G1 Therapeutics Presents Updated Data at ESMO 2019 from Randomized Phase 2 Trial of Trilaciclib in Combination with Chemotherapy in Metastatic Triple-Negative Breast Cancer Demonstrating Significant Improvement in Overall Survival

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-- Trial results published simultaneously in The Lancet Oncology --

-- Company also to present updated Phase 2 results demonstrating myelopreservation benefits in small cell lung cancer (SCLC) patients receiving trilaciclib and chemotherapy in combination with Tecentriq® --

-- Company to begin rolling New Drug Application (NDA) submission for SCLC in 4Q19 --

-- Company to host investor and analyst event, webcast and conference call at 12:45 p.m. ET on September 29, 2019 --

RESEARCH TRIANGLE PARK, N.C. and BARCELONA, Spain, Sept. 28, 2019 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today reported preliminary overall survival (OS) data from the company's randomized Phase 2 trial of trilaciclib in combination with chemotherapy for the treatment of metastatic triple-negative breast cancer (mTNBC). In the trial, median overall survival for patients treated with trilaciclib in combination with a chemotherapy regimen of gemcitabine/carboplatin (GC) was 20.1 months, compared with 12.6 months for patients receiving chemotherapy alone. These data were reported as part of a late-breaking oral presentation (LBA22) at the European Society for Medical Oncology (ESMO) 2019 Congress and featured in a concurrent publication in *The Lancet Oncology*.

Updated data from a separate randomized Phase 2 trial of trilaciclib in small cell lung cancer (SCLC) will be presented during a poster session (1742PD) on Sunday, September 29 at ESMO 2019 in Barcelona, Spain.

"Triple-negative breast cancer is the most aggressive form of breast cancer and tends to have a poorer prognosis than other breast cancers. We need new therapeutic approaches that improve outcomes for women diagnosed with triple-negative breast cancer," said Joyce A. O'Shaughnessy, M.D., Baylor University Medical Center, Texas Oncology, U.S. Oncology, and lead investigator for the trial. "As an oncologist specializing in triple-negative breast cancer, I am encouraged that trilaciclib has the potential to improve the survival of patients diagnosed with this disease."

"Trilaciclib is a first-in-class therapy that has improved outcomes for people with cancer being treated with chemotherapy in four randomized Phase 2 trials. The findings from these trials in small cell lung cancer and triple-negative breast cancer indicate that the clinical benefits of trilaciclib are meaningful and context-dependent," said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. "In metastatic triple-negative breast cancer, the benefit manifests as improved overall survival. In small cell lung cancer, patients experience myelopreservation benefits, including reduced rates of neutropenia, anemia and other chemotherapy-related side effects, and a corresponding decrease in the use of rescue therapies required to address those toxicities. Importantly, patient-reported outcome measures across all of our trials showed that trilaciclib improved the patient experience on chemotherapy."

Mark Velleca, M.D., Ph.D., Chief Executive Officer, added: "Based on feedback from our pre-NDA meeting with the FDA, we will begin a rolling NDA submission for small cell lung cancer in the fourth quarter of this year, which we expect to complete in the second quarter of 2020. We have also had initial discussions with the FDA regarding development of trilaciclib in triple-negative breast cancer, including the preliminary design of a Phase 3 trial. In 2020, we plan to initiate a Phase 3 trial in triple-negative breast cancer and a Phase 3 trial in colorectal cancer, with the goal of demonstrating the benefits of trilaciclib to patients receiving chemotherapy for multiple tumor types."

Overall survival benefit in mTNBC
The randomized, open-label Phase 2 study (NCT02978716) of trilaciclib in combination with GC, a current standard of care for TNBC, enrolled 102 patients who had received up to two prior chemotherapy regimens for locally recurrent or metastatic TNBC. In this three-arm trial, all three groups received a chemotherapy regimen of GC. 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). Primary endpoints for the trial included myelopreservation measures; secondary endpoints included additional myelopreservation measures and anti-tumor efficacy measures of overall response rate (ORR), progression-free survival (PFS) and OS. Myelopreservation and preliminary anti-tumor efficacy results from the trial were reported at the 2018 San Antonio Breast Cancer Symposium (press release here). Topline OS findings were announced in June 2019 (press release here); detailed OS results were reported for the first time at ESMO 2019.

