

G1 Therapeutics, Inc. and Bionical Emas Launch Expanded Access Program for Trilaciclib in Small Cell Lung Cancer in the United States

August 17th, 2020. G1 Therapeutics, Inc. (Nasdaq:GTHX), a clinical-stage oncology company, and Bionical Emas, a global specialist Clinical Research Organization (CRO), today announced the launch of an Expanded Access Program (EAP) for trilaciclib, a first-in-class United States Food and Drug Administration (FDA) designated Breakthrough Therapy designed to improve the outcomes for people with cancer treated with chemotherapy. In June 2020, a New Drug Application (NDA) for trilaciclib was submitted to the FDA for myelopreservation in small cell lung cancer (SCLC). The FDA has granted Priority Review status with a Prescription Drug User Fee Act (PDUFA) date of February 15, 2021.

The EAP is open to eligible SCLC patients who are unable to enter clinical trials and for whom there are no appropriate alternative treatments while trilaciclib is under regulatory review by the FDA. Additional information regarding the trilaciclib EAP may be found at NCT04504513 on ClinicalTrials.gov site.

Chemotherapy-induced myelosuppression (CIM), including chemotherapy-induced neutropenia (CIN) and chemotherapy-induced anemia (CIA), is a clinically significant side effect of chemotherapy. Patients continue to suffer from CIM despite the evolution in chemotherapy regimens and supportive care interventions intended to improve its management. Treatment of SCLC is particularly notable for the degree of myelotoxicity caused by standard treatment regimens.

Complications from CIM for patients receiving chemotherapy for SCLC can include infections, sepsis, bleeding, and fatigue, often resulting in hospitalizations, need for hematopoietic growth factor support and red blood cell (RBC) and/or platelet transfusions, and even death. Chemotherapy dose reductions and dose delays, with potential reductions in chemotherapy dose intensity and anti-tumor efficacy, can stem from complications of CIM^{1,2}.



“If approved, trilaciclib has the potential to be the first proactively administered myelopreservation therapy for patients with SCLC receiving chemotherapy,” said **Raj Malik**, M.D., Chief Medical Officer and Senior Vice President, R&D, G1 Therapeutics, Inc. “We believe trilaciclib has the potential to improve outcomes across multiple solid tumors and chemotherapy regimens and we are focused on bringing this new treatment to patients.”

“We are very excited to be supporting this Expanded Access Program for such an important treatment option for patients suffering from SCLC.” said **Tom Watson**, Executive Vice President, Bionical Emas.

“Chemotherapy-induced myelosuppression can lead to many clinically significant side effects and substantially impair the quality of life of patients with SCLC,” said **John Efthimiou**, M.D., Chief Medical Officer, Bionical Emas. “We are pleased to support this EAP as it provides an important new opportunity for those patients who are unable to enter clinical trials and for whom there are no appropriate alternative treatments.”

Healthcare professionals wishing to request access to trilaciclib under the EAP or who would like to find out more should do so by emailing patient.access.us@Bionical-emas.com. Further details concerning the EAP can be found on [Clinicaltrials.gov](https://clinicaltrials.gov).

About G1 Therapeutics, Inc.

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, Inc. 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).



About Bionical Emas

Bionical Emas is a specialist CRO combining Clinical Development, Early Access Programs and Clinical Trial Supply.

Our Early Access Programs provide access to pre-approved medicines to help patients with unmet medical needs.

Access is provided in response to physician requests, where no alternative treatment options are available, and the patient is not eligible for clinical trials for the condition.

<https://bionicalemas.com>

<https://twitter.com/bionicalemas>

<https://www.linkedin.com/company/emas>

About Trilaciclib

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.

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References:

1. Lyman GH. Chemotherapy dose intensity and quality cancer care. *Oncology (Williston Park)*. 2006;20(14 Suppl 9):16-25.
2. Smith RE. Trends in recommendations for myelosuppressive chemotherapy for the treatment of solid tumors. *J Natl Compr Canc Netw*. 2006; 4:649-58.