



Plus Therapeutics Announces Completion of U.S. FDA Meeting on Future Clinical Development Plans for REYOBIQ™ in Leptomeningeal Metastases

November 24, 2025

HOUSTON, Nov. 24, 2025 (GLOBE NEWSWIRE) -- [Plus Therapeutics, Inc.](https://www.plustherapeutics.com) (Nasdaq: [PSTV](https://www.plustherapeutics.com)) (the "Company"), a healthcare company developing and commercializing precision diagnostics and radiopharmaceuticals for central nervous system (CNS) cancers, announced it has completed a Type B meeting with the U.S. Food and Drug Administration (FDA) on November 7th to discuss its REYOBIQ clinical development plans for leptomeningeal metastases (LM) including the design of a planned pivotal or registrational trial.

"Our recent FDA meeting was very constructive, building on multiple previous positive meetings with the FDA on the clinical development and manufacturing of Reyobiq for CNS cancers," said Dr. Marc H. Hedrick, President & Chief Executive of Plus Therapeutics. "Following receipt of the FDA meeting minutes, the Company expects to provide an update and guidance on next steps early in 2026. We also will implement certain focused amendments to our LM trial that should help advance the overall clinical development timeline in alignment with the FDA recommendations."

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 obisbameda)

REYOBIQ (rhenium Re186 obisbameda) 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 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 of the cerebrospinal fluid that informs and improves 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.

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.

Investor Contact

CORE IR

investor@plustherapeutics.com