Plus Therapeutics Announces Read Out of Type B Meeting with the FDA with Goal of Accelerating Approval of REYOBIQ™ for Leptomeningeal Metastases

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On track to define optimal dosing interval and advance manufacturing scale up of REYOBIQ for pivotal trial readiness in late 2026

HOUSTON, Jan. 08, 2026 (GLOBE NEWSWIRE) -- Plus Therapeutics, Inc. (Nasdaq: PSTV) ("Plus" or the "Company"), a healthcare company developing and commercializing precision diagnostics and radiopharmaceuticals for central nervous system (CNS) cancers, announces the completion of a Type B meeting with the U.S. Food and Drug Administration (FDA) on next steps on REYOBIQ pivotal trial strategy for leptomeningeal metastases (LM). The meeting resulted in constructive discussion with the FDA regarding key elements of the potential pivotal study design for REYOBIQ in LM. Plus intends to incorporate the FDA's feedback in the current dose optimization trial and seek alignment with the FDA on a revised protocol, likely later this year. The company's goal is to be ready for a potential pivotal trial following completion of the current dose optimization trial and, ultimately, work towards the potential approval of REYOBIQ for patients affected by LM.

Highlights of FDA responses to the Company's key enquiries:

- Accelerated approval – FDA indicated that accelerated approval may be appropriate for the LM indication, but there are insufficient data to support the use of circulating tumor cells (CTCs) as an intermediate clinical endpoint. FDA and Plus discussed that additional steps would be necessary to validate CTCs as a surrogate endpoint to potentially support other future applications.
- Primary and key endpoints – FDA recommended that the study evaluate an endpoint with established clinical benefit, such as overall survival, while encouraging further study of patient reported outcomes and neurologic function as endpoints that could potentially support a marketing application. FDA and Plus aligned that CTCs could be considered for use as a secondary endpoint.
- Trial design and comparator group - FDA and Plus discussed a randomized controlled trial design approach and that the study may include an intrathecal chemotherapeutic as a comparator, as well as approaches to standardize the comparator and any additional interventions available under the trial protocol.
- Treated populations - FDA conveyed it may be reasonable to incorporate multiple histologies (i.e., multiple underlying disease etiologies) in a single trial.

"Our recent FDA end of phase meeting was constructive, and we hope will help us speed up our clinical development timelines and facilitate faster submission of an application for the approval of REYOBIQ for patients with LM," said Dr. Marc H. Hedrick, President & Chief Executive of Plus Therapeutics. "As there are no approved drugs for LM, this discussion with the FDA early in clinical development will allow us to make relevant amendments to our current trial protocol and to begin meaningful planning for an anticipated pivotal trial. Furthermore, based in part on this meeting, we will plan to accelerate REYOBIQ commercial manufacturing and scale-up activities to meet an expedited timeline."

About LM
Leptomeningeal metastases (LM) are a rare but severe complication of advanced cancer, affecting the fluid-lined structures of the central nervous system. LM occurs in approximately 5% of patients with metastatic cancer, with breast cancer, lung cancer, and melanoma being the most common sources. Median survival is typically 2-6 months, and effective treatment options are limited, highlighting the urgent need for novel therapies.

About REYOBIQ™ (rhenium Re186 obisbemeda)
REYOBIQ (rhenium Re186 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, leptomeningeal metastases, and pediatric brain cancer in the ReSPECT-GBM, ReSPECT-LM, and ReSPECT-PBC 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 ReSPECT-PBC 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 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 of the cerebrospinal fluid that informs and improves the management of patients with leptomeningeal metastases. For more information, visit https://www.cnside-dx.com/.

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 the potential study design for REYOBIQ in LM and the Company's plans to plan to accelerate REYOBIQ commercial manufacturing, among others. 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.

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; 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 position 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 the Company; 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. The Company discusses some of these matters more fully, as well as certain risk factors that could affect its business, financial condition, results of operations, and prospects, in its reports filed with the SEC, including its 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 the Company makes may turn out to be wrong and can be affected by inaccurate assumptions it 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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