G1 Therapeutics Provides Initial Update on Phase 2 Bladder Cancer Trial; Progression Free Survival (PFS) Data Expected in Mid-2023

January 4, 2023

RESEARCH TRIANGLE PARK, N.C., Jan. 04, 2023 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided an initial update on PRESERVE 3, an ongoing Phase 2, randomized, open-label study of first-line platinum-based chemotherapy and maintenance therapy with the immune checkpoint inhibitor, avelumab, administered alone, or in combination with trilaciclib, in patients with untreated, locally advanced or metastatic urothelial carcinoma (mUC). Additional safety and efficacy data, including the primary endpoint of progression free survival (PFS), are anticipated in the middle of 2023.

Initial Phase 2 Results

- The confirmed objective response rate (ORR) per RECIST v1.1 was comparable between arms; ORR was 40.0% (n=18/45) and 46.7% (n=21/45) among evaluable patients in the trilaciclib and control arms, respectively. Longer-term follow-up is required to characterize additional anti-tumor endpoints including median duration of confirmed objective response and PFS, which is the primary endpoint of the study.

- Safety is reviewed by the data monitoring committee (DMC) on an ongoing basis, and it has recommended that the study continue as planned. Though early, the safety and tolerability profile of trilaciclib administered prior to chemotherapy is generally consistent with that expected in patients treated with gemcitabine plus cisplatin/carboplatin and avelumab maintenance for previously untreated advanced or metastatic urothelial carcinoma.

“The immunomodulatory mechanism of action of trilaciclib lends itself to longer term anti-tumor efficacy endpoints like PFS, as opposed to shorter term response rate endpoints, as was noted in the Phase 2 trial in triple negative breast cancer (TNBC),” said Raj Malik, M.D., Chief Medical Officer at G1 Therapeutics. “We look forward to the results of the maintenance portion of this trial, particularly given the preclinical work that we have conducted showing the potential synergy of trilaciclib with checkpoint inhibitors – which we seek to validate clinically in this study with longer term duration of response and PFS data. We would expect to present these results at a medical meeting in 2023.”

Trilaciclib, an IV-administered transient CDK4/6 inhibitor, is a first-in-class therapy designed to preserve bone marrow and immune system function during chemotherapy to improve patient outcomes. Depending on the tumor type and the chemotherapy backbone, this mechanistic profile can drive patient benefits of myeloprotection and/or anti-tumor efficacy. Its mechanism of action of improving overall immune response by improving long term immune surveillance lends itself to longer term endpoints, such as progression free survival.

Phase 2 Trial Design

In this Phase 2 randomized, open-label study, 94 patients with mUC were randomized (1:1) to receive either gemcitabine/platinum chemotherapy (induction phase) followed by avelumab (checkpoint inhibitor) maintenance therapy (maintenance phase) or trilaciclib prior to gemcitabine/platinum chemotherapy followed by trilaciclib plus avelumab maintenance therapy.

The primary endpoint is to evaluate the anti-tumor efficacy of trilaciclib when combined with platinum-based chemotherapy and the checkpoint inhibitor avelumab maintenance therapy as measured by PFS during the overall study. Key secondary endpoints include evaluation of the anti-tumor efficacy of trilaciclib as measured by ORR, duration of objective response, PFS in the maintenance period, overall survival, and probability of survival at Month 16, and evaluation of the myeloprotective effects of trilaciclib on chemotherapy-induced myelosuppression.

About Bladder Cancer
Bladder cancer is the most common malignancy involving the urinary system and is the sixth most common cancer in the United States. The American Cancer Society estimates that approximately 84,000 new cases of bladder cancer will be diagnosed in the U.S. in 2021. Approximately 2.4% of the US

population will be diagnosed with bladder cancer at some point during their lifetime; the average age at diagnosis is 73 years and it is rarely diagnosed in people less than 40 years of age. Urothelial carcinoma, also known as transitional cell carcinoma (TCC), urothelial bladder cancer, or urothelial cell carcinoma (UCC) of the urinary tract, is the most common type of bladder cancer in the U.S. and Europe, where it accounts for 90% of all bladder cancers. It also accounts for up to 15% of kidney cancers diagnosed in adults. The overall 5-year survival rate for metastatic urothelial carcinoma is approximately 5.5%, which has remained unchanged over the past 25 years.

About G1 Therapeutics

G1 Therapeutics, Inc. is a commercial-stage biopharmaceutical company focused on the development and commercialization of next generation therapies that improve the lives of those affected by cancer, including the Company's first commercial product, COSELA® (trilaciclib). G1 has a deep clinical pipeline and is executing a tumor-agnostic development plan evaluating trilaciclib in a variety of solid tumors, including colorectal, breast, lung, and bladder cancers. G1 Therapeutics is based in Research Triangle Park, N.C. For additional information, please visit www.g1therapeutics.com and follow us on Twitter @G1Therapeutics.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this press release include, but are not limited to, that immunomodulatory mechanism of action of trilaciclib lends itself to longer term endpoints, are based on the company's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause the company's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in the company's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein and include, but are not limited to, the company's dependence on the commercial success of COSELA; the development and commercialization of new drug products is highly competitive; the company's ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; the company's initial success in ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials; the inherent uncertainties associated with developing new products or technologies and operating as a development-stage company; and market conditions. Except as required by law, the company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

G1 Therapeutics Contacts:

Will Roberts
Vice President, Investor Relations & Corporate Communications
919-907-1944
wroberts@g1therapeutics.com

Rebecca Levine
Director, Corporate Communications and Public Relations
(919) 667-8711
rlevine@g1therapeutics.com

Source: G1 Therapeutics