Plus Therapeutics Granted U.S. FDA Orphan Drug Designation for Rhenium (186Re) Obisbemeda for the Treatment of Leptomeningeal Metastases in Patients with Lung Cancer

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HOUSTON, March 06, 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 cancers, today announces that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to Rhenium (^{186}Re) Obisbemeda for the treatment of leptomeningeal metastases (LM) in patients with lung cancer.

"Receiving Orphan Drug Designation for Rhenium (^{186}Re) Obisbemeda marks a significant milestone in our efforts to develop a much-needed therapy for lung cancer patients with leptomeningeal metastases," said Mike Rosol, Ph.D., Plus Therapeutics Chief Development Officer. "These patients currently have limited treatment options, and the growing incidence of LM in lung cancer underscores the urgency for new therapies. This designation, in combination with our previously granted Fast Track designation, strengthens our pathway toward delivering an innovative, targeted radiotherapeutic solution for this highly underserved patient population."

The FDA grants ODD status to an investigational drug or biologic intended to prevent, diagnose, or treat a rare disease or condition affecting fewer than 200,000 people in the United States. ODD provides certain benefits to drug developers, including seven potential years of market exclusivity, tax credits for qualified clinical trials, and exemptions from significant regulatory fees, including the Prescription Drug User Fee Act (PDUFA) charge of $4.3 million in 2025 and the Pediatric Research Equity Act (PREA) requirements.

This milestone follows the recent completion of the ReSPECT-LM Phase 1 single-dose trial, which established the recommended Phase 2 dose (RP2D). The Company is now advancing a Phase 2 single-dose expansion trial and a Phase 1 multiple-dose trial while actively engaging the FDA to define the optimal pivotal trial strategy.

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 Rhenium (^{186}Re) obisbemeda

Rhenium (^{186}Re) obisbemeda is a novel injectable radiotherapy specifically formulated to deliver highly targeted high dose radiation in CNS tumors in a safe, effective and convenient manner to optimize patient outcomes. Rhenium (^{186}Re) obisbemeda has the potential to reduce 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 live imaging. Rhenium (^{186}Re) obisbemeda is being evaluated for the treatment of recurrent glioblastoma and leptomeningeal metastases in the ReSPECT-GBM and ReSPECT-LM 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).

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 "potential," "believe," and similar expressions. 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 relating to the significance of the FDA ODD grant to the advancement of Rhenium (^{186}Re) Obisbemeda as potential treatment of patients who suffer from LM from breast and lung cancer patients; statements regarding the potential promise of rhenium (^{186}Re) obisbemeda, including the next steps in developing the Company's product candidates; and, the Company's clinical trials, including statements regarding the Company's engagement with the FDA with respect to the possibility of defining a pivotal trial strategy for certain of the

Company's clinical trials.

Results or events in future periods 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.

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