G1 Therapeutics to Continue Pivotal Phase 3 Trial of Trilaciclib in Metastatic Triple Negative Breast Cancer Following Interim Analysis by Independent Data Monitoring Committee

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RESEARCH TRIANGLE PARK, N.C., Feb. 12, 2024 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced that the independent Data Monitoring Committee (DMC) recommended continuation of the pivotal Phase 3 trial (PRESERVE 2), evaluating trilaciclib in combination with gemcitabine and carboplatin for the first line treatment of metastatic triple negative breast cancer (mTNBC), to the final analysis. This final analysis evaluating Overall Survival (OS) is estimated to occur in the third quarter of 2024 and will be conducted on the intent-to-treat (ITT) population. The DMC did not express any concerns regarding safety or recommend any other changes to the study. G1 remains blinded to all data as the early stopping criteria were not met during the interim analysis.

“We remain confident in the ability of trilaciclib to ultimately achieve the OS primary endpoint based on the robust survival benefit demonstrated in the prior randomized Phase 2 study, which continued to meaningfully increase over time as patients received subsequent therapies, as well as the increased statistical power for the final analysis of this pivotal study,” said Jack Bailey, Chief Executive Officer at G1 Therapeutics. “While a positive interim analysis would have enabled us to bring this therapy to patients in need sooner, we look forward to completing the study and potentially making this meaningful new treatment option available to patients with this highly aggressive form of breast cancer as early as next year.”

Trilaciclib, an IV-administered transient CDK4/6 inhibitor, is a first-in-class therapy designed to preserve bone marrow and immune system function during cytotoxic therapy to improve patient outcomes. PRESERVE 2 is a global, multi-center, randomized placebo-controlled, line extension pivotal Phase 3 trial of trilaciclib in patients with locally advanced unresectable or metastatic TNBC. Patients meeting eligibility requirements were randomized 1:1 to receive either trilaciclib or placebo administered prior to first-line gemcitabine and carboplatin (GCb). The regimen is given intravenously (IV) on Days 1 and 8 in 21-day cycles. Treatment is administered until disease progression.

About Triple Negative Breast Cancer (TNBC)
Breast cancer is the most commonly diagnosed cancer worldwide, with over 2.3 million new cases each year. 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 oncology biopharmaceutical company whose mission is to develop and deliver next-generation therapies that improve the lives of those affected by cancer, including the Company’s first commercial product, COSELA® (trilaciclib). The Company is also evaluating therapies in combination with cytotoxic therapies and/or immunotherapy in areas of high unmet need including triple-negative breast cancer and extensive stage small cell lung cancer. G1’s goal is to provide innovative therapeutic advances for people living with cancer. G1 is based in Research Triangle Park, N.C. For additional information, please visit http://www.g1therapeutics.com and follow us on X (formerly known as Twitter) @G1Therapeutics and LinkedIn.

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," “could”, “believe,” “goal”, “projections,” "estimate," "intend," “indicate,” “potential,” “opportunity,” “suggest,” 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 the survival benefit observed in the

Phase 2 trial appears to meaningfully increase over time as patients received subsequent therapies, and that completion of the trial will enable G1 to make this potentially meaningful new treatment available to patients living with mTNBC as early as next year, 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 (trilaciclib); 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 commercial-stage company; chemotherapy shortages and market conditions. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties. 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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