Retrospective Analysis of Pooled Results from Three Studies Shows COSELA™ (Trilaciclib) Reduced Use of Supportive Care Interventions in Extensive Stage Small Cell Lung Cancer Patients Who Receive the Drug Prior to Chemotherapy

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Proactive use of trilaciclib prior to chemotherapy in certain patients significantly reduced the use of G-CSFs, ESAs, and RBC transfusions on or after week five of chemotherapy

RESEARCH TRIANGLE PARK, N.C., Oct. 07, 2021 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced results from a retrospective analysis of the pooled results of three randomized trilaciclib studies showing that patients with extensive-stage small-cell lung cancer (ES-SCLC) who received the drug prior to each chemotherapy treatment had significantly lower use of supportive care therapies for chemotherapy-induced myelosuppression than patients who received placebo. Results of the retrospective analysis are published in the online edition of the journal *Cancer Medicine.*

COSELA™ (trilaciclib) is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer.

In the study, the researchers assessed the impact of trilaciclib versus placebo on subsequent use of supportive therapies—including granulocyte colony stimulating factor (G-CSF), erythropoiesis-stimulating agents (ESAs), and red blood cell transfusions—following chemotherapy treatments for ES-SCLC. The results showed that trilaciclib significantly reduced the duration and occurrence of chemotherapy-induced severe neutropenia and the occurrence of grade 3 or greater chemotherapy-induced anemia, with a corresponding reduction in the use of supportive care therapies to manage these adverse events.

The publication titled, “Trilaciclib Prior to Chemotherapy Reduces the Usage of Supportive Care Interventions for Chemotherapy-Induced Myelosuppression in Patients with Small Cell Lung Cancer: Pooled Analysis of Three Randomized Phase 2 Trials,” can be accessed here.

Specifically, the analysis showed that administering trilaciclib prior to chemotherapy:

- Significantly reduced the occurrence of severe neutropenia—11.4% in the trilaciclib group versus 52.9% in the placebo group ($p < 0.0001$).
  - with a corresponding reduction in G-CSF use by approximately half in the trilaciclib group compared with placebo
  - Consistency of treatment effects on occurrence of severe neutropenia with or without concomitant G-CSF use was tested and results indicated that the effect of trilaciclib was consistent regardless of whether or not a G-CSF was administered.
- Significantly reduced the occurrence of grade 3/4 anemia compared with placebo—20.3% in the trilaciclib group versus 31.9% in the placebo group ($p = 0.0279$)
  - with a corresponding reduction of ESA treatment: 3.3% trilaciclib versus 11.8% placebo ($p = 0.0254$)
  - and a corresponding reduction of red blood cell transfusions on or after week five: 14.6% trilaciclib versus 26.1% placebo ($p = 0.0252$)
- In a separate analysis, the use of trilaciclib significantly reduced patient hospitalizations due to chemotherapy induced myelosuppression (CIM) or sepsis, with 4.1% of patients hospitalized in the trilaciclib arm versus 13.6% of patients hospitalized in the placebo arm

The findings were derived from a retrospective analysis of pooled data obtained from three randomized, Phase 2 clinical trials of trilaciclib or placebo administered prior to chemotherapy in 242 patients with ES-SCLC. The authors suggest that the pooled data indicate that the administration of trilaciclib prior to chemotherapy has the potential to reduce the burden of CIM on health care systems.

“The results from our analysis show clear myeloprotection benefits associated with the administration of trilaciclib prior to chemotherapy in patients with ES-SCLC,” said Renata Ferrarotto, MD, Associate Professor, Department of Thoracic/Head and Neck Medical Oncology at MD Anderson Cancer Center and lead author of the study. “By reducing the need for associated supportive care, trilaciclib has the potential to reduce both the societal and economic burden of chemotherapy-induced myelosuppression.”

Chemotherapy-induced myelosuppression (CIM) is one of the most common, dose-limiting complications of cancer treatment, and is associated with a range of symptoms that can significantly impact patients’ quality of life. The researchers concluded that “trilaciclib may help to reduce the burden of chemotherapy-induced myelosuppression on patients, caregivers, and health care systems.”

