



Plus Therapeutics Announces Presentation of Data from the ReSPECT™-GBM Trial and Plans for Treating Pediatric Brain Cancer

August 21, 2021

Data shows that the administration of Rhenium-186 NanoLiposome (^{186}RNL) via convection enhanced delivery for recurrent glioblastoma is well tolerated at significantly higher doses of radiotherapy than with standard modalities

Company and academic collaborators outline plans for a Phase 1 dose-finding and efficacy study of ^{186}RNL for pediatric brain tumors to start by mid-2022

AUSTIN, Texas, Aug. 21, 2021 (GLOBE NEWSWIRE) -- [Plus Therapeutics, Inc.](#) (Nasdaq: [PSTV](#)) (the "Company"), a U.S. clinical-stage pharmaceutical company developing innovative, targeted radiotherapeutics for rare and difficult-to-treat cancers, today presented data from the NIH-supported ReSPECT™ Phase 1 clinical trial evaluating its lead investigational drug, Rhenium-186 NanoLiposome (^{186}RNL), in recurrent glioblastoma (GBM). Data from the trial shows that the administration of ^{186}RNL , which is designed to allow for targeted beta radiation to the tumor via convection enhanced delivery (CED) with limited exposure to surrounding tissues, was well tolerated in adult patients with recurrent GBM at significantly higher doses than with standard treatment modalities such as external beam radiation therapy (EBRT).

This data is being presented as an E-Poster video entitled "A two-part, Phase 1 study of Rhenium-186 NanoLiposome (^{186}RNL) delivered by convection enhanced delivery for recurrent, refractory, or progressive ependymoma and high-grade glioma (HGG) and newly diagnosed diffuse intrinsic pontine glioma (DIPG)" at the 2021 American Association of Neurological Surgeons (AANS) Annual Scientific Meeting, which is being held virtually August 21-25, 2021.

"The ReSPECT™ trial demonstrates how ^{186}RNL can deliver a very high dose of radiation directly to adult brain tumors safely, effectively and conveniently," said Michael G. DeCuypere, MD, PhD, FAANS, Northwestern University Feinberg School of Medicine, and presenter of the E-Poster. "Children with brain tumors have limited options and ^{186}RNL delivered with a minimally invasive procedure could be an important new potential option for these patients."

Additional key findings from ReSPECT™ clinical trial for adult recurrent GBM:

- The mean dose of ^{186}RNL when coverage was 75% or greater (n=10) was 392 Gy (CI 306 – 478).
- The treatment has been well tolerated, with no dose-limiting toxicity or serious adverse events observed (n=18).

"We are eager to explore the use of ^{186}RNL in children with pediatric brain tumors of various types," stated Marc Hedrick, M.D., President and Chief Executive Officer of Plus Therapeutics. "Dr. DeCuypere and the team at Lurie Children's Hospital in Chicago have been great academic partners and are uniquely positioned to bring RNL forward rapidly to treat these tough problems in children."

In addition, the Company presented plans for a proposed two-part, Phase 1 dose-finding study to be followed by an expansion cohort to explore the efficacy of ^{186}RNL in pediatric patients with brain tumors. Part one of the trial will enroll up to 18 subjects to determine the maximum feasible dose of ^{186}RNL administered by CED with the tumor diameter limited to four centimeters and a volume of 34 milliliters. While Part two of the study will independently evaluate ^{186}RNL in up to 39 patients across three different cohorts based on their specific disease diagnosis. The primary endpoint of the study will be the overall response rate, and the secondary endpoints will include progression free survival-24 and overall survival-24 or progression free survival-12 and overall survival-12 in cohort A and cohorts B and C, respectively. Patient enrollment for this study is expected to begin by mid 2022.

A copy of the presentation will be made available under the Presentations tab of the Investors section of the Company's website when presentations go live at www.plustherapeutics.com.

About Plus Therapeutics, Inc.

Plus Therapeutics (Nasdaq: PSTV) is a clinical-stage pharmaceutical company whose radiotherapeutic portfolio is concentrated on nanoliposome-encapsulated radionuclides for several cancer targets. Central to the Company's drug development is a unique nanotechnology platform designed to reformulate, deliver and commercialize multiple drugs targeting rare cancers and other diseases. The platform is designed to facilitate new delivery approaches and/or formulations of safe and effective, injectable drugs, potentially enhancing the safety, efficacy and convenience for patients and healthcare providers. More information may be found at PlusTherapeutics.com and ReSPECT-Trials.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 "will," "believe," "plan," "can," "enable," "design," "intend," "potential," "expect," "estimate," "project," "prospect," "target," "focus," "anticipate," "could," "should," 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 design and potential of the Plus Therapeutics portfolio to reformulate, deliver and commercialize multiple novel, proprietary drugs targeting rare cancers and other diseases and to facilitate new delivery approaches and/or formulations of safe and effective, injectable drugs; the potential of the Company's in-licensed portfolio of investigational drugs; the Company's intent to advance its CNS oncology portfolio through the clinical development

process; the ability of RNL to safely, effectively and conveniently deliver a very high dose of radiation directly into the brain tumor; anticipated benefits of strategic collaborations and license agreements, intellectual property, FDA approval process and government regulation; and the Company's anticipated milestones and events, including with respect to additional sites, enrollment, pivotal trial planning, IND process, and clinical phase plans for RNL, pipeline expansion through additional drug development candidates, and partnership discussions for RNL, DocePLUS and DoxoPLUS; and future development and/or expansion of its product candidates and therapies in its markets. 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 risk that the Company is not able to successfully develop product candidates that can leverage the FDA's accelerated regulatory pathways; the early stage of the Company's product candidates and therapies, the results of its research and development activities, including uncertainties relating to the clinical trials of its product candidates and therapies; the Company's history of losses; the Company's need for, and ability to raise, additional cash or obtain other sources of funding in the immediate future; the Company's ability to: (a) obtain and maintain regulatory approvals, (b) continue as a going concern, (c) remain listed on the Nasdaq Capital Market, (d) to obtain or maintain sufficient levels of reimbursement for its tests, and (d) to repay or refinance some or all of its outstanding indebtedness; the outcome of the Company's partnering/licensing efforts; market and economic conditions; the impact of the COVID-19 pandemic on the Company and the effectiveness of the efforts it has taken or may take in the future in response thereto; 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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