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

November 3, 2023

AUSTIN, Texas, Nov. 03, 2023 (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 cancers, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to rhenium (^{186}Re) obisbemeda for the treatment of breast cancer with leptomeningeal metastases (LM).

ODD status is granted by the FDA to an investigational drug or biological product intended to prevent, diagnose or treat a rare diseases or condition affecting fewer than 200,000 people in the United States. Companies granted ODD are eligible for certain benefits, including assistance in the drug development process, tax credits for clinical costs, exemptions from certain FDA fees and 7 years of post-approval marketing exclusivity.

"Receiving Orphan Drug Designation from the FDA is important validation of our radiotherapeutic candidate for breast cancer patients with LM who currently have no FDA-approved treatment options," said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. "LM is a rapidly progressing and fatal complication of several cancers, including breast cancer, and incidence continues to rise. ODD status, together with the previously granted Fast Track designation, underscores the significant and urgent need for new treatment options for LM. We believe rhenium (^{186}Re) obisbemeda has the potential to address this unmet need, and we look forward to continued progress of our ReSPECT-LM program."

Rhenium (^{186}Re) obisbemeda is currently being evaluated in the ReSPECT-LM Phase 1/2a dose escalation clinical trial. Cohort 4 of the ReSPECT-LM trial recently completed enrollment, and the Company anticipates moving into Cohort 5 following standard safety review. Updates on the ReSPECT-LM trial will be presented at the Society for Neuro-Oncology Annual Meeting November 15-19, 2023. In addition to ODD, the FDA previously granted rhenium (^{186}Re) obisbemeda Fast Track designation for the treatment of LM.

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 leptomeningeal metastases (LM). The Company has built a robust 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. 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 "designed to," "will," "can," "potential," "focus," "preparing," "next steps," "possibly," 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 regarding the following: the Company's proposed share repurchase program; expectations as to the Company's future performance including the next steps in developing the Company's current assets; the Company's clinical development plan and trials; and the intended functions of the Company's platform and expected benefits from such functions.

The forward-looking statements included in this press release are subject to a number of risks and uncertainties that may cause actual results to differ materially from those discussed in such forward-looking statements. These risks and uncertainties include, but are not limited to: the Company's actual results may differ, including materially, from those anticipated in these forward-looking statements as a result of various factors, including, but 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; restrictions under the Company's debt facility; the inability to repurchase shares, or a decision not to repurchase shares; future changes in strategic direction; unexpected expenses; 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, among others; and additional risks described under the heading "Risk Factors" in the Company's Securities and Exchange Commission filings, including in the Company's annual and quarterly reports. There may be events in the future that the Company is unable to predict, or over which it has no control, and its business, financial condition, results of operations and prospects may change in the future. 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
Corey Davis, Ph.D.
LifeSci Advisors
(212) 215-2577
cdavis@lifesciadvisors.com