



Plus Therapeutics Completes Dosing in Cohort 5 of ReSPECT-LM Phase 1 Trial of Rhenium (^{186}Re) Obisbameda in Leptomeningeal Metastases

March 11, 2024

A total of 18 patients have been dosed in the trial to date

Company anticipates moving into Cohort 6 in Q2 2024 following standard safety review

AUSTIN, Texas, March 11, 2024 (GLOBE NEWSWIRE) -- [Plus Therapeutics, Inc.](https://www.plustherapeutics.com) (Nasdaq: [PSTV](https://www.plustherapeutics.com)) (the "Company"), a clinical-stage pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system (CNS) cancers, today announced it has completed dosing in Cohort 5 of the ReSPECT-LM Phase 1 dose escalation clinical trial of rhenium (^{186}Re) obisbameda for the treatment of leptomeningeal metastases (LM) from solid tumors.

Three patients were dosed as part of Cohort 5, bringing the total to 18 patients dosed in the ReSPECT-LM trial to date. There have been no dose limiting toxicities observed to date with administered radiation doses up to 66.14 millicuries in Cohort 5, a ten-fold increase over Cohort 1. The Company plans to initiate dosing in Cohort 6 in the second quarter of 2024, pending Data Safety Monitoring Board (DSMB) approval. In addition, five new clinical trial sites were added to this trial over the last year, bringing the total number of sites to seven. The Company anticipates that this will allow for continued maximal enrollment allowed under the protocol.

The FDA has granted Fast Track designation to rhenium (^{186}Re) obisbameda for LM and Orphan Drug Designation for the treatment of breast cancer with LM, and the ReSPECT-LM program continues to be funded in part by a 3-year \$17.6M grant from the Cancer Prevention & Research Institute of Texas (CPRIT). Patients interested in learning more about the ReSPECT-LM trial can visit [ClinicalTrials.gov](https://clinicaltrials.gov) ([NCT05034497](https://clinicaltrials.gov/ct2/show/study/NCT05034497)).

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) obisbameda

Rhenium (^{186}Re) obisbameda is a novel injectable radiotherapy specifically formulated to deliver direct targeted high dose radiation in CNS tumors in a safe, effective, and convenient manner to optimize patient outcomes. Rhenium (^{186}Re) obisbameda has the potential to reduce off target 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) obisbameda 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 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," "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 regarding the following: the potential promise of rhenium (^{186}Re) obisbameda including the ability of rhenium (^{186}Re) obisbameda 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, ReSPECT-LM and ReSPECT-PBC and increase of ten o, clinical trials; possible negative effects of rhenium (^{186}Re) obisbameda; the continued evaluation of rhenium (^{186}Re) obisbameda 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 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, 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, 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

Corey Davis, Ph.D.

LifeSci Advisors

(212) 215-2577

cdavis@lifesciadvisors.com