G1 Therapeutics Presents Additional Phase 2 Data on Trilaciclib in Small Cell Lung Cancer at 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

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RESEARCH TRIANGLE PARK, N.C., June 01, 2019 (GLOBE NEWSWIRE) -- ***- New patient-reported outcomes data shows trilaciclib improves chemotherapy experience for patients -***

G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today presented additional findings from a randomized Phase 2 clinical trial demonstrating the myelopreservation benefits of trilaciclib in patients undergoing chemotherapy treatment for 2nd/3rd-line small cell lung cancer (SCLC). Trilaciclib is a first-in-class myelopreservation agent designed to protect the bone marrow from damage by chemotherapy and improve patient outcomes.

The abstract titled “Trilaciclib, a CDK 4/6 inhibitor, mitigates myelosuppression in patients with previously treated extensive stage small cell lung cancer receiving topotecan” (#8505) was selected for oral presentation at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting.

In December 2018, the company announced topline data showing that SCLC patients receiving trilaciclib + topotecan (a chemotherapy agent) experienced statistically significant reductions in the duration and occurrence of Grade 4 neutropenia, and that trilaciclib treatment resulted in a reduction in the number of granulocyte colony-stimulating factor (G-CSF) administrations and red blood cell (RBC) transfusions, compared to patients receiving placebo + topotecan. Overall, patients receiving trilaciclib + topotecan showed an improved safety profile compared to those receiving placebo + topotecan.

An analysis of patient-reported outcomes (PRO) data showed clinically meaningful improvements in the treatment experience for patients receiving trilaciclib + topotecan compared to those receiving placebo + topotecan. Patients receiving trilaciclib reported significant improvements in several areas, including: general and physical wellbeing, quality-of-life (QoL) measures specific to lung cancer patients, symptoms and impact of fatigue, and symptoms and effects on physical and functional wellbeing due to anemia.

“Chemotherapy is an effective treatment option for those with cancer. As a treating physician, I regularly see how it also negatively impacts patient health and quality of life. Chemotherapy often causes bone marrow damage that can result in anemia and neutropenia, subsequently leaving patients with severe fatigue and at increased risk of infection,” said Lowell Hart, M.D., Scientific Director of Research, Florida Cancer Specialists and trilaciclib clinical trial investigator. “It was encouraging to observe that in this trial, use of trilaciclib made chemotherapy safer, reducing the rates of chemotherapy-related side effects and the use of rescue interventions commonly used to treat them. Importantly, patient-reported outcomes data showed that the myelopreservation benefits of trilaciclib improved their overall experience on chemotherapy.”

Key findings of the trial included:

- Patients receiving trilaciclib + topotecan demonstrated statistically significant reductions in both of the trial’s primary endpoints compared to patients receiving placebo + topotecan: duration of Grade 4 neutropenia in cycle 1 and occurrence of Grade 4 neutropenia.
- Trilaciclib treatment reduced the number of G-CSF administrations per cycle and the number of RBC transfusions (on/after week 5) per week compared to placebo.
- PRO data showed clinically meaningful improvements in the treatment experience of patients receiving trilaciclib + topotecan compared to those who received placebo + topotecan.
- Anti-tumor efficacy measures of overall response rate (ORR), progression-free survival (PFS) and overall survival (OS) were comparable between the trilaciclib + topotecan and placebo + topotecan arms.
- Consistent with the three other randomized Phase 2 trials, trilaciclib was well tolerated and there were fewer ≥ Grade 4 treatment emergent adverse events (TEAEs) in the trilaciclib arm compared to the placebo arm.

Following meetings with U.S and European regulatory authorities to review data from three randomized, placebo-controlled SCLC clinical trials, including data presented at the 2019 ASCO Annual Meeting, the company announced plans to submit marketing applications for trilaciclib for myelopreservation in SCLC. The company expects to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) in 2020.

About Chemotherapy and Trilaciclib
Chemotherapy is an effective and important treatment against cancer. However, chemotherapy does not differentiate between healthy cells and cancer cells, killing both, including important stem cells in the bone marrow that produce white blood cells (WBCs), RBCs and platelets. This chemotherapy-induced bone marrow damage is known as myelosuppression. When WBCs, RBCs and platelets become depleted, chemotherapy patients are at increased risk of infection, experience anemia and fatigue, and are at increased risk of bleeding. Myelosuppression often requires the administration of rescue interventions such as growth factors and blood or platelet transfusions, and may also result in chemotherapy dose delays and reductions.

Trilaciclib is a first-in-class myelopreservation agent designed to protect the bone marrow from damage by chemotherapy and improve patient outcomes. G1 expects to submit marketing applications in the U.S. and Europe for trilaciclib for myelopreservation in small cell lung cancer in 2020, and plans to initiate new label expansion trials 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 and lerociclib are designed to enable more effective combination treatment strategies and improve patient outcomes across multiple oncology indications. G1T48 is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. G1 also has an active discovery program focused on cyclin-dependent kinase targets.

G1 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, lerociclib and G1T48 and the timing for next steps with regard to the trilaciclib marketing applications, 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; the Company's development of a CDK4/6 inhibitor to reduce chemotherapy-induced myelosuppression is novel, unproven and rapidly evolving and may never lead to a marketable product; 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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