Plus Therapeutics Announces Initial Patients Successfully Treated in ReSPECT-LM Dose Optimization Trial for REYOBIQ™ in Leptomeningeal Metastases

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Substantial clinical need expected to facilitate rapid overall trial enrollment

HOUSTON, July 08, 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, today announced the treatment of its initial patients in the Company's ReSPECT-LM dose optimization trial for REYOBIQ ™ (rhenium Re^{186} obisbemeda) for the treatment of leptomeningeal metastases (LM). The dose optimization trial builds on promising results from the Company's completed Phase 1 single-dose escalation study, which demonstrated the feasibility of REYOBIQ for treating LM. The trial is designed in alignment with the FDA's Project Optimus to identify the optimal dosing regimen that maximizes efficacy and safety.

"Based on the promising, recently completed Phase 1 single-dose escalation study and lack of FDA approved therapies for LM, we expect trial enrollment to proceed rapidly in accordance with the trial protocol," said Andrew Brenner, M.D., Ph.D., Professor-Research, Departments of Medicine, Neurology, and Neurosurgery & S & B Kolitz/CTRC-Zachry Endowed Chair Neuro-Oncology Research, Mays Cancer Center at UT Health San Antonio. "Furthermore, assuming REYOBIQ continues its attractive safety profile, we expect that we will enroll all required patients and doses in Cohort 1 by the end of this year."

Patients and family members interested in enrolling in the ReSPECT-LM Dose Optimization Trial can learn more here.

ReSPECT-LM Dose Optimization Trial
The study aims to optimize treatment dosing for maximum efficacy and safety, with the primary objectives of determining the safety and tolerability of multiple REYOBIQ doses administered via intraventricular catheter at defined intervals in patients with LM from any primary solid tumor cancer, and to identify both the maximum tolerated dose and minimum effective dose. Previously announced details of the study, including primary, secondary, and exploratory endpoints, can be found here.

The dose optimization study builds on encouraging results from the Company's previously announced Phase 1 trial, which showed a single dose of REYOBIQ delivered up to an average absorbed dose of >250 Gy to the cranial subarachnoid space. It also demonstrated that 5 of 7 patients achieving an over 80% reduction in LM tumor cells in the cerebrospinal fluid survived at least one year post-treatment. Additional details can be found here.

The Company anticipates presenting these data and additional information from the completed single-dose escalation trial at the upcoming SNO/ASCO CNS Metastases Conference on August 14-16, 2025, in Baltimore, MD. The company will also request an End of Phase 1 Type B meeting with the FDA to align on the clinical development plan and the design of a potential registrational trial.

The ReSPECT-LM dose optimization trial benefits from a $17.6 million grant from the Cancer Prevention & Research Institute of Texas (CPRIT), the second largest public funding source for cancer research in the world.

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 Re^{186} obisbemeda)
REYOBIQ (rhenium Re^{186} 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 Cancer Prevention & Research Institute of Texas (CPRIT)
The Cancer Prevention & Research Institute of Texas (CPRIT) is a $6 billion cancer research and prevention initiative legislated in Texas. CPRIT accepts applications and award grants for a wide variety of innovative cancer-related research and product development and for the delivery of evidence-based cancer prevention programs and services by public and private entities located in Texas. CPRIT is the largest state cancer research investment in the history of the United States and the second largest cancer research and prevention program in the world with a three-part mission, established by the Texas Legislature, to invest in the research prowess of Texas universities and research organizations; create and expand life science infrastructure across the state; and expedite innovation in research and enhance the potential of breakthroughs in prevention and cures.

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), recurrent glioblastoma (GBM), and pediatric brain cancer (PBC). 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://plustherapeutics.com/ or contact info@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 statements regarding the potential promise of REYOBIQ™, expectations as to the Company's future performance, including the next steps in developing the Company's product candidates; the Company's clinical trials, including statements regarding the timing and characteristics of the ReSPECT-LM single dose and multi-dose clinical trials. 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; 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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