G1 Therapeutics Receives Fast Track Designation from U.S. Food and Drug Administration for COSELA™ (Trilaciclib) in Combination with Chemotherapy for the Treatment of Locally Advanced or Metastatic Triple Negative Breast Cancer

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RESEARCH TRIANGLE PARK, N.C., July 19, 2021 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to COSELA™ (trilaciclib) investigation for use in combination with chemotherapy for the treatment of locally advanced or metastatic triple negative breast cancer (TNBC). COSELA is currently being evaluated in PRESERVE 2, a pivotal Phase 3, randomized, double-blind, placebo-controlled study (NCT04799249) in patients receiving first- or second-line gemcitabine and carboplatin chemotherapy for TNBC. (press release)

Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill unmet medical needs. The purpose is to get important new drugs to the patient earlier. A drug that receives Fast Track designation may be eligible for more frequent engagements with the FDA to discuss the drug's clinical development plan, eligibility for Accelerated Approval and Priority Review, and Rolling Review in which the Company can submit completed sections of its New Drug Application (NDA) for FDA review rather than waiting until every section of the NDA is completed before the entire application can be reviewed.

"Fast Track designation underscores the urgent need for innovative drugs that can significantly improve TNBC patient outcomes," said Raj Malik, M.D., Chief Medical Officer at G1 Therapeutics. "It provides an important pathway to help expedite the development and regulatory review of COSELA in this indication. We look forward to working closely with the FDA as we advance this pivotal program in TNBC and continue to work to unlock the broader potential of this pipeline-in-a-molecule compound that we hope will help patients across multiple tumor types."

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% to 20% of such diagnosed breast cancers. TNBC is cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2 protein. Because TNBC cells lack key growth-signaling receptors, patients do not respond well to medications that block estrogen, progesterone, or HER2 receptors. Instead, treating TNBC 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 TNBC compared to other forms of breast cancer, and TNBC 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, COSELA's (trilaciclib) possibility to improve patient outcomes in this Phase 3 trial of COSELA in metastatic triple negative breast cancer and in our other investigative trials, these trials may or may not result in endpoints that achieve statistical significance, and the safety and effectiveness of COSELA in this treatment regimen and the other treatment regimens we are investigating have not been yet determined nor approved by the FDA. 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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