Plus Therapeutics Announces FDA Meeting Summary for Lead Drug Candidate

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NIH-funded ReSPECT-GBM Phase 2 trial to start in 2022

ReSPECT-GBM Phase 2 to focus on ^{186}RNL dose expansion, safety and efficacy data to support future registrational trial

AUSTIN, Texas, Sept. 06, 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 a summary of its Type C Clinical meeting minutes with the U.S. Food and Drug Administration (FDA) relating to its lead investigational targeted radiotherapeutic, Rhenium-186 NanoLiposome (^{186}RNL), for the treatment of patients with recurrent glioblastoma (GBM).

The FDA and Plus Therapeutics agreed that the ReSPECT-GBM clinical trial should proceed to the planned Phase 2. The key focus areas of clinical investigation of the Phase 2 trial will be: 1) further dose exploration, including both increased dosing and multiple doses, and 2) collecting additional safety and efficacy data to inform the design of the future registrational trial. Furthermore, there was agreement that in a planned future registrational trial, overall survival should be used as the primary endpoint. The Company and the FDA also agreed to hold future meeting(s) to consider the use of external data to augment the control arm in the registrational trial.

“Our first formal FDA clinical meeting after in-licensing the Rhenium NanoLiposome radiotherapeutic platform was an important milestone for us,” said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. “We received clear feedback and, as a result, we intend to begin the ReSPECT-GBM Phase 2 trial utilizing our cGMP ^{186}RNL drug, which should begin later this year. We will provide more details in our moderated oral presentation at the European Society for Medical Oncology (ESMO) Congress later this month.”

In August 2022, the Company reported FDA feedback on its Chemistry, Manufacturing and Controls (CMC) focused Type C meeting. Planned cGMP production of ^{186}RNL targeted radiotherapeutic is expected to begin in the second half of 2022 to support the ReSPECT Phase 2 clinical trial. On September 9, 2022, the ReSPECT-GBM trial principal investigator, Andrew Brenner, M.D., Ph.D., Professor of Medicine, Neurology, and Neurosurgery at The University of Texas Health Science Center at San Antonio, will provide a full update on the Phase 1 trial and discuss the clinical development overview during the ESMO Congress.

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.

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