G1 Therapeutics Announces Investigator Initiated Study of Trilaciclib and Lurbinectedin in Patients with Extensive Stage Small Cell Lung Cancer

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RESEARCH TRIANGLE PARK, N.C., Oct. 26, 2022 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced that it is supporting a Phase 2 investigator initiated study (ISS) of trilaciclib and lurbinectedin in patients with extensive stage small cell lung cancer (ES-SCLC). An ISS is a study that is proposed, developed, and conducted by a qualified sponsor external to G1 Therapeutics who assumes full responsibility for the conduct of the study.

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.

“Pretreatment with trilaciclib may improve the therapeutic potential of lurbinectedin, another important medication for SCLC, in multiple ways,” said Jared Weiss, M.D., Professor of Medicine, Division of Oncology, Lineberger Comprehensive Cancer Center at the University of North Carolina Chapel Hill, NC and principal investigator in this study. “Trilaciclib is a proven myeloprotective agent, but studies to date have only assessed it in the context of topotecan-containing and platinum/etoposide-containing chemotherapeutic regimens. Lurbinectedin is effective, but also highly myelosuppressive, which is particularly problematic given recent data that clarify the importance of maintaining adequate exposure for efficacy. The opportunity for immunological synergy with lurbinectedin - which potently suppresses myeloid derived suppressor cells (MDSCs) - is also evident given data that suggest trilaciclib’s ability to induce novel T cell clonality, improve the CD8+ T cell/Treg ratio, and increase antigen expression and presentation.”

This is a prospective, non-randomized, single-arm Phase 2 study, to evaluate trilaciclib administered intravenously prior to lurbinectedin in approximately 30 subjects with platinum refractory ES-SCLC. Patients will receive trilaciclib and lurbinectedin on day one of each 21-day cycle until discontinuation or disease progression.

The primary endpoint is the rate of grade 4 neutropenia in any cycle when trilaciclib is administered prior to lurbinectedin in subjects with extensive stage small cell lung cancer (ES-SCLC). Secondary endpoints include mean duration (days) of grade 4 neutropenia in cycle 1, overall survival (OS), progression-free survival (PFS), overall rate of response (ORR), quality of life assessments, and the use of secondary/reactive supportive measures including G-CSF administration.

About Small Cell Lung Cancer
In the United States, about 29,000 cases of small cell lung cancer (SCLC) are diagnosed each year. SCLC, one of the two main types of lung cancer, accounts for about 10% to 15% of all lung cancers. SCLC is an aggressive disease and tends to grow and spread faster than NSCLC. It is usually asymptomatic; once symptoms do appear, it often indicates that the cancer has spread to other parts of the body. About 70% of people with SCLC will have cancer that has metastasized at the time they are diagnosed. The severity of symptoms usually increases with increased cancer growth and spread. From the time of diagnosis, the general 5-year survival rate for people with SCLC is 6%. The five-year survival rates for limited-stage (the cancer is confined to one side of the chest) SCLC is 12% to 15%, and for extensive stage (cancer has spread to the other lung and beyond), survival rates are less than 2%. Chemotherapy is the most common treatment for SCLC.

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 and lurbinectedin to preserve immune system function and improve survival of patients with extensive stage small cell lung cancer. 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; 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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