard of care for CNS Mets diagnosis, CSF cytology, was developed over a century ago and offers suboptimal test sensitivity leading to missed or delayed diagnosis and treatment.

By comparison, the comprehensive CNSide CSF Assay is a highly sensitive platform that diagnoses, monitors, and guides treatment, demonstrating significant advantages over the current standard of care. The superior clinical utility of CNSide has been shown in 8 peer-reviewed publications, a completed clinical trial, and has been validated in the market through real-world use. More than 11,000 CNSide tests have been performed at over 200 U.S. cancer institutions since 2020, delivering high sensitivity (92%) and specificity (95%), while influencing treatment decisions in 90% of cases. The Company believes that the CNSide CSF Assay Platform provides both clinical and economic value relative to the standard of care for CNS cancer management, with further substantial value added to the Company's lead developmental radiotherapeutic candidate, REYOBIQ, for patients with a common form of CNS Mets, leptomeningeal metastases.

CNSide Progress Since Acquisition to Support Commercial Readiness
Since acquiring CNSide in 2024, the Company has established infrastructure to support a scalable and centralized testing laboratory in Houston, TX that will service the U.S. market. The Company has been executing on its commercial market access strategy, which includes prioritized state licensure, proprietary reimbursement codes, commercial and government payor coverage, and value-based pricing to optimize revenue. The Company anticipates introducing the CNSide platform first in Texas in the second half of 2025, followed rapidly by expansion into additional states in late 2025 and 2026. In parallel, additional expanded CNS testing capabilities are also expected to roll out over the next year.

When the CNSide CSF Assay Platform was previously commercially available, market acceptance and adoption were widespread, with several national and regional commercial payor agreements in place and the test in regular use at major cancer centers across the U.S. The Company is now in contact with the legacy payors and healthcare providers in anticipation of the planned 2025 launch, and later this year will be expanding those contacts to support a 50-state strategy. Finally, Plus has hired experienced leadership with expertise in the development and commercialization of clinical diagnostic technologies on a large scale, including its recent hire of Mr. Russ Bradley as CNSide Diagnostics, LLC President and General Manager.

"We believe CNSide is uniquely differentiated by providing physicians with superior tools for the detection, enumeration, and characterization of metastatic cancer cells in the central nervous system," said Mr. Bradley. "This foundation is supported by prior market acceptance and rapid adoption of the CNSide technology by over 200 unique physician providers at more than 120 separate institutions when it was first previewed in 2020. As we move toward reintroducing CNSide to healthcare providers in the U.S., we anticipate strong clinical demand, as several payor reimbursement agreements were previously negotiated and in place."

CNSide Financials and Guidance for the Remainder of 2025
"Plus Therapeutics will update investors on the commercial progress of CNSide later this year," said Andrew Sims, Plus Therapeutics' Vice President and Chief Financial Officer. "We anticipate that while CNSide's launch is on track for 2025, given our current forecasts the revenue contributions of the CNSide subsidiary will become meaningful to Plus Therapeutics' operations in fiscal year 2026."

Webcast and Conference Call Details
Plus Therapeutics will host a conference call and webcast today, June 26, 2025, at 9:00 a.m. ET to discuss and provide additional details on its CNSide diagnostic business. Participants can register here any time before the call through the dial-in link. Once registration is completed, participants will be provided a dial-in number with a personalized conference code to access the call. A live webcast of the conference call will be available here as well as on the Investor Relations section of the Company's website at ir.plustherapeutics.com. The webcast will be archived on the website following the completion of the call.

About CNSide Diagnostic, LLC

CNSide Diagnostics, LLC is a wholly owned subsidiary of Plus Therapeutics, Inc. that develops and commercializes proprietary laboratory-developed tests, such as CNSide®, designed to identify tumor cells that have metastasized to the central nervous system in patients with carcinomas and melanomas. The CNSide® CSF Assay Platform enables quantitative analysis and molecular characterization of tumor cells and circulating tumor DNA in the cerebrospinal fluid that inform and improve the management of patients with leptomeningeal metastases.

About Leptomeningeal Metastases (LM)
LM is a rare complication of cancer in which the primary cancer spreads to the cerebrospinal fluid (CSF) and leptomeninges surrounding the brain and spinal cord. All malignancies originating from solid tumors, primary brain tumors, or hematological malignancies have this LM complication potential with breast cancer as the most common cancer linked to LM, with 3-5% of breast cancer patients developing LM. Additionally, lung cancer, GI cancers and melanoma can also spread to the CSF and result in LM. LM occurs in approximately 5% of people with cancer and is usually terminal with 1-year and 2-year survival of just 7% and 3%, respectively. The incidence of LM is on the rise, partly because cancer patients are living longer and partly because many standard chemotherapies cannot reach sufficient concentrations in the spinal fluid to kill the tumor cells, yet there are no FDA-approved therapies specifically for LM patients, who often succumb to this complication within weeks to several months, if untreated.

