Plus Therapeutics Reports ReSPECT-LM Phase 1 Trial Data at the 2023 SNO/ASCO CNS Cancer Conference

August 11, 2023

Dose escalation trial demonstrates preliminary safety and efficacy results including median overall survival of 10 months for patients with leptomeningeal metastases

FDA approves continuation to Phase 1 Part B of the ReSPECT-LM clinical trial

Leading academic neuro-oncologists, radiotherapeutic analyst, and CEO to discuss data today at 8:00 a.m. ET

AUSTIN, Texas, Aug. 11, 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 reported positive data from the ReSPECT-LM clinical study evaluating the Company's lead radiotherapeutic, rhenium (^{186}Re) obisbemeda, for the treatment of leptomeningeal metastases (LM) at the Society for Neuro Oncology (SNO)/American Society of Clinical Oncology (ASCO) Central Nervous System (CNS) Cancer Conference taking place August 10-12, 2023 in San Francisco, California.

"We are very encouraged by the initial safety and survival data in the ReSPECT-LM clinical trial following a single administration of a relatively low dose of rhenium (^{186}Re) obisbemeda," said Andrew J. Brenner, M.D., Ph.D., Professor of Medicine, Neurology, and Neurosurgery at The University of Texas Health Science Center at San Antonio and principal investigator of the ReSPECT-LM clinical trial. "Based on the Phase 1 Part A data, we believe we can substantially dose escalate and develop a multiple dosing regimen that could yield meaningful clinical benefits including a survival benefit for the extremely tough clinical problem of leptomeningeal metastases."

"Our principal corporate goal is to dramatically improve the health and length of life of patients that have the most lethal CNS cancers," said Marc H. Hedrick, M.D., M.B.A., President and Chief Executive Officer of Plus Therapeutics. "Similar to our promising Phase 1 and 2 data for glioblastoma, this most recent data indicates that LM, which is ten times more common than glioblastoma, may be similarly addressable with targeted radiotherapy using rhenium (^{186}Re) obisbemeda."

The poster presentation is titled, **Preliminary Clinical Data in the Phase 1/2a Dose Escalation Trial of Rhenium (^{186}Re) Obisbemeda (^{186}RNL) in Leptomeningeal Metastases (LM): The ReSPECT-LM Trial** [LMAP-21].

Findings in Brief:

- **Feasibility:** Ten treated patients received a single escalating dose (6.6-26.4 mCi by intraventricular catheter or Ommaya reservoir) of rhenium (^{186}Re) obisbemeda, which circulated throughout the cerebrospinal fluid (CSF) space within minutes following administration and had durable CSF retention for at least 7 days.
- **Safety:** No dose limiting toxicities were observed and a maximum tolerated dose or maximum feasible dose was not reached. Most adverse events were mild (Grade 1, 58.7%) or moderate (Grade 2, 24%), with the majority not related to treatment.
- **Survival:** Currently, 5 of the 10 treated patients remain alive with a median overall survival (OS) of 10 months.
- **Next Steps:** U.S. Food and Drug Administration (FDA) has approved continued dose escalation.

Additional Findings:

- CSF tumor cell counts decreased from pre-dose levels 28 days after treatment by up to 91% (mean decrease = 53%).
- Increases in administered dose correlated with linear increases in absorbed dose to the target tissue.
- Non-CNS organ dosimetry analysis of rhenium (^{186}Re) obisbemeda confirmed these radiation levels were low, with the spleen, liver, and bladder having the most prominent rhenium (^{186}Re) obisbemeda clearance, but still significantly below critical organ toxicity levels.

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.

Key Opinion Leader Roundtable on Data Presented at the 2023 SNO/ASCO CNS Cancer Conference - Webcast Details

A key opinion leader roundtable discussion will be held on Friday, August 11, 2023, at 8:00 a.m. ET to discuss the data from the ReSPECT-LM clinical trial of rhenium (^{186}Re) obisbemeda presented at the SNO/ASCO CNS Cancer Conference. The webinar will feature a comprehensive discussion about the ongoing ReSPECT-LM Phase 1/2a dose escalation clinical trial, including key safety, tolerability, dosing, feasibility, and efficacy data.

A webinar with accompanying slides will be available in the Events page of the Investor Relations section of the Plus Therapeutics website beginning Friday, August 11, 2023 at 8:00 a.m. ET. The webcast will be available on the Company's website for 90 days following the live call.

Copies of the presentations will be made available under the Presentations tab of the Investors section of the Company's website following the meeting at https://ir.plustherapeutics.com.

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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