G1 Therapeutics and Simcere Announce Exclusive License Agreement for Trilaciclib in Greater China

August 3, 2020

- *Simcere to lead clinical development, regulatory submissions and commercialization of trilaciclib across all indications in Greater China*
- *G1 to receive $14 million upfront payment, sales royalties and up to $156 million in future milestone payments*

RESEARCH TRIANGLE PARK, N.C., U.S, and NANJING, China, Aug. 03, 2020 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, and Simcere Pharmaceutical Group, a pharmaceutical company rapidly transitioning to an innovative and R&D-driven company in China, today announced an exclusive license agreement for the development and commercialization of trilaciclib across all indications in Greater China (mainland China, Hong Kong, Macau and Taiwan). Discovered and developed by G1, trilaciclib is a first-in-class investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy.

“Trilaciclib has the potential to be the first proactively administered myelopreservation therapy that can improve outcomes for patients receiving chemotherapy. We are excited to collaborate with Simcere, an established leader in innovative drug development and commercialization in China, to advance this new therapy in China,” said Mark Velleca, M.D., Ph.D., Chief Executive Officer of G1. “Simcere has extensive experience conducting clinical trials and securing regulatory approvals in China, and an expansive commercial infrastructure that supports education and access. These strengths make them an important strategic partner for G1 to achieve our vision of bringing trilaciclib to patients around the world.”

Under the terms of the agreement, G1 will receive an upfront payment of $14 million and be eligible to receive up to $156 million in development and commercial milestone payments. Simcere will also pay G1 tiered low double-digit royalties on annual net sales of trilaciclib in Greater China. Simcere will have exclusive development and commercialization rights for trilaciclib for all indications in Greater China, and will participate in global clinical trials of trilaciclib. G1 retains development and commercialization rights to trilaciclib in all territories outside of Greater China. The companies will be responsible for all development and commercialization costs in their respective territories.

Pin Wang, Ph.D., Chief Scientific Officer of Simcere, said: “Chemotherapy is the cornerstone therapy for cancer patients. China, as a major user of this treatment modality, has a considerable patient population who are suffering from myelosuppression caused by chemotherapy. We are delighted to form this alliance with G1 Therapeutics to develop and commercialize world’s first-in-class investigational myelopreservation therapy, trilaciclib, in China. We look forward to further expanding its clinical value based on the unique mechanism of trilaciclib. It is hoped that through the joint efforts of both parties trilaciclib will soon address a key unmet medical need in the treatment of cancer patients globally.”

Lung cancer is the most common cancer worldwide, with small cell lung cancer accounting for approximately 15% of all lung cancer cases. According to the World Health Organization’s (WHO) specialized cancer agency, the International Agency for Research on Cancer (IARC), there were almost 750,000 new lung cancer cases in China in 2018.

About Trilaciclib
Trilaciclib is a first-in-class investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy. Trilaciclib has received Breakthrough Therapy Designation based on myelopreservation data from three randomized, double-blind, placebo-controlled clinical trials in which trilaciclib was administered prior to chemotherapy treatment in patient with small cell lung cancer (SCLC). 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. In June 2020, G1 submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for trilaciclib for myelopreservation in SCLC and began a study in neoadjuvant breast cancer as part of the I-SPY 2 TRIAL. The company expects to initiate a registrational Phase 3 trial in colorectal cancer in the fourth quarter of 2020.

About Simcere Pharmaceutical Group
Simcere Pharmaceutical Group is rapidly transitioning to an innovation and R&D-driven pharmaceutical company, with a mission of “providing today’s patients with medicines of the future.” Continuously recognized as one of the “Top 10 Innovative Pharmaceutical Enterprises in China” and “Top 100 Pharmaceutical Manufacturing Enterprises of China,” it has established three R&D centers in Nanjing, Shanghai and Boston (the United States), respectively; with the approval of the Ministry of Science and Technology, Simcere has also established a national key laboratory of translational medicine and innovative pharmaceuticals. Simcere focuses on oncology, central nervous system disease and autoimmune disease therapeutic areas, with a diversified product portfolio and industry-leading capabilities. Simcere has established a unique open innovation model, building up collaborative relationships with leading domestic and international pharmaceutical companies and biotechnology companies. Simcere aims to bring more global life science breakthroughs to China, in an effort to benefit more patients and boost the country’s healthcare industry growth and development.

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 FDA-designated Breakthrough Therapy designed to improve outcomes for patients being treated with chemotherapy. Rintodestrant is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. Lerociclib is a differentiated oral CDK4/6 inhibitor designed to enable more effective combination treatment strategies.

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, rintodestrant and lerociclib, the timing of marketing applications in the U.S. and Europe for trilaciclib in SCLC, trilaciclib's possibility to improve patient outcomes across multiple indications, rintodestrant's potential to be best-in-class oral SERD, lerociclib's differentiated safety and tolerability profile over other marketed CDK4/6 inhibitors and the impact of pandemics such as COVID-19 (coronavirus), and are based on G1 Therapeutics' 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 G1 Therapeutics' actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in G1 Therapeutics' filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein and include, but are not limited to, G1 Therapeutics' ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; G1 Therapeutics' 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, G1 Therapeutics and Simcere Pharmaceutical Group assume 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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