Updated results from the trial showed:

- **The addition of trilaciclib to chemotherapy resulted in a significant increase in OS in both treatment groups compared to chemotherapy alone.**
    - Compared to GC alone (Group 1), OS was improved for both trilaciclib arms (Groups 2 and 3) with median OS of 12.6 months, 20.1 months and 17.8 months, respectively (Group 2: HR=0.33, p=0.0283; Group 3: HR=0.34, p=0.0023). The median OS for Groups 2 and 3 combined was 20.1 months (HR=0.36, p=0.0015). The median OS for GC alone (Group 1, 12.6 months) was consistent with historical data.

• PFS and ORR were consistent with previously reported data.
• The safety and tolerability of trilaciclib were consistent with previously reported data.

- There have been no serious adverse events attributed to treatment with trilaciclib in this trial.

• Patient-reported outcome (PRO) measures related to anemia were improved in patients receiving trilaciclib versus patients receiving chemotherapy alone.
• As previously reported, primary endpoints (myelopreservation measures) were not met.

Trilaciclib in SCLC
On Sunday, September 29, G1 Therapeutics will present updated results from its randomized, double-blind, placebo-controlled Phase 2 trial (NCT03041311) evaluating trilaciclib in extensive-stage SCLC patients receiving first-line chemotherapy and the checkpoint inhibitor Tecentriq® (atezolizumab). The findings were consistent with previously reported data (press release here):

- Trilaciclib demonstrated myelopreservation benefits, as shown by statistically significant and clinically meaningful improvement in reduction of myelosuppression endpoints, reduction of chemotherapy side effects and reduction of rescue interventions.
- Trilaciclib was well tolerated, with fewer ≥ Grade 3 adverse events (AEs) compared to placebo.
- PRO measures related to anemia were improved in patients receiving trilaciclib versus patients receiving placebo.
- Trilaciclib did not adversely impact chemotherapy anti-tumor efficacy as measured by ORR, PFS and OS.

Additionally, data from another randomized Phase 1b/2 trial of trilaciclib in patients with SCLC receiving first-line chemotherapy were recently published in *Annals of Oncology*, the official journal of ESMO. Data in this trial demonstrated the myelopreservation benefits of trilaciclib as indicated by statistically significant reduction in clinically relevant consequences of myelosuppression compared to placebo, resulting in fewer supportive care interventions and dose reductions. Trilaciclib did not adversely impact the anti-tumor efficacy of chemotherapy.

Webcast and Conference Call Details
G1 Therapeutics will host a webcast and conference call of its investor and analyst event on Sunday, September 29, 2019, at 6:45 p.m. CEST (12:45 p.m. ET) to review the data being presented at ESMO 2019, as well as long-range development plans for all three of its clinical-stage therapies and commercial plans for trilaciclib. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 5878315. A live and archived webcast will be available on the Events & Presentations page of the company's website at www.g1therapeutics.com. The webcast will be archived on the same page for 90 days following the event.

About Trilaciclib
Trilaciclib is a first-in-class investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy. Based on results from three randomized trials in patients with small cell lung cancer, trilaciclib has received Breakthrough Therapy Designation, and G1 Therapeutics expects to submit marketing applications in the U.S. and Europe for myelopreservation in small cell lung cancer in 2020. In a randomized trial of women with metastatic triple-negative breast cancer, trilaciclib improved overall survival when administered in combination with chemotherapy compared with chemotherapy alone. The company plans to initiate a Phase 3 clinical trial in triple-negative breast cancer and a Phase 3 clinical trial in colorectal cancer in 2020.

About G1 Therapeutics
G1 Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development and delivery of innovative therapies that improve the lives of those affected by cancer. The company is advancing three clinical-stage programs. Trilaciclib is a first-in-class therapy designed to improve outcomes for patients being treated with chemotherapy. Trilaciclib has received Breakthrough Therapy Designation from the FDA; a rolling NDA submission for small cell lung cancer will begin in 4Q19 and is expected to be completed in the second quarter of 2020. Lerociclib is a differentiated oral CDK4/6 inhibitor designed to enable more effective combination treatment strategies. G1T48 is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. G1 Therapeutics also has an active discovery program focused on cyclin-dependent kinase targets.

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 news release include, but are not limited to, the therapeutic potential of trilaciclib, the timing for the commencement and completion of marketing applications in the U.S. and Europe for trilaciclib in SCLC, and plans to initiate additional trials in colorectal cancer and TNBC, 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 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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