



Plus Therapeutics Receives FDA Fast Track Designation for ¹⁸⁶RnL Targeted Radiotherapeutic for Leptomeningeal Metastases

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AUSTIN, Texas, Nov. 09, 2021 (GLOBE NEWSWIRE) -- [Plus Therapeutics, Inc.](#) (Nasdaq: [PSTV](#)) (the "Company"), a clinical-stage pharmaceutical company developing innovative, targeted radiotherapeutics for rare and difficult-to-treat cancers, today announced that the U.S. Food and Drug Administration (FDA) has granted the Company Fast Track designation for Rhenium-186 NanoLiposome (¹⁸⁶RnL) for the treatment of leptomeningeal metastases (LM), a rare complication in which the disease spreads to the membranes (meninges) surrounding the brain and spinal cord, affecting nearly 5% of people living with cancer. The Company recently [announced](#) clearance of its Investigational New Drug (IND) application from the FDA, and expects to initiate patient accrual in the ReSPECT-LM Phase 1 dose escalation clinical trial of ¹⁸⁶RnL in the fourth quarter of 2021.

"The incidence of LM is rising and represents a rapidly progressing and fatal complication of several cancer types," said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. "Based on our clinical experience with ¹⁸⁶RnL in glioma and preclinical studies in LM models, we are optimistic that ¹⁸⁶RnL may have a therapeutic role in management of this increasingly common cancer."

Fast Track designation confers several benefits to the drug development program including 1) more frequent meetings with FDA to discuss the drug's development plan, 2) more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers, 3) eligibility for Accelerated Approval and Priority Review, if relevant criteria are met, and 4) Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

About the ReSPECT-LM Study

The ReSPECT-LM clinical trial is a multicenter, sequential cohort, open-label, single dose, dose escalation Phase 1 study. It will evaluate the maximum tolerated dose, maximum feasible dose, safety, and efficacy of a single administration of ¹⁸⁶RnL via intraventricular catheter for LM following standard surgical, radiation, and/or chemotherapy treatment. The primary endpoint of the study is the incidence and severity of adverse events/serious adverse events and dose limiting toxicities. Secondary endpoints include overall response rate, duration of response, progression free survival, and overall survival.

About Leptomeningeal Metastases (LM)

LM is a rare complication of cancer in which the disease spreads to the membranes (meninges) surrounding the brain and spinal cord. LM occurs in approximately 5% of people with cancer, or 110,000 people in the U.S. each year, and is usually terminal with a median survival of approximately 2-3 months following treatment. LM occurs with cancers that are most likely to spread to the central nervous system. The most common cancers to include the leptomeninges are breast cancer, lung cancer, and melanomas.

About Plus Therapeutics, Inc.

Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company focused on the development, manufacture, and commercialization of complex and innovative treatments for patients battling cancer and other life-threatening diseases.

Our proprietary nanotechnology platform is currently centered around the enhanced delivery of a variety of drugs using novel liposomal encapsulation technology. Liposomal encapsulation has been extensively explored and undergone significant technical and commercial advances since it was first developed. Our 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 "designed to," "will," "plan," "can," "design," "intend," "potential," "expect," "target," "focus," 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 Company's anticipated expenditures, including research and development, sales and marketing, and general and administrative expenses; anticipated benefits of strategic collaborations and license agreements, intellectual property, FDA approval process and government regulation; the ability of ¹⁸⁶RnL to safely and effectively deliver radiation directly to the tumor at high doses; the Company's ability to expand clinical testing of ¹⁸⁶RnL to additional sites and additional indications, such as leptomeningeal metastases and pediatric brain cancer; the Company's clinical trials including statements regarding the timing and characteristics of the ReSPECT-LM or the ReSPECT-PBC trials; the potential size of the market for the Company's product candidates; the Company's research and development efforts; the Company's IP strategy; competition; future development and/or expansion of its product candidates and therapies in its markets; its ability to obtain and maintain regulatory approvals including statements regarding the Company's intent to submit any new IND application; expectations as to the Company's future performance; the Company's need for additional financing and the availability thereof; its ability to fully access its equity line with Lincoln Park; any changes to its interest expenses; the Company's ability to continue as a going concern; operating results; and the potential enhancement of the Company's cash position through development, marketing, and licensing arrangements.

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 regenerative medicine 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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