G1 Therapeutics and Boehringer Ingelheim Announce Co-Promotion Agreement for Trilaciclib in Small Cell Lung Cancer in the United States and Puerto Rico

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- Partnership leverages Boehringer Ingelheim's oncology expertise to lead trilaciclib SCLC launch sales engagements
- G1 to retain full development and commercialization rights and book revenue for trilaciclib
-New Drug Application (NDA) for trilaciclib submitted in June 2020

RESEARCH TRIANGLE PARK, N.C. and RIDGEFIELD, Conn., June 30, 2020 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX) and Boehringer Ingelheim today announced that the companies have entered into a co-promotion agreement for trilaciclib in the United States and Puerto Rico. Under the terms of the three-year agreement, G1 and Boehringer Ingelheim will collaborate on the commercialization of trilaciclib for its first potential indication in small cell lung cancer (SCLC), with the Boehringer Ingelheim oncology commercial team, well-established in lung cancer, leading sales force engagement initiatives. Discovered and developed by G1, trilaciclib is a first-in-class investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy.

"We believe that trilaciclib has the potential to benefit patients with cancer being treated with chemotherapy across a broad range of solid tumors," said Mark Velleca, M.D., Ph.D., Chief Executive Officer of G1. "Our clinical trials of trilaciclib in small cell lung cancer have demonstrated significant myelopreservation benefits, and we are excited to collaborate with Boehringer Ingelheim's experienced commercial oncology team to bring this innovative therapy to patients with SCLC. In addition, this capital efficient launch structure provides us with the ability to make investments in a robust development program to assess trilaciclib in other solid tumors, including colorectal cancer and breast cancer."

Under the terms of the agreement, G1 will book revenue in the United States and Puerto Rico and retain global development and commercialization rights to trilaciclib. In the U.S. and Puerto Rico, G1 will lead marketing, market access and medical engagement initiatives; Boehringer Ingelheim will lead sales force engagements. G1 will make initial payments to Boehringer Ingelheim to cover start-up expenses and pre-approval initiatives to support a successful commercial launch. G1 will pay a promotion fee of a mid-twenties percentage of net sales in the first year of commercialization, which decreases to a low double-digit/high single-digit percentage in the second and third years of commercialization, respectively (subject to certain adjustments for sales above pre-specified levels to reward out-performance). There are no payments due by either party beyond the expiration of the three-year term of the agreement. The agreement does not extend to additional indications that G1 may pursue for trilaciclib.

"Boehringer Ingelheim's commitment to transform treatment expectations for the oncology community extends beyond research and drives us to explore innovative solutions for patients. We are pleased to be collaborating with G1 Therapeutics and applying our commercial strengths focused on lung cancer to support a new therapy for patients with clear synergies across customer audiences," said Kelli Moran, Senior Vice President, Specialty Care, Boehringer Ingelheim. "This strategic agreement builds on Boehringer Ingelheim's achievements in oncology and contributes to our long-term vision to give patients new hope by taking cancer on."

G1 received Breakthrough Therapy Designation for trilaciclib from the U.S. Food and Drug Administration (FDA) in 2019 and submitted a New Drug Application (NDA) in June 2020. More than 25,000 people in the U.S. and Puerto Rico are diagnosed with SCLC each year. Approximately 90% of SCLC patients receive first-line chemotherapy treatment, and approximately 60% of those patients receive subsequent second-line chemotherapy treatment. Chemotherapy is an effective and important weapon against cancer. However, chemotherapy does not differentiate between healthy cells and cancer cells and kills both. One of the most common side effects of chemotherapy is myelosuppression – the result of damage to stem cells in the bone marrow that produce white blood cells, red blood cells and platelets. 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. Immune cell damage may decrease the ability of the immune system to fight the cancer, as well as infection. Trilaciclib has the potential to be the first proactively administered myelopreservation therapy that can make chemotherapy safer and improve the patient experience.

Additional information regarding this agreement is disclosed in a Current Report on Form 8-K filed by G1 with the U.S. Securities and Exchange Commission (available here).

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 positive myelopreservation data from three randomized, double-blind, placebo-controlled clinical trials in which trilaciclib was administered prior to chemotherapy treatment in patients with small cell lung cancer (SCLC). In a randomized trial of women with metastatic triple-negative breast cancer, trilaciclib improved overall survival when administered prior to chemotherapy. In June 2020, G1 submitted a New Drug Application (NDA) 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 Phase 3 trial in colorectal cancer in the fourth quarter of 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 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.

About Boehringer Ingelheim in Oncology

Cancer takes. Takes away time. Takes away loved ones. At Boehringer Ingelheim Oncology, we are giving patients new hope by taking cancer on. We are dedicated to collaborating with the oncology community on a shared journey to deliver leading science. Our primary focus is in lung and gastrointestinal cancers, with the goal of delivering breakthrough, first-in-class treatments that can help win the fight against cancer. Our commitment to innovation has resulted in pioneering treatments for lung cancer and we are advancing a unique pipeline of cancer cell directed agents, immune oncology therapies and intelligent combination approaches to help combat many cancers.

About Boehringer Ingelheim
Making new and better medicines for humans and animals is at the heart of what we do. Our mission is to create breakthrough therapies that change lives. Since its founding in 1885, Boehringer Ingelheim is independent and family-owned. We have the freedom to pursue our long-term vision, looking ahead to identify the health challenges of the future and targeting those areas of need where we can do the most good.

As a world-leading, research-driven pharmaceutical company, more than 51,000 employees create value through innovation daily for our three business areas: Human Pharma, Animal Health, and Biopharmaceutical Contract Manufacturing. In 2019, Boehringer Ingelheim achieved net sales of around $21.3 billion (19 billion euros). Our significant investment of over $3.9 billion (3.5 billion euros) in R&D drives innovation, enabling the next generation of medicines that save lives and improve quality of life.

We realize more scientific opportunities by embracing the power of partnership and diversity of experts across the life-science community. By working together, we accelerate the delivery of the next medical breakthrough that will transform the lives of patients now, and in generations to come.

Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. subsidiary of Boehringer Ingelheim Corporation and is part of the Boehringer Ingelheim group of companies. In addition, there are Boehringer Ingelheim Animal Health in Duluth, GA and Boehringer Ingelheim Fremont, Inc. in Fremont, CA.

Boehringer Ingelheim is committed to improving lives and strengthening our communities. Please visit www.boehringer-ingelheim.us/csr to learn more about Corporate Social Responsibility initiatives. For more information, please visit www.boehringer-ingelheim.us, or follow us on Twitter @BoehringerUS.

G1 Therapeutics 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. 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 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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