G1 Therapeutics Announces Permanent J-Code from Centers for Medicare and Medicaid Services

October 1, 2021

Effective Today, New J-code to Streamline Reimbursement

RESEARCH TRIANGLE PARK, North Carolina, Oct. 01, 2021 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced that the permanent J-code for COSELA™ (trilaciclib) that was issued in July 2021 by the Centers for Medicare & Medicaid Services (CMS) is now effective for provider billing for all sites of care. The permanent J-code for COSELA, J1448 (Injection, trilaciclib, 1mg.), published online on the CMS website here (page 5).

J-codes are permanent, product specific reimbursement codes assigned to outpatient and physician administered “buy and bill” products under Medicare Part B and are used by commercial insurers and government payers to facilitate and standardize claims submissions and reimbursements for medications like COSELA. With the permanent J-code now in effect, all hospital outpatient departments, ambulatory surgery centers and physician offices in the United States will have one consistent Healthcare Common Procedure Coding System (HCPCS) code to standardize the submission and payment of COSELA insurance claims across Medicare, Medicare Advantage, Medicaid and commercial plans.

“Given the emergent presentation of extensive-stage small cell lung cancer, and the clinical benefits of COSELA as a proactive multilineage myeloprotection drug when give prior to chemotherapy, it is absolutely essential that patients have timely access to it,” said Jack Bailey, Chief Executive Officer of G1 Therapeutics. "We are pleased to receive this new permanent J-code for all sites of care as it will enable a more efficient billing process, which will ultimately help facilitate patient access to COSELA.”

G1’s new technology add-on payment (NTAP) for COSELA which provides additional payment to inpatient hospitals above the standard Medicare Severity Diagnosis-Related Group (MS-DRG) payment amount also became effective for provider billing today, October 1, 2021.

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.

Important Safety Information
COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

Warnings and precautions include injection-site reactions (including phlebitis and thrombophlebitis), acute drug hypersensitivity reactions, interstitial lung disease (pneumonitis), and embryo-fetal toxicity.

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

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.

About 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 the urgent need for COSELA (trilaciclib) and the company’s ability to facilitate access to COSELA. 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 dependence on the commercial success of COSELA; the development and commercialization of new drug products is highly competitive; 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.

Will Roberts
Vice President, Investor Relations & Corporate Communications
919-907-1944
wroberts@g1therapeutics.com

Rebecca Levine
Director, Corporate Communications and Public Relations
(919) 667-8711
rlevine@g1therapeutics.com

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