About REYOBIQ™ (rhenium 186re obisbemeda)
REYOBIQ™ (rhenium 186re obisbemeda) is a novel injectable radiotherapy specifically formulated to deliver direct targeted high dose radiation in CNS tumors in a safe, effective, and convenient manner to optimize patient outcomes. REYOBIQ™ has the potential to reduce off target risks and improve outcomes for CNS cancer patients, versus currently approved therapies, with a more targeted and potent radiation dose. Rhenium-186 is an ideal radioisotope for CNS therapeutic applications due to its short half-life, beta energy for destroying cancerous tissue, and gamma energy for real-time imaging. REYOBIQ is being evaluated for the treatment of recurrent glioblastoma and leptomeningeal metastases in the ReSPECT-GBM and ReSPECT-LM clinical trials. ReSPECT-GBM is supported by an award from the National Cancer Institute (NCI), part of the U.S. National Institutes of Health (NIH), and ReSPECT-LM is funded by a three-year $17.6M grant by the Cancer Prevention & Research Institute of Texas (CPRIT). The Company's clinical trial for pediatric brain cancer is supported by a $3 million grant from the U,S, Department of Defense's Peer Reviewed Cancer Research Program.

About Plus Therapeutics
Headquartered in Houston, Texas, Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company developing targeted radiotherapeutics for difficult-to-treat cancers of the central nervous system with the potential to enhance clinical outcomes. Combining image-guided local beta radiation and targeted drug delivery approaches, the Company is advancing a pipeline of product candidates with lead programs in leptomeningeal metastases (LM) and recurrent glioblastoma (GBM). The Company has built a supply chain through strategic partnerships that enable the development, manufacturing, and future potential commercialization of its products. For more information, visit https://www.plustherapeutics.com.

Forward-Looking Statements
This press release contains statements that may be deemed "forward-looking statements" within the meaning of U.S. securities laws, including statements regarding clinical trials, expected operations and upcoming developments. All statements in this press release other than statements of historical fact are forward-looking statements. These forward-looking statements may be identified by future verbs, as well as terms such as "expect" "potential," "anticipating," "planning" and similar expressions or the negatives thereof. Such statements are based upon certain assumptions and assessments made by management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

These statements include, without limitation, statements regarding the potential market for the CNSide CSF Assay, the timing in which the CNSide CSF Assay is commercially launched and commercialization is expanded, revenue and corporate profitability expectations including support reimbursements and payments for the CNSide CSF Assay, the development and utility of the CNSide CSF Assay and expectations as to the Company's future performance, including the next steps in developing the Company's product candidates.

The forward-looking statements included in this press release could differ materially from those expressed or implied by these forward-looking statements because of risks, uncertainties, and other factors that include, but are not limited to, the following: the Company's ability to maintain the listing of its common stock on Nasdaq; risks related to a halt in trading or delisting of the Company's common stock on Nasdaq; Medicare and private payors may not provide coverage and reimbursement or may breach, rescind or modify their contracts or reimbursement policies or delay payments; the risk that our products and services may not perform as expected; the early stage of the Company's product candidates and therapies; the results of the Company's research and development activities, including uncertainties relating to the clinical trials of its product candidates and therapies; the Company's liquidity and capital resources and its ability to raise additional cash; the outcome of the Company's partnering/licensing efforts, risks associated with laws or regulatory requirements applicable to it; market conditions, product performance, litigation or potential litigation, and competition within the cancer diagnostics and therapeutics field; ability to develop and protect proprietary intellectual property or obtain licenses to intellectual property developed by others on commercially reasonable and competitive terms; challenges associated with radiotherapeutic manufacturing, production and distribution capabilities necessary to support the Company's clinical trials and any commercial level product demand; and material security breach or cybersecurity attack affecting the Company's operations or property. This list of risks, uncertainties, and other factors is not complete. Plus Therapeutics discusses some of these matters more fully, as well as certain risk factors that could affect Plus Therapeutics' business, financial condition, results of operations, and prospects, in its reports filed with the SEC, including Plus Therapeutics' annual report on Form 10-K for the fiscal year ended December 31, 2024, quarterly reports on Form 10-Q, and current reports on Form 8-K. These filings are available for review through the SEC's website at www.sec.gov. Any or all forward-looking statements Plus Therapeutics makes may turn out to be wrong and can be affected by inaccurate assumptions Plus Therapeutics might make or by known or unknown risks, uncertainties, and other factors, including those identified in this press release. Accordingly, you should not place undue reliance on the forward-looking statements made in this press release, which speak only as of its date. The Company assumes no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made unless the Company has an obligation under U.S. federal securities laws to do so.

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[1] The Company has derived this number based on published CNS cancer incidence data, third-party projections of test utilization, and established market benchmarks.