G1 Therapeutics Initiates Randomized Double Blind Placebo Controlled Phase 2 Study of COSELA™ (trilaciclib) in Non-Small Cell Lung Cancer (PRESERVE 4)

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PRESERVE 4 Will Evaluate the Survival and Myeloprotection Benefits of COSELA in 146 Patients with Non-Small Cell Lung Cancer (NSCLC) Previously Treated with Checkpoint Inhibitors

RESEARCH TRIANGLE PARK, N.C., May 10, 2021 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced that the Company has initiated PRESERVE 4, a multicenter randomized, double blind, placebo controlled Phase 2 study of COSELA™ (trilaciclib) administered prior to docetaxel in patients with metastatic non-small cell lung cancer (NSCLC) in the 2nd and 3rd line setting who have previously been treated with a checkpoint inhibitor and chemotherapy. Anti-tumor efficacy and myeloprotection endpoints are being assessed in this study. Results of this study are expected in the first half of 2023.

“Non-small cell lung cancer is the most common type of lung cancer, accounting for nearly 85% of all diagnoses, and remains a great unmet medical need,” said Raj Malik, M.D., Chief Medical Officer at G1 Therapeutics. “Despite improvements in therapy for metastatic NSCLC, including the use of PD-1 or PD-L1 inhibitors, the majority of patients ultimately progress during or after treatment with immunotherapy and chemotherapy. In addition to the need for therapies that more effectively extend overall survival, patients treated in the metastatic setting are particularly vulnerable to chemotherapy-induced myelosuppression and health-related quality of life impacts associated with systemic chemotherapy. We are exploring both potential benefits of COSELA in PRESERVE 4.”

Patient enrollment in PRESERVE 4 is now underway. The study will enroll approximately 146 patients, who will be randomly assigned (1:1) to receive COSELA or placebo prior to docetaxel on Day 1 of each 21-day cycle. There will be 2 stratification factors for randomization: Country and Eastern Cooperative Oncology Group (ECOG) performance status. Prior treatment must include a maximum of 1 line of platinum-containing chemotherapy for recurrent/metastatic disease and a maximum of 1 line of PD-1/PD-L1 monoclonal antibody-containing regimen for recurrent/metastatic disease.

Study drugs are administered as follows: COSELA or placebo administered as a 30-minute IV infusion no more than 4 hours prior to chemotherapy on each day chemotherapy is administered, and IV docetaxel (75 mg/m^2) on Day 1. Treatment cycles will occur consecutively without interruption, except when necessary, to manage toxicities or for administrative reasons. Study drug administration will continue until disease progression per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 or clinical progression as determined by the Investigator, unacceptable toxicity, withdrawal of consent, discontinuation by Investigator, or the end of the trial, whichever occurs first. Upon discontinuation of study treatment, patients will be followed for survival.

The primary endpoint of the trial is to evaluate the anti-tumor effect of COSELA on overall survival (OS) compared to placebo. Secondary endpoints include the effect of COSELA on other anti-tumor endpoints compared to placebo, including progression-free survival (PFS), overall response rate (ORR), and duration of response (DOR); and evaluation of the multilineage myeloprotection benefit of COSELA compared to placebo. The safety and tolerability of COSELA in NSCLC will also be assessed.

About Non-Small Cell Lung Cancer
This year, an estimated 236,000 adults in the United States will be diagnosed with lung cancer; the American Cancer Society estimates that in 2020, there will be approximately 135,000 lung cancer deaths in the US alone. Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, accounting for 84% of all lung cancer diagnoses. The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma, and large cell carcinoma. These subtypes, which start from different types of lung cells are grouped together as NSCLC because their treatment and prognoses (outlook) are often similar. Other subtypes of NSCLC, such as adenosquamous carcinoma and sarcomatoid carcinoma, are much less common. Smoking causes approximately 90% of non-small cell lung cancer. For people diagnosed with localized NSCLC, the overall 5-year survival rate is 63%. For regional NSCLC, the 5-year survival rate is about 35%. When cancer has spread to distant parts of the body, called metastatic lung cancer, the 5-year survival rate is 7%.

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 COSELA 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, COSELA’s (trilaciclib) possibility to improve patient outcomes, and to determine additional clinical support for COSELA. This Phase 2 study may or may not replicate or further elucidate the survival benefit observed in our other COSELA trials. Delays in the enrollment of patients in this trial of COSELA may delay or prevent our plans, and COSELA may fail to achieve the degree of market acceptance for commercial success, and 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.

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