About Small Cell Lung Cancer

In the United States, approximately 30,000 small cell lung cancer patients are treated annually. SCLC, one of the two main types of lung cancer, accounts for about 10% to 15% of all lung cancers. SCLC is an aggressive disease and tends to grow and spread faster than NSCLC. It is usually asymptomatic; once symptoms do appear, it often indicates that the cancer has spread to other parts of the body. About 70% of people with SCLC will have cancer that has metastasized at the time they are diagnosed. The severity of symptoms usually increases with increased cancer growth and

spread. From the time of diagnosis, the general 5-year survival rate for people with SCLC is 6%. The five-year survival rates for limited-stage (the cancer is confined to one side of the chest) SCLC is 12% to 15%, and for extensive stage (cancer has spread to the other lung and beyond), survival rates are less than 2%. Chemotherapy is the most common treatment for ES-SCLC.

About COSELA™ (trilaciclib) for Injection

COSELA (trilaciclib) was approved by the U.S. Food and Drug Administration on February 12, 2021.

Indication
COSELA™ (trilaciclib) is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer.

Select Important Safety Information

CONTRAINDICATION
COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

WARNINGS AND PRECAUTIONS
Injection-Site Reactions, Including Phlebitis and Thrombophlebitis
COSELA administration can cause injection-site reactions, including phlebitis and thrombophlebitis, which occurred in 56 (21%) of 272 patients receiving COSELA in clinical trials, including Grade 2 (10%) and Grade 3 (0.4%) adverse reactions. Injection-site reactions led to discontinuation of treatment in 3 (1%) of the 272 patients.

Acute Drug Hypersensitivity Reactions
COSELA administration can cause acute drug hypersensitivity reactions, which occurred in 16 (6%) of 272 patients receiving COSELA in clinical trials, including Grade 2 reactions (2%).

Interstitial Lung Disease/Pneumonitis
Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with cyclin-dependent kinases (CDK)4/6 inhibitors, including COSELA, with which it occurred in 1 (0.4%) of 272 patients receiving COSELA in clinical trials.

Embryo-Fetal Toxicity
Based on its mechanism of action, COSELA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use an effective method of contraception during treatment with COSELA and for at least 3 weeks after the final dose.

ADVERSE REACTIONS
The most common adverse reactions (≥10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

Serious adverse reactions occurred in 30% of patients receiving COSELA. Serious adverse reactions reported in >3% of patients who received COSELA included respiratory failure, hemorrhage, and thrombosis. Fatal adverse reactions were observed in 5% of patients receiving COSELA. Fatal adverse reactions for patients receiving COSELA included pneumonia (2%), respiratory failure (2%), acute respiratory failure (<1%), hemoptysis (<1%), and cerebrovascular accident (<1%).

This information is not comprehensive. Please click here for full Prescribing Information. https://www.g1therapeutics.com/cosela/pi/

To report suspected adverse reactions, contact G1 Therapeutics at 1-800-790-G1TX or call FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

G1 Therapeutics
G1 Therapeutics, Inc. is a commercial-stage biopharmaceutical company focused on the development and commercialization of next generation therapies that improve the lives of those affected by cancer, including the Company's first commercial product, COSELA™ (trilaciclib). G1 has a deep clinical pipeline and is executing a tumor-agnostic development plan evaluating COSELA in a variety of solid tumors, including colorectal, breast, lung, and bladder cancers. 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 expectations for the commercial launch of COSELA (trilaciclib), the therapeutic potential of COSELA (trilaciclib), and COSELA's (trilaciclib) possibility to significantly lower the use of supportive care therapies for chemotherapy-induced myelosuppression presented in the scientific analyses described above, and COSELA (trilaciclib) may fail to achieve the degree of market acceptance for commercial success, 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 a successful commercial launch for COSELA (trilaciclib); the company's ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates other than COSELA (trilaciclib); 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 commercial-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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