Plus Therapeutics Announces Topline Results from Recurrent Glioblastoma External Control Analysis at ASCO 2023

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Plus Therapeutics' partnership with Medidata resulted in a valid historical control arm for the Company's Phase 1/2 clinical and potential Phase 3 trials evaluating rhenium (^{186}Re) obisbemeda in recurrent glioblastoma (rGBM)

799 control rGBM patients treated by either bevacizumab or convection enhanced delivery show median overall survival of 7.9 and 8.4 months, respectively

AUSTIN, Texas, May 30, 2023 (GLOBE NEWSWIRE) -- Plus Therapeutics, Inc. (Nasdaq: PSTV) (the "Company"), a clinical-stage pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system cancers, today announced that a new analysis from its partner Medidata, a Dassault Systèmes company, was accepted for online publication at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place June 2-6, in Chicago, Illinois.

The abstract titled, "Clinical characterization of patients with recurrent glioblastoma in trials involving CED and non-CED treatment [#417610]," included data sourced from Medidata's more than 30,000 clinical trials involving more than nine million de-identified participants. Aggregate summary statistics comparing bevacizumab and convection-enhanced delivery (CED) patients were based on combined study-level and patient-level data using sample size weighted means, incidence and overall survival.

A total of 799 patients were evaluated from MEDS and studies referenced in D'Amico [J Neurooncol 2021]. Both cohorts (bevacizumab and CED, respectively) were comparable in terms of median age (56 years vs. 55 years), Caucasian race (91% vs. 93%), male sex (68% vs. 65%) and median overall survival (7.9 months vs. 8.4 months).

"The purpose of this analysis was to determine whether bevacizumab patients could form an appropriate external control for evaluating overall survival in current and upcoming CED trials," said Norman LaFrance, M.D., Chief Medical Officer of Plus Therapeutics. "The results of this analysis provide confidence in the use of an external control arm formed from aggregated clinical trial data of patients previously treated with bevacizumab to interpret the results of the ReSPECT-GBM Phase 1/2 trials. Thus far, our clinical outcomes are promising compared to those using an external control. In a potential future pivotal trial, the use of a historical control arm will enable Plus Therapeutics to more rapidly enroll the trial while simultaneously reducing trial costs."

In April 2022, the Company entered into an expanded partnership with Medidata to utilize the Synthetic Control Arm® platform in its Phase 2 trial for rGBM, in a manner that has historically been favorably received by the U.S. Food and Drug Administration.

About the Synthetic Control Arm®
Medidata's Synthetic Control Arm (SCA) – a type of external control – is formed by carefully selecting patients from Medidata's extensive repository of historical clinical trials to match the baseline demographic and disease characteristics of the patients treated with the new investigational product. Case studies have shown that SCAs can effectively mimic a classic randomized control and, therefore, can be used to accurately interpret the treatment effects of an investigational product.

SCAs can help enhance the scientific validity of single-arm trials and, in certain indications, enhance randomized clinical trials to expose fewer prospective patients to control and/or ineffective or existing standard-of-care treatments that might not provide a benefit to the patient. This is done while still providing highly valid scientific evidence. These factors can influence a patient's willingness to participate in a trial where there is a very poor prognosis and perceived inadequate standard of care.

About Plus Therapeutics
Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company developing targeted radiotherapeutics for difficult-to-treat cancers of the central nervous system with the potential to enhance clinical outcomes for patients. Combining image-guided local beta radiation and targeted drug delivery approaches, the Company is advancing a pipeline of product candidates with lead programs in recurrent glioblastoma (GBM) and leptomeningeal metastases (LM). The Company has built a robust supply chain through strategic partnerships that enable the development, manufacturing and future potential commercialization of its products. Plus Therapeutics is led by an experienced and dedicated leadership team and has operations in key cancer clinical development hubs including Austin and San Antonio, Texas. For more information, visit https://plustherapeutics.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}Re including the ability of ^{186}Re 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 and ReSPECT-LM clinical trials; possible negative effects of ^{186}Re; the continued evaluation of ^{186}Re 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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