Plus Therapeutics Initiates Part B of ReSPECT-LM Phase 1/2a Trial for Leptomeningeal Metastase

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AUSTIN, Texas, Sept. 05, 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 treatment of the first patient in Part B (Cohort 4) of the ReSPECT-LM Phase 1/2a dose escalation clinical trial of rhenium (^{186}Re) obisbemeda for the treatment of leptomeningeal metastases (LM) from solid tumors.

"The Phase 1/Part A data in the ReSPECT-LM clinical trial is encouraging," said Norman LaFrance M.D., Chief Medical Officer of Plus Therapeutics. "In Phase 1/Part B, we plan to dose escalate to the maximum tolerated single dose while simultaneously collaborating with the U.S. Food and Drug Administration (FDA) to implement multiple dosing into the trial."

The maximum total radiation activity administered in Phase 1/Part A was 26.4 millicuries (mCi). In Phase 1/Part B the maximum administered total radiation activity will be 110.0 mCi in cohort 7.

Positive data from Part A (Cohorts 1-3) of the ReSPECT-LM clinical study evaluating the Company's lead radiotherapeutic, rhenium (^{186}Re) obisbemeda, for the treatment of LM were presented at the Society for Neuro Oncology (SNO)/American Society of Clinical Oncology (ASCO) Central Nervous System (CNS) Cancer Conference in August 2023. In summary, the findings in the Phase 1/Part A showed:

- Ten patients were treated with a maximum absorbed dose of 85 Gray (Gy) and up to 26.4 mCi of radiation activity.
- No dose limiting toxicities have been observed and a maximum tolerated dose or maximum feasible dose has not been reached in Part A.
- Cerebrospinal fluid (CSF) tumor cell counts, evaluated using a molecular diagnostic assay, decreased an average of 53% measured at 28 days post-treatment.
- In addition, five of the 10 treated patients in Part A remain alive with a median overall survival of 10 months.

The FDA has granted Fast Track designation to rhenium (^{186}Re) obisbemeda for the treatment of LM. The ReSPECT-LM clinical trial is funded, in part, by a 3-year, $17.6 million grant by the Cancer Prevention & Research Institute of Texas.

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 directly deliver targeted high-dose radiation in CNS tumors in a safe, effective, and convenient administration. 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 real-time 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 potential promise of ^{186}Re including the ability of ^{186}Re to safely and effectively deliver radiation directly to the tumor at high doses; expectations as to the Company's future performance including the next steps in

developing the Company's current assets; the Company's clinical trials including statements regarding the timing and characteristics of the ReSPECT-GBM and ReSPECT-LM clinical trials; possible negative effects of ^{186}Re; the continued evaluation of ^{186}Re including through evaluations in additional patient cohorts; 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, 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, 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.

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