



## Plus Therapeutics Announces Two Significant Milestones Toward cGMP Manufacture of its Lead Investigational Radiotherapeutic

January 4, 2022

*IsoTherapeutics Group LLC to develop and supply cGMP grade Rhenium-186 isotope for Plus Therapeutics' Rhenium-186 NanoLiposome ( <sup>186</sup>RNL) radiotherapeutic*

*Plus Therapeutics completes technology transfer of analytical test methods with Piramal Pharma Solutions for <sup>186</sup>RNL drug product intermediate*

AUSTIN, Texas, Jan. 04, 2022 (GLOBE NEWSWIRE) -- [Plus Therapeutics, Inc.](https://www.plus-therapeutics.com) (Nasdaq: [PSTV](https://www.pstv.com)) (the "Company"), a clinical-stage pharmaceutical company developing innovative, targeted radiotherapeutics for rare and difficult-to-treat cancers, today announced it has met two significant milestones as it progresses toward cGMP manufacture of Rhenium-186 NanoLiposome (<sup>186</sup>RNL).

The Company has entered into a master services agreement (MSA) with IsoTherapeutics Group LLC for the development, manufacture and supply of current Good Manufacturing Practices (cGMP) grade Rhenium-186 isotope for the Company's <sup>186</sup>RNL investigational radiotherapeutic. This agreement will help ensure Rhenium-186 meets U.S. Food and Drug Administration requirements for use in late-stage clinical trials. Under the MSA, IsoTherapeutics will develop a synthesis process and in-process manufacturing controls, test method development and validation, stability studies, as well as manufacture cGMP Rhenium-186. The Company anticipates that the MSA will lead to clinical and commercial supply agreements for the drug product with IsoTherapeutics at the appropriate stage of development. This agreement will strengthen the Company's long term cGMP supply sustainability strategy, as it will own the intellectual property rights for the manufacturing and testing of the Rhenium-186 target.

Additionally and importantly, Plus Therapeutics completed the technology transfer of analytical test methods with Piramal Pharma Solutions (PPS) for <sup>186</sup>RNL drug product intermediate. This is an important milestone as it precedes the completion of the process transfer and the manufacturing of cGMP drug product intermediate. [As previously disclosed](#), Plus Therapeutics entered into a MSA with PPS in early 2021 for the development, manufacture and supply of Plus Therapeutics' <sup>186</sup>RNL intermediate drug product.

"These are important steps towards our goal to confirm fully compliant <sup>186</sup>RNL available by mid-2022 for our ongoing clinical trials in adults with recurrent glioblastoma, leptomeningeal metastases and other life cycle management trials," said Marc Hedrick, M.D., President and Chief Executive Officer of Plus Therapeutics. "We are delighted to develop a strong, effective collaboration with IsoTherapeutics, a company with extensive capabilities in radiopharmaceuticals technology and development. Their demonstrated expertise is precisely what we are looking for in a manufacturing partner."

### **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](https://www.PlusTherapeutics.com) and [ReSPECT-Trials.com](https://www.ReSPECT-Trials.com).

### **About IsoTherapeutics Group LLC**

IsoTherapeutics Group LLC is a radiopharmaceutical company that offers technologies for developing novel diagnostic and therapeutic agents for severe diseases. ITG scientists, while previously employed at the Dow Chemical Company, developed QUADRAMET®, a radiopharmaceutical, and have received over 100 patents for developing chemistry and radiopharmaceutical formulations. For more information, please visit <http://isotherapeutics.com/about-us/>.

### **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 <sup>186</sup>RNL including the ability of <sup>186</sup>RNL 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-LM or the ReSPECT-PBC trials; possible negative effects of <sup>186</sup>RNL; the continued evaluation of <sup>186</sup>RNL including through evaluations via a seventh patient cohort; 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 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.

**Investor Contact**

Peter Vozzo  
ICR Westwicke  
(443) 377-4767  
[Peter.Vozzo@westwicke.com](mailto:Peter.Vozzo@westwicke.com)

**Media Contact**

Terri Clevenger  
ICR Westwicke  
(203) 856-4326  
[Terri.Clevenger@westwicke.com](mailto:Terri.Clevenger@westwicke.com)



Source: Plus Therapeutics Inc.