



G1 Therapeutics Announces Acceptance and Priority Review of NDA for Trilaciclib for Patients with Small Cell Lung Cancer

August 17, 2020

- PDUFA action date of February 15, 2021 assigned by U.S. Food and Drug Administration
- Priority Review for trilaciclib is based on positive data from three randomized clinical trials showing robust myelopreservation benefits
- G1 launching expanded access program (EAP) for patients with small cell lung cancer in the U.S.

RESEARCH TRIANGLE PARK, N.C., Aug. 17, 2020 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for trilaciclib for small cell lung cancer (SCLC) patients being treated with chemotherapy and granted Priority Review with a Prescription Drug User Fee Act (PDUFA) action date of February 15, 2021. Trilaciclib is a first-in-class investigational therapy designed to preserve bone marrow and immune system function during chemotherapy and improve patient outcomes.

"There are currently no available therapies to protect patients from chemotherapy-induced toxicities before they occur," said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. "If approved, trilaciclib would be the first proactively administered myelopreservation therapy that is intended to make chemotherapy safer and reduce the need for rescue interventions, such as growth factor administrations and blood transfusions."

The FDA grants Priority Review to applications for potential therapies that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. The trilaciclib NDA was supported by compelling myelopreservation data from three randomized, double-blind, placebo-controlled clinical trials in which trilaciclib was administered prior to chemotherapy treatment in patients with SCLC. Trilaciclib has been granted Breakthrough Therapy Designation by the FDA. In the NDA acceptance letter, the FDA also stated that it is currently not planning to hold an advisory committee meeting to discuss this application.

"While undergoing chemotherapy, many patients experience significant myelosuppression, become fatigued and susceptible to infection, and often require transfusions and growth factor administrations," said Jared Weiss, M.D., Lineberger Comprehensive Cancer Center, University of North Carolina Chapel Hill, NC. "Preventing bone marrow damage proactively is an opportunity to improve the quality of life of patients receiving chemotherapy for small cell lung cancer and reduce costly rescue interventions."

Myelosuppression is the result of damage to bone marrow stem cells and is one of the most common side effects of chemotherapy. Myelosuppression can lead to serious conditions such as anemia, neutropenia or thrombocytopenia, which have broad ranging clinical, patient experience and economic impacts on ongoing cancer treatment and overall outcomes. In clinical trials, trilaciclib significantly reduced chemotherapy-induced myelosuppression, and patients receiving trilaciclib experienced fewer dose delays/reductions, infections, hospitalizations, and need for rescue therapies compared to patients receiving chemotherapy alone.

Expanded Access Program

G1 is making trilaciclib available to SCLC patients in the U.S., who are unable to enter clinical trials and for whom there are no appropriate alternative treatments while the trilaciclib NDA is under regulatory review, pursuant to [FDA's expanded access program](#) (EAP). To facilitate needed access through the EAP, G1 is collaborating with Bionical Emas, a global specialist clinical research organization (CRO). For more information about the EAP access to trilaciclib, email patient.access.us@Bionical-emas.com.

"Complications from myelosuppression have been a long-standing challenge when treating patients with SCLC," said Dr. Malik. "Establishing an expanded access program provides qualified patients in serious need with access to trilaciclib while the NDA is under review."

Trilaciclib in Small Cell Lung Cancer

Trilaciclib is a first-in-class investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy. In 2019, trilaciclib received FDA Breakthrough Therapy Designation, and, in June 2020, G1 submitted the NDA based on myelopreservation data from three randomized, double-blind, placebo-controlled clinical trials in which trilaciclib was administered prior to chemotherapy in patients with small cell lung cancer (SCLC). In August 2020, G1 received FDA Priority Review with the Prescription Drug User Fee Act (PDUFA) date of February 15, 2021.

In June 2020, G1 announced a co-promotion agreement with Boehringer Ingelheim for trilaciclib in small cell lung cancer in the U.S. and Puerto Rico. If approved, G1 will lead marketing, market access and medical engagement initiatives for trilaciclib. The Boehringer Ingelheim oncology commercial team, well-established in lung cancer, will lead sales force engagement initiatives. G1 will book revenue and retain development and commercialization rights to trilaciclib and pay Boehringer Ingelheim a promotional fee based on net sales. The three-year agreement does not extend to additional indications that G1 is evaluating for trilaciclib. Press release details of the G1/Boehringer Ingelheim agreement can be found [here](#).

Evaluating Trilaciclib in Other Cancers

In a randomized trial of women with metastatic triple-negative breast cancer, preliminary data showed that trilaciclib improved overall survival when administered in combination with chemotherapy compared with chemotherapy alone. The company plans to present final overall survival data from this trial in the fourth quarter of 2020. Trilaciclib is being evaluated in neoadjuvant breast cancer as part of the I-SPY 2 TRIAL™, and the company expects to initiate a Phase 3 trial in patients treated with chemotherapy for 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 next generation therapies that improve the lives of those affected by cancer. The company is developing and advancing two novel therapies: trilaciclib is a first-in-class 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. In 2020, the company out-licensed global development and commercialization rights to its

differentiated oral CDK4/6 inhibitor, lerociclib.

G1 Therapeutics is based in Research Triangle Park, N.C. For additional information, please visit www.g1therapeutics.com and follow us on Twitter [@G1Therapeutics](https://twitter.com/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, our reliance on partners to develop and commercial licensed products, and the impact of pandemics such as COVID-19 (coronavirus), 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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