Plus Therapeutics Announces Summary of FDA Meeting on Company's cGMP Manufacturing Process for Lead Drug Candidate

August 29, 2022

cGMP production of ^{186}RNL targeted radiotherapeutic beginning in second half of 2022 to support ongoing and future ReSPECT™ clinical trials

AUSTIN, Texas, Aug. 29, 2022 (GLOBE NEWSWIRE) -- Plus Therapeutics, Inc. (Nasdaq: PSTV), a clinical-stage pharmaceutical company developing innovative, targeted radiotherapeutics for rare and difficult-to-treat cancers, announced today an update following receipt of formal minutes from a Type C meeting with the U.S. Food and Drug Administration (FDA) specific to Chemistry, Manufacturing and Controls (CMC). The meeting focused on the Company's Current Good Manufacturing Practice (cGMP) clinical and commercial manufacturing process for its lead investigational targeted radiotherapeutic, BMEDA-chelated Rhenium-186 NanoLiposome (^{186}RNL), for recurrent glioblastoma (GBM).

The FDA indicated agreement with the Company's proposed application of cGMP guidance for radiotherapeutics, small molecule drug products and liposome drug products for Plus Therapeutics' novel ^{186}RNL in support of ongoing and future glioblastoma clinical trials, manufacturing scale up and commercialization. Alignment with the FDA includes support of the Company's proposed controls and release strategy for the new drug substance and new drug product. The Company expects that this FDA feedback will apply to ^{186}RNL used in other clinical development programs, including leptomeningeal metastases and pediatric brain cancer.

"We had a constructive and detailed discussion with the FDA and obtained clarity on various key CMC requirements to mitigate the risk of future delays for potential Investigational New Drug and New Drug Applications," said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. "The Company remains on track, on time and on budget to have cGMP ^{186}RNL available in the second half of 2022 for all ongoing and planned ReSPECT™ clinical trials."

About Plus Therapeutics

Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company developing innovative, targeted radiotherapeutics for adults and children with rare and difficult-to-treat cancers. Our proprietary radiotherapeutic platform is centered around the precise delivery of powerful doses of rhenium, a beta-gamma emitting radioisotope that irradiates and kills tumor cells using novel microsphere and nanoliposome technologies. Our radiotherapeutics are designed and intended to potentially offer enhanced safety, efficacy and convenience for patients and healthcare providers. The ^{186}RNL development programs for recurrent glioblastoma and leptomeningeal metastases are supported, in part, by the U.S. National Institutes of Health (NIH) and the Cancer Prevention and Research Institute of Texas (CPRIT), respectively. 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," "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}RNL including the ability of ^{186}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-GBM, ReSPECT-LM, and ReSPECT-PBC clinical trials; possible negative effects of ^{186}RNL; the continued evaluation of ^{186}RNL 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.

Investor Contact

Peter Vozzo

ICR Westwicke

(443) 377-4767

Peter.Vozzo@westwicke.com

Media Contact

Terri Clevenger

ICR Westwicke

(203) 856-4326

Terri.Clevenger@westwicke.com