G1 Therapeutics Announces Completion of Enrollment in Global Multi-Center Phase 3 Clinical Trial of Trilaciclib in Patients with Metastatic Colorectal Cancer

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Initial Data Expected in Early 2023 Including the Primary Endpoint of Myeloprotection

RESEARCH TRIANGLE PARK, N.C., June 13, 2022 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced that the last patient has been randomized in the Phase 3 clinical trial of trilaciclib for patients with metastatic colorectal cancer (mCRC) receiving chemotherapy (PRESERVE 1). Enrollment is complete at 326 randomized patients; the trial was over-enrolled by approximately 10 percent to compensate for potential loss to follow up at trial sites in Ukraine.

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. It is approved by the U.S. Food and Drug Administration in another indication.

"FOLFOXIRI is an important chemotherapeutic backbone for people diagnosed with CRC because it is highly efficacious and has shown a survival advantage compared to other chemotherapeutic options; however, it is also the most myelotoxic regimen, so patients may have dose delays and reductions or receive less effective chemotherapeutic regimens - both of which could impact patient outcome and survival," said Raj Malik, M.D., G1's Chief Medical Officer. "Trilaciclib may be an important addition to this regimen due to its unique ability to preferentially protect the bone marrow from chemotherapy-induced toxicities, and its potential to preserve immune system function and improve survival. Both endpoints are being assessed in PRESERVE 1. We are happy to have completed enrollment, and look forward to presenting initial data, including the primary endpoint of the trial, in the first quarter of 2023. This is a registrational trial; if the data from the primary endpoint are positive, we would work closely with the FDA to expedite our filing for regulatory approval in this indication."

Dr. Malik continued, "I'd like to thank the patients enrolled in the trial, the clinical investigators, our CRO partners, and the G1 and Simcere teams who worked tirelessly and under extraordinarily challenging conditions to advance the trial to this stage."

PRESERVE 1 is a global multi-center, randomized placebo-controlled, line extension pivotal Phase 3 trial of trilaciclib in 326 patients with metastatic CRC receiving first line trilaciclib or placebo administered prior to FOLFOXIRI (a combination of fluorouracil (5-FU), folinic acid, oxaliplatin and irinotecan) and bevacizumab. The regimen is given for two consecutive days of every 14-day cycle. Patients are receiving trilaciclib or placebo administered prior to their chemotherapy for a maximum of 12 cycles of induction followed by maintenance therapy. Treatment is administered until disease progression.

The primary endpoint is myeloprotection as measured by duration of severe neutropenia (DSN) and the occurrence of severe neutropenia (SN) during induction. Key secondary endpoints include the effects of trilaciclib on chemotherapy-induced fatigue compared with placebo and the effect of trilaciclib on progression free survival (PFS) and overall survival (OS) compared with placebo.

About Colorectal Cancer

Colorectal cancer is the third most common cancer in men and women, excluding certain skin cancers. Globally, it is the second leading cause of cancer death, with more than 1.8 million people newly diagnosed with colorectal cancer each year. In the United States, there are approximately 150,000 new cases of colorectal cancer diagnosed each year. Chemotherapy is the standard of care for colorectal cancer, and the majority of patients in the United States, Europe and Japan receive chemotherapy – commonly 5-FU-based regimens - as part of their treatment regimen.

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, those relating to the therapeutic potential of trilaciclib to preserve immune system function and improve survival of patients with metastatic colorectal cancer. Forward-looking statements 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 ability to complete clinical trials for, obtain approvals for and commercialize trilaciclib in additional indications; 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 commercial-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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