G1 Therapeutics Completes Enrollment in Global Multi-Center Phase 3 Clinical Trial of Trilaciclib in Patients with Metastatic Triple Negative Breast Cancer (TNBC)

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RESEARCH TRIANGLE PARK, N.C., Oct. 10, 2022 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced that the last patient has been randomized in PRESERVE 2, G1's Phase 3 clinical trial of trilaciclib in patients with metastatic triple negative breast cancer (TNBC) receiving chemotherapy. The trial includes 187 patients receiving first line trilaciclib or placebo prior to gemcitabine and carboplatin (GC).

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. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to trilaciclib investigation for use in combination with chemotherapy for the treatment of locally advanced or metastatic triple negative breast cancer (TNBC).

"TNBC tumors are aggressive and difficult to treat; and while chemotherapy with or without targeted therapy remains first line TNBC standard of care, there is a great need to improve survival beyond that expected from it – particularly without increasing toxicity," said Raj Malik, M.D., G1's Chief Medical Officer. "PRESERVE 2 is exciting as it is evaluating trilaciclib in mTNBC to build on the robust survival benefit observed in the Phase 2 program. Completion of enrollment is an important milestone for G1 and the patients we seek to treat, and we look forward to the interim analysis, which is expected to occur in the second half of 2023. This is a registrational trial for which we have been granted Fast Track designation by the U.S. Food and Drug Administration - and if the results are positive, we will work closely with the FDA to expedite our regulatory filing for 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 together to reach this enrollment milestone."

About PRESERVE 2

PRESERVE 2 is a global multi-center, randomized placebo-controlled, line extension pivotal Phase 3 trial of trilaciclib in patients with metastatic TNBC receiving first line trilaciclib or placebo administered prior to GC. The regimen is given intravenously (IV) on Days 1 and 8 in 21-day cycles. Treatment is administered until disease progression.

The primary endpoint is to evaluate the effect of trilaciclib on overall survival (OS) compared with placebo in patients receiving first-line GC. Key secondary endpoints include assessment of the effect of trilaciclib on patients' quality of life compared with placebo, myeloprotection measures, progression free survival (PFS), and overall rate of response (ORR). G1 expects the interim OS analysis to be conducted by its data monitoring committee at 70% of events in the second half of 2023. If the trial meets the interim analysis stopping rule, it will terminate, and G1 will report the topline results. If it does not, the trial will continue to the final analysis.

Fast Track Designation in TNBC

In July 2021, the Company announced that the UFDA has granted Fast Track designation to trilaciclib investigation for use in combination with chemotherapy for the treatment of locally advanced or metastatic triple negative breast cancer (TNBC). 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.

Results from Randomized Phase 2 Trial of trilaciclib in mTNBC

G1 presented Phase 2 data at the 2020 the San Antonio Breast Cancer Symposium (SABCS) showing that trilaciclib significantly improved overall

survival (OS) in patients with mTNBC treated with trilaciclib prior to administration of a chemotherapy regimen of gemcitabine/carboplatin (GC) compared with GC alone, and that trilaciclib enhanced immune system function. Patients were randomized to receive GC only (Group 1) or GC plus one of two dosing schedules of trilaciclib: trilaciclib administered on the day of chemotherapy (Group 2) or trilaciclib administered the day prior to and the day of chemotherapy (Group 3). Compared to GC alone (Group 1), statistically significant improvements in OS were achieved in both trilaciclib arms (Group 2: HR=0.31, p=0.0016; Group 3: HR=0.40, p=0.0004). As of the data cutoff of July 17, 2020, the median OS was 12.6 months in patients receiving GC alone, not yet reached for Group 2, and 17.8 months in Group 3. The median OS for Groups 2 and 3 combined was 19.8 months (HR=0.37, p<0.0001). Patients with both PD-L1-positive and PD-L1-negative tumors treated with trilaciclib and GC demonstrated improvement in OS compared to patients receiving GC alone, with the PD-L1-positive subset achieving statistically significant improvement. Data from T-cell clonality analysis suggest that administering trilaciclib prior to chemotherapy enhanced immune system function. (Poster here)

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.

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, improve survival of patients with triple-negative breast cancer, including the assessment of the effect of trilaciclib on patients' quality of life compared with placebo, myeloprotection measures, progression free survival, and overall rate of response, and our expectation that the interim OS analysis in PRESERVE 2 will be conducted in the second half of 2023. 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, including colorectal, breast, lung, and bladder cancers; 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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