



FDA Approves G1 Therapeutics' COSELA™ (trilaciclib): The First and Only Myeloprotection Therapy to Decrease the Incidence of Chemotherapy-Induced Myelosuppression

February 13, 2021

- COSELA is the only FDA-approved therapy that helps proactively deliver multilineage myeloprotection to patients with **extensive-stage small cell lung cancer** being treated with chemotherapy -

- Myeloprotective efficacy of COSELA resulted in reductions in the incidence and duration of severe neutropenia, and impacted anemia and the need for rescue interventions such as growth factors and red blood cell transfusions -

- G1 will host conference call Tuesday, February 16, 2021 at 8:00 a.m. ET -

RESEARCH TRIANGLE PARK, N.C., Feb. 12, 2021 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: [GTHX](#)), a commercial-stage oncology company, today announced that the U.S. Food and Drug Administration (FDA) has approved COSELA™ (trilaciclib) for injection 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 (ES-SCLC). It is the first and only therapy designed to help protect bone marrow (myeloprotection) when administered prior to treatment with chemotherapy. COSELA is expected to be commercially available through G1's specialty distributor partner network in early March.

"The approval of trilaciclib (COSELA) is an important advance in the treatment of patients with extensive-stage small cell lung cancer receiving chemotherapy," said Dr. Jeffrey Crawford, Geller Professor for Research in Cancer in the Department of Medicine and Duke Cancer Institute. "The most serious and life-threatening side effect of chemotherapy is myelosuppression, or damage to the bone marrow, resulting in reduced white blood cells, red blood cells and platelets. Chemotherapy-induced myelosuppression may lead to increased risks of infection, severe anemia, and/or bleeding. These complications impact patients' quality of life and may also result in chemotherapy dose reductions and delays. To date, approaches have included the use of growth factor agents to accelerate blood cell recovery after the bone marrow injury has occurred, along with antibiotics and transfusions as needed. By contrast, trilaciclib provides the first proactive approach to myelosuppression through a unique mechanism of action that helps protect the bone marrow from damage by chemotherapy. In clinical trials, the addition of trilaciclib to extensive-stage small cell lung cancer chemotherapy treatment regimens reduced myelosuppression and improved clinical outcomes. The good news is that these benefits of trilaciclib will now be available for our patients in clinical practice."

Chemotherapy is an effective and important weapon against cancer. However, chemotherapy does not differentiate between healthy cells and cancer cells. It kills both, including important hematopoietic stem and progenitor cells (HSPCs) in the bone marrow that produce white blood cells (immune cells that help fight infection), red blood cells (cells that carry oxygen from the lungs to the tissues), and platelets (cells that prevent bleeding from cancer, surgeries, chronic diseases, and injuries). This chemotherapy-induced bone marrow damage, known as myelosuppression, can lead to increased risk of infection, anemia, thrombocytopenia, and other complications. Myeloprotection is a novel approach of protecting HSPCs in the bone marrow from chemotherapy-induced damage. This approach can help reduce some chemotherapy-related toxicity, making chemotherapy safer and more tolerable, while also reducing the need for reactive rescue interventions.

"Chemotherapy is the most effective and widely used approach to treating people diagnosed with extensive-stage small cell lung cancer; however, standard of care chemotherapy regimens are highly myelosuppressive and can lead to costly hospitalizations and rescue interventions," said Jack Bailey, Chief Executive Officer at G1 Therapeutics. "COSELA will help change the chemotherapy experience for people who are battling ES-SCLC. G1 is proud to deliver COSELA to patients and their families as the first and only therapy to help protect against chemotherapy-induced myelosuppression."

COSELA is administered intravenously as a 30-minute infusion within four hours prior to the start of chemotherapy and is the first FDA-approved therapy that helps provide proactive, multilineage protection from chemotherapy-induced myelosuppression. The approval of COSELA is based on data from three randomized, placebo-controlled trials that showed patients receiving COSELA prior to the start of chemotherapy had clinically meaningful and statistically significant reduction in the duration and severity of neutropenia. Data also showed a positive impact on red blood cell transfusions and other myeloprotective measures. The trials evaluated COSELA in combination with carboplatin/etoposide (+/- the immunotherapy atezolizumab) and topotecan chemotherapy regimens. Approximately 90% of all patients with ES-SCLC will receive at least one of these regimens during the course of their treatment.

The majority of adverse reactions reported with COSELA were mild to moderate in severity. 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. Grade 3/4 hematological adverse reactions occurring in patients treated with COSELA and placebo included neutropenia (32% and 69%), febrile neutropenia (3% and 9%), anemia (16% and 34%), thrombocytopenia (18% and 33%), and leukopenia (4% and 17%), respectively.

