G1 Therapeutics to Present Data Showing Myelopreservation Benefits of Trilaciclib in Patients with Small Cell Lung Cancer at the ASCO20 Virtual Scientific Program

May 13, 2020

- Trilaciclib significantly reduced myelosuppression and need for related supportive care interventions for patients with small cell lung cancer (SCLC) receiving chemotherapy

- New Drug Application (NDA) submission for trilaciclib in SCLC on track for completion in 2Q20

RESEARCH TRIANGLE PARK, N.C., May 13, 2020 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today announced that data across three randomized, double-blind, placebo-controlled Phase 2 trials of the investigational therapy trilaciclib in small cell lung cancer (SCLC) will be presented on May 29 at the ASCO20 Virtual Scientific Program of the American Society of Clinical Oncology (ASCO). In these trials, trilaciclib was administered prior to chemotherapy treatment and significantly reduced rates of myelosuppression and the need for related supportive care interventions compared with patients receiving chemotherapy treatment alone. In addition, two abstracts on the real-world burden of chemotherapy-induced myelosuppression will be published.

“The data shared at ASCO highlight the significant potential for trilaciclib to improve outcomes for patients undergoing chemotherapy,” said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. “Patients with chemotherapy-induced myelosuppression are especially vulnerable and often require multiple rescue interventions that are burdensome to both the patient and the healthcare system. Trilaciclib has the potential to be the first proactively administered myelopreservation therapy that can make chemotherapy safer and improve the patient experience.”

Myelosuppression is the result of damage to bone marrow cells, and is one of the most common side effects of chemotherapy. 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 is a first-in-class investigational therapy designed to preserve bone marrow and immune system function during chemotherapy and improve patient outcomes.

The company plans to complete an NDA submission for trilaciclib for myelopreservation in SCLC in 2Q20. Trilaciclib has been assigned Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA).

G1 abstract titles are below; more details are available on the ASCO20 Virtual Scientific Program website.

Title: Myelopreservation and reduced use of supportive care with trilaciclib in patients with small cell lung cancer
Abstract: 12096
Poster Number: 384
Date/Time: Friday, May 29 at 8:00 a.m. ET
Presenter: Jared Weiss, MD, Lineberger Comprehensive Cancer Center, University of North Carolina Chapel Hill, NC
Background/Key Findings:

- Across three separate randomized, double-blind, placebo-controlled Phase 2 trials, 123 patients with extensive-stage SCLC were treated with trilaciclib administered prior to chemotherapy and 119 SCLC patients received chemotherapy alone.
- The addition of trilaciclib significantly decreased measures of myelosuppression and the need for supportive care interventions.
- Fewer patients receiving trilaciclib administered prior to chemotherapy had Grade 3/4 hematologic adverse events (n=54 [44.3%]) compared with those receiving chemotherapy alone (n=91 [77.1%]).
- Statistically significant reductions in the rate and duration of severe neutropenia, administration of G-CSF, Grade 3/4 anemia, and red blood cell transfusions were observed in patients receiving trilaciclib prior to chemotherapy compared with those receiving chemotherapy alone.
- Median overall survival (OS) and progression-free survival (PFS) were comparable between patients receiving trilaciclib prior to chemotherapy and those receiving chemotherapy alone.

Title: Real-world burden of chemotherapy-induced myelosuppression: results of a U.S. online survey of patients with cancer
Abstract: e19299
Authors: Robert S. Epstein, MD, MS, Epstein Health, LLC, et al
Background/Key Findings:

- 301 people with cancer (breast cancer = 153, lung cancer = 100, colorectal cancer = 48) who were treated with chemotherapy in the past year and experienced at least one episode of myelosuppression completed an online survey to assess the impact of chemotherapy-induced myelosuppression.
- Nearly nine in ten (89%) survey participants reported that myelosuppression had a moderate or major impact on their lives (moderate life impact = 49%, major life impact = 40%).
- Fatigue was the most commonly reported side effect of chemotherapy, experienced by almost three-quarters of survey participants (72%), with more than half (55%) rating it as highly bothersome (9 or 10 on a 1–10 scale of ‘bothersomeness’).

Additional data from this survey will be presented at the Virtual ISPOR 2020 meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), being held May 18-20.

Title: Real-world burden of myelosuppression in patients with small cell lung cancer: retrospective, longitudinal data analysis.
Abstract: e19300
Authors: Robert S. Epstein, MD, MS, Epstein Health, LLC, et al
Background/Key Findings:

- Data from Providence St. Joseph Health electronic medical records over a three-year period (January 2016 - December 2019) were analyzed to assess hematologic adverse events, treatment patterns, and hospital-based healthcare resource utilization and treatment costs of 347 SCLC patients who had chemotherapy-induced Grade 3/4 myelosuppression.
- The average total 12-month cost of care for SCLC patients without Grade 3/4 hematologic events was $67,802. Average annual cost of care was higher for SCLC patients experiencing Grade 3/4 hematologic events: $131,047 for those with neutropenia, $95,954 for those with anemia, and $90,053 for those with thrombocytopenia.

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 2020, the company plans to complete a New Drug Application (NDA) submission for trilaciclib for myelopreservation in SCLC, initiate a registrational Phase 3 clinical trial in colorectal cancer, and begin a neoadjuvant trial in breast cancer as part of the I-SPY 2 TRIAL.

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 therapy designed to improve outcomes for patients being treated with chemotherapy. Trilaciclib has received Breakthrough Therapy Designation from the FDA; a rolling NDA submission for small cell lung cancer is expected to be completed in the second quarter of 2020. 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.

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