Plus Therapeutics Announces Successful Accreditation and Certification for Its CNSide® Diagnostics Clinical Laboratory

September 18, 2025

Certification critical to broad U.S. market release of the CNSide CSF Assay Platform

CNSide now meets key federal and state regulatory requirements, including those set by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Lab Improvement Amendments (CLIA)

HOUSTON, Texas, Sept. 18, 2025 (GLOBE NEWSWIRE) -- CNSide Diagnostics, LLC, a wholly-owned subsidiary of Plus Therapeutics, Inc. (Nasdaq: PSTV) ("Plus" or the "Company"), a clinical-stage pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system (CNS) cancers, announces that it has received a certificate of accreditation from CMS for its lab located in Houston, Texas. Following the recent planned laboratory audit, successful certificate of accreditation deems the lab compliant with Clinical Laboratory Improvement Amendments (CLIA) regulations enforced by the Centers for Medicare & Medicaid Services (CMS), which are federal standards for laboratories performing testing on human specimens.

"This is a key milestone on our trajectory to bring the CNSide cerebrospinal fluid (CSF) assay platform to the broadest possible set of patients with or at risk for CNS cancers and simultaneously underscores our commitment to the highest quality standards," said Russ Bradley, CNSide Diagnostics, LLC President and General Manager. "Furthermore, accreditation is the latest tangible accomplishment in our U.S. market access and launch strategy."

The certification ensures laboratories meet all requirements for proficiency testing, personnel qualifications, and quality control. Furthermore, achievement of this milestone is necessary to achieve a number of additional milestones such as:

- **Obtaining state licensure in 48 of 50 states**
- **Ensuring broad-based commercial insurance coverage:** Lab accreditation is necessary to secure reimbursement for patient testing from the broadest possible set of private payors
- **Accessing government payor coverage:** Lab accreditation is a mandatory requirement for labs to enroll in Medicare and Medicaid programs and receive payments for testing services
- **Expanding payment coding**: Lab accreditation is a necessary step for broad pursuit and registration of unique reimbursement billing codes

About CNSide Diagnostics, 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 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.

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