G1 Therapeutics Announces Initiation of New Phase 2 Trial of Trilaciclib in Combination with the Antibody-Drug Conjugate (ADC), Trodelvy® (Sacituzumab Govitecan-Hziy)

November 29, 2021

Trial Will Evaluate Anti-Tumor Efficacy and Myeloprotection Endpoints in Patients with Unresectable Locally Advanced or Metastatic Triple-Negative Breast Cancer (TNBC)

RESEARCH TRIANGLE PARK, N.C., Nov. 29, 2021 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced that the Company has initiated a Phase 2, single arm, open-label study of trilaciclib administered prior to the antibody-drug conjugate (ADC), Trodelvy® (sacituzumab govitecan-hziy) in patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC). Antitumor efficacy and myeloprotective endpoints are being assessed in this trial. Initial results of this study are expected in the second half of 2022.

“All of our clinical programs are designed to maximize the utility of trilaciclib and evaluate its ability to transform treatments for patients living with cancer, including potential synergies with newer promising agents, such as ADCs,” said Raj Malik, M.D., Chief Medical Officer at G1 Therapeutics. “We are excited to develop this combination in TNBC, an area where trilaciclib in our Phase 2 trial and Trodelvy have both shown clinically meaningful and substantial improvements in overall survival and could act synergistically to improve patient outcomes with fewer myelosuppressive side effects. We believe strongly in the clinical rationale underlying this combination and that the data generated from this study will be instructive as we contemplate combinations of trilaciclib and ADCs in other treatment settings and tumor types.”

Patient recruitment in this trial is now underway. Approximately 40 patients will be enrolled in this exploratory Phase 2, multicenter, open-label, single arm study evaluating the safety and efficacy of trilaciclib administered prior to sacituzumab govitecan-hziy in patients with unresectable, locally advanced or metastatic TNBC who received at least 2 prior treatments, at least 1 in the metastatic setting. Trilaciclib will be administered as a 30-minute IV infusion completed within 4 hours prior to the start of sacituzumab govitecan-hziy treatment on day 1 and day 8 of each 21-day cycle.

Study drug administration will continue until progressive disease per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 or clinical progression as determined by the Investigator, unacceptable toxicity, withdrawal of consent, Investigator decision, or the end of the study, whichever occurs first.

The primary objective is to evaluate the anti-tumor efficacy of trilaciclib when administered prior to sacituzumab govitecan-hziy as measured by progression-free survival (PFS). Key secondary endpoints include evaluation of the anti-tumor efficacy as measured by the objective response rate (ORR), duration of objective response (DOR), clinical benefit rate (CBR), and overall survival (OS); and evaluation of the myeloprotective effects of trilaciclib.

About Triple Negative Breast Cancer (TNBC)

According to the American Cancer Society, nearly 300,000 new cases of invasive breast cancer are diagnosed annually in the U.S. Triple-negative breast cancer makes up approximately 15-20% of such diagnosed breast cancers. TNBC is cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2 protein. Because mTNBC cells lack key growth-signaling receptors, patients do not respond well to medications that block estrogen, progesterone, or HER2 receptors. Instead, treating mTNBC typically involves chemotherapy, radiation, and surgery. TNBC is considered to be more aggressive and have a poorer prognosis than other types of breast cancer. In general, survival rates tend to be lower with mTNBC compared to other forms of breast cancer, and mTNBC is also more likely than some other types of breast cancer to return after it has been treated, especially in the first few years after treatment. It also tends to be higher grade than other types of breast cancer.

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, trilaciclib’s possibility to act synergistically to improve patient outcome and reduce myelosuppressive side effects, the stated primary and secondary endpoints may not achieve statistical significance, delays in the enrollment of patients in this trial of trilaciclib may delay or prevent our plans, 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.

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