



G1 Therapeutics to Host Virtual COSELA™ (trilaciclib) Kickoff Analyst and Investor Summit on April 9, 2021

April 1, 2021

RESEARCH TRIANGLE PARK, N.C., April 01, 2021 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: [GTHX](#)), a commercial-stage oncology company, today announced that the Company will host a virtual COSELA Kickoff Analyst and Investor Summit on Friday, April 9, 2021 from 9:00 a.m. to 11:00 a.m. EDT.

G1 Therapeutics will review its U.S. launch strategy for the first-in-class myeloprotection therapy, COSELA, in extensive-stage small cell lung cancer. COSELA is the only FDA-approved therapy that helps proactively deliver multilineage myeloprotection benefit to patients with extensive-stage small cell lung cancer being treated with chemotherapy. The program will also feature insights about the urgent need to proactively treat patients for myelosuppression from the following leading clinicians:

- Jared Weiss, M.D., Thoracic and Head/Neck Oncologist & Associate Professor, Division of Oncology, University of North Carolina at Chapel Hill
- Tajuana Bradley, MS, FNP-BC, Nurse Practitioner, Georgia Cancer Specialists

A webcast of the event can be accessed on the [Events & Presentations](#) page of www.g1therapeutics.com. The webcast will be archived on the same page for 90 days following the event.

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 commercial product, COSELA™ (trilaciclib). G1 has a deep clinical pipeline evaluating targeted cancer therapies 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](https://twitter.com/G1Therapeutics).

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Contact:

Will Roberts
G1 Therapeutics, Inc.
Vice President
Investor Relations and Corporate Communications
(919) 907-1944
wroberts@g1therapeutics.com



Source: G1 Therapeutics