Plus Therapeutics Advances Lead Drug Rhenium (186Re) Obisbemeda for Patients with Leptomeningeal Metastases

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ReSPECT- LM Phase 1 single dose is now complete, and the recommended Phase 2 dose (RP2D) for single administration therapy has been determined

AUSTIN, Texas, Feb. 26, 2025 (GLOBE NEWSWIRE) -- Plus Therapeutics, Inc. (Nasdaq: PSTV) (the “Company” or “Plus Therapeutics”), a clinical-stage pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system (CNS) cancers, today announced the completion of the ReSPECT-LM Phase 1 single-dose escalation trial, having determined an RP2D.

The ReSPECT-LM single-dose escalation trial assessed the safety, tolerability, and potential efficacy of intrathecally administered Rhenium (^{186}Re) Obisbemeda in patients with leptomeningeal metastases (LM). Enrollment in Cohort 6 was recently completed (75.0 mCi). The Cohort 4 dose (44.1 mCi) was determined to be the RP2D; no dose-limiting toxicities were observed at this dose level. One patient at the Cohort 4 dose was observed to have achieved a complete response, as evidenced by the eradication of tumor cells in the cerebrospinal fluid—a key therapeutic endpoint.

"With the RP2D established, we are advancing both a single dose-expansion Phase 2 trial and a multiple-dose Phase 1 trial of 44.1 mCi fractionated into three doses to further assess safety and efficacy," said Marc H. Hedrick, M.D., Plus Therapeutics President and Chief Executive Officer. "We remain on track to complete enrollment in both trials this year and are simultaneously engaging the U.S. Food & Drug Administration to define the optimal pivotal trial pathway."

Additional details on the ReSPECT-LM trial can be found here.

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 Plus Therapeutics
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 for patients. Combining image-guided local beta radiation and targeted drug delivery approaches, the Company is advancing a pipeline of product candidates with lead programs in recurrent glioblastoma (GBM) and LM. The Company has built a supply chain through strategic partnerships that enable the development, manufacturing and future potential commercialization of its products. Plus Therapeutics is led by an experienced and dedicated leadership team and has operations in key cancer clinical development hubs, including Austin and San Antonio, Texas. For more information, visit https://plustherapeutics.com/.

Cautionary Statement Regarding 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 under the heading Upcoming Events and Expected Milestones, and statements regarding the following: the potential promise of rhenium (^{186}Re) obisbemeda; 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; the continued evaluation of rhenium (^{186}Re) obisbemeda including through evaluations in additional patient cohorts.

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 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, including the ability of the Company to come into compliance with The Nasdaq Capital Market listing requirements; 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, 2023, 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
Charles Y. Huang, MBA
Director of Capital Markets and Investor Relations
Office: (202)-209-5751 | Direct (301)-728-7222
chuang@plustherapeutics.com