



## Plus Therapeutics Completes Phase 1/Part A of the ReSPECT-LM Clinical Trial for Leptomeningeal Metastases

April 18, 2023

*The Company plans to meet with U.S. FDA to discuss next steps for the Phase 1/Part B trial in the third quarter of 2023*

*Expanded the number of active clinical trial sites by adding Northwestern Memorial Hospital, a world-class medical center and leader in clinical research, and the Company's first site outside of Texas*

*Data readout of Phase 1/Part A trial expected second half of 2023*

AUSTIN, Texas, April 18, 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 the completion of Cohort 3 of the ReSPECT-LM Phase 1/2a dose-escalation clinical trial of rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of leptomeningeal metastases (LM) from solid tumors less than one month since its initiation, demonstrating rapid enrollment. Additionally, the Company has expanded the number of clinical trial sites to include Northwestern Memorial Hospital in Chicago, marking the first expansion of the ReSPECT-LM trial beyond Texas. Thus far, 10 patients have been treated across three cohorts in the ReSPECT-LM Phase 1/Part A dose escalation clinical trial.

"We are excited to accelerate enrollment in our ReSPECT-LM clinical trial and look forward to working with our site partners to expand the reach of this study to new and existing patients, including our compassionate use program where we retreated a patient with LM who might benefit from this novel, well-tolerated therapy," said Norman LaFrance, M.D., Chief Medical Officer of Plus Therapeutics. "Throughout all three cohorts of this study, no dose-limiting toxicities have been observed with administered radiation doses of up to 26.4 millicuries, signaling the potential to maximize the potency of rhenium ( $^{186}\text{Re}$ ) obisbameda in order to effectively destroy tumor cells within the cerebrospinal fluid. We are preparing to reconvene with the U.S. Food and Drug Administration (FDA) to provide data from Cohorts 1 through 3 and determine next steps for Part B of the Phase 1 trial."

Previous Phase 1 data presented at the Society for Neuro-Oncology Annual Meeting in November 2022 has shown that a single administered dose of rhenium ( $^{186}\text{Re}$ ) obisbameda was feasible, safe, and well-tolerated. Across two dosages, the four patients from Cohorts 1 and 2 experienced a decreased cerebrospinal fluid tumor cell count of 46% to 92% by 48 hours following treatment. The Company anticipates presenting the entire Phase 1/Part A data at medical meetings in the second half of 2023.

The FDA has granted Fast Track designation to rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of LM. ReSPECT-LM is funded, in part, by a 3-year, \$17.6 million grant by the Cancer Prevention & Research Institute of Texas (CPRIT). Patients interested in learning more about the ReSPECT-LM trial can visit [ClinicalTrials.gov](#) ([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 is 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 ( $^{186}\text{Re}$ ) obisbameda

Rhenium ( $^{186}\text{Re}$ ) obisbameda 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 ( $^{186}\text{Re}$ ) obisbameda 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.

### 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  $^{186}\text{Re}$  including the ability of  $^{186}\text{Re}$  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  $^{186}\text{Re}$ ; the continued evaluation of  $^{186}\text{Re}$  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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