"Quite often, people diagnosed with extensive-stage small cell lung cancer rely on chemotherapy to not only extend their lives, but also to acutely alleviate their symptoms," said Bonnie J. Addario, lung cancer survivor, co-founder and board chair of the Go2 Foundation for Lung Cancer. "Unfortunately, the vast majority will experience chemotherapy-induced side effects, resulting in dose delays and reductions, and increased utilization of healthcare services. G1 shares our organization's goal to improve the quality of life of those diagnosed with lung cancer and to transform survivorship among people living with this insidious disease. We are thrilled to see new advancements that can help improve the lives of those living with small cell lung cancer."

Approximately 30,000 small cell lung cancer patients are treated in the United States annually. G1 is committed to helping patients with

extensive-stage small cell lung cancer in the U.S. gain access to treatment with COSELA. For more information on access and affordability programs, patients and providers should call the G1toOne support center at 833-G1toONE (833-418-6663) from 8:00 a.m. to 8:00 p.m. Eastern time.

G1 received Breakthrough Therapy Designation from the FDA in 2019 based on positive data in small cell lung cancer patients from three randomized Phase 2 clinical trials. As is common with breakthrough-designated products that receive priority review, G1 will conduct certain post-marketing activities, including in vitro drug-drug interaction and metabolism studies, and a clinical trial to assess impact of trilaciclib on disease progression or survival in patients with ES-SCLC with chemotherapy-induced myelosuppression treated with a platinum/etoposide-containing or topotecan-containing regimen with at least a two year follow up. G1 intends to initiate the post-approval clinical trial in 2022.

Webcast and Conference Call

The management team will host a webcast and conference call at 8:00 a.m. ET on Tuesday, February 16, 2021 to discuss the FDA approval of COSELA (trilaciclib). The live call may be accessed by dialing 866-763-6020 (domestic) or (210) 874-7713 (international) and entering the conference code: 6195528. A live and archived webcast will be available on the [Events & Presentations](#) page of the company's website: www.g1therapeutics.com. The webcast will be archived on the same page for 90 days following the event.

COSELA (trilaciclib) Co-Promotion Agreement with Boehringer Ingelheim

In June 2020, G1 announced a three-year co-promotion agreement with Boehringer Ingelheim for COSELA in small cell lung cancer in the U.S. and Puerto Rico. G1 will lead marketing, market access and medical engagement initiatives for COSELA. 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 COSELA 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](#).

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.

COSELA™(trilaciclib) for Injection

INDICATION

COSELA 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 (ES-SCLC).

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. Monitor patients for signs and symptoms of injection-site reactions, including infusion-site pain and erythema during infusion. For mild (Grade 1) to moderate (Grade 2) injection-site reactions, flush line/cannula with at least 20 mL of sterile 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP after end of infusion. For severe (Grade 3) or life-threatening (Grade 4) injection-site reactions, stop infusion and permanently discontinue COSELA. 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%). Monitor patients for signs and symptoms of acute drug hypersensitivity reactions. For moderate (Grade 2) acute drug hypersensitivity reactions, stop infusion and hold COSELA until the adverse reaction recovers to Grade \leq 1. For severe (Grade 3) or life-threatening (Grade 4) acute drug hypersensitivity reactions, stop infusion and permanently discontinue COSELA.

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. Monitor patients for pulmonary symptoms of ILD/pneumonitis. For recurrent moderate (Grade 2) ILD/pneumonitis, and severe (Grade 3) or life-threatening (Grade 4) ILD/pneumonitis, permanently discontinue COSELA.

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

- 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%).
- Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received COSELA. Adverse reactions leading to permanent discontinuation of any study treatment for patients receiving COSELA included pneumonia (2%), asthenia (2%), injection-site reaction, thrombocytopenia, cerebrovascular accident, ischemic stroke, infusion-related reaction, respiratory failure, and myositis (<1% each).
- Infusion interruptions due to an adverse reaction occurred in 4.1% of patients who received COSELA.
- The most common adverse reactions (≥10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

DRUG INTERACTIONS

- COSELA is an inhibitor of OCT2, MATE1, and MATE-2K. Co-administration of COSELA may increase the concentration or net accumulation of OCT2, MATE1, and MATE-2K substrates in the kidney (e.g., dofetilide, dalfampridine, and cisplatin).

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

Please see full Prescribing Information [here](#)

For more information about COSELA, please call 1-800-790-G1TX (1-800-790-4189)

About G1 Therapeutics

G1 Therapeutics, Inc. is a commercial-stage biopharmaceutical company focused on the discovery, development and delivery of next generation therapies that improve the lives of those affected by cancer, including the Company's first commercially available product COSELA™ (trilaciclib), a first-in-class therapy approved by the U.S. Food and Drug Administration to help protect against chemotherapy-induced myelosuppression in patients with extensive-stage small cell lung cancer being treated with chemotherapy. Trilaciclib is also being evaluated in other solid tumors, including colorectal, breast 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](https://twitter.com/G1Therapeutics).

Tecentriq® (atezolizumab) is a registered trademark of Genentech.

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 COSELA (trilaciclib), and COSELA's (trilaciclib) possibility to improve patient outcomes, 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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COSELA (trilaciclib) image



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