



G1 Therapeutics to Present Phase 1b Data on G1T38 in Combination with Faslodex for Treatment of Breast Cancer at 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

May 16, 2018

RESEARCH TRIANGLE PARK, N.C., May 16, 2018 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq:GTHX), a clinical-stage oncology company, today announced that preliminary data from its Phase 1b/2a clinical trial of G1T38 in combination with Faslodex® (fulvestrant) will be presented in a poster session on June 2 at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting, being held June 1-5 in Chicago, IL. These data showed promising safety and tolerability when G1T38 was dosed continuously as a treatment for people with estrogen receptor-positive, HER2-negative (ER+, HER2-) breast cancer.

G1T38 is an oral CDK4/6 inhibitor with broad therapeutic potential in many forms of cancer and may serve as backbone therapy for multiple combination regimens.

"The combination of G1T38 and Faslodex has been well tolerated in this Phase 1b clinical trial, with no treatment-related serious adverse events reported. CDK4/6 inhibition can cause dose-limiting neutropenia that may require a treatment holiday. Importantly, chronic use of G1T38 in this trial resulted in dose-dependent decreases in absolute neutrophil counts that plateaued after four to five weeks of therapy. This allowed for continuous dosing of G1T38 without a drug holiday," said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. "The dose escalation portion of this clinical trial is ongoing, and we are encouraged by the early safety, tolerability and efficacy findings that support the continued development of G1T38 as a potential best-in-class oral CDK4/6 inhibitor."

Details on the presentation are listed below and are also available on the 2018 ASCO Annual Meeting website: <http://abstracts.asco.org/>.

Title: [G1T38, an oral CDK4/6 inhibitor, dosed continuously in combination with fulvestrant for HR+ breast cancer: Preliminary Phase 1b results.](#)

Abstract Number: 1061

Session: Breast Cancer – Metastatic

Poster Number: 142

Date / Time / Location: June 2, 8-11:30 a.m. CT; McCormick Place South, Hall A, Chicago, IL

Presenter: Iurie Bulat, M.D. (ARENSIA Exploratory Medicine Research Unit, Institute of Oncology)

For more information about the 2018 ASCO Annual Meeting, please visit <https://am.asco.org/>.

About G1T38

G1T38 is a potential best-in-class oral CDK4/6 inhibitor being developed for use in combination with other targeted therapies in multiple oncology indications. Preclinical data presented at the American Association for Cancer Research 2016 Annual Meeting and published in *Molecular Cancer Therapeutics* and *Oncotarget* demonstrated the compound's differentiation from other CDK4/6 inhibitors.

G1T38 is currently being evaluated in two Phase 1/2 clinical trials: a trial in combination with Faslodex® for people with ER+, HER2- breast cancer ([NCT02983071](#)), and a trial in combination with Tagrisso® for people with EGFR-mutant non-small cell lung cancer ([NCT03455829](#)).

About Faslodex®

Faslodex, developed and commercialized by AstraZeneca, represents a hormonal treatment approach that helps to slow tumor growth by blocking and degrading the estrogen receptor – a key driver of disease progression. Faslodex is indicated for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy, or with disease relapse on or after adjuvant anti-estrogen therapy, or disease progression on anti-estrogen therapy.

Faslodex has also been licensed for use with CDK4/6 inhibitors, palbociclib (in the U.S., EU and several other markets) and abemaciclib (in the U.S. only) for the treatment of women with ER+, HER2- advanced breast cancer, whose cancer has progressed after endocrine therapy. In Japan, Faslodex is also approved for use in combination with any CDK4/6 inhibitor.

About G1 Therapeutics

G1 Therapeutics, Inc., is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for the treatment of cancer. Two of the company's pipeline assets, trilaciclib and G1T38, are CDK4/6 inhibitors, a validated and promising class of oncology therapeutics. Trilaciclib and G1T38 have broad therapeutic potential in many forms of cancer and may serve as backbone therapy of multiple combination regimens. Trilaciclib is a short-acting IV CDK4/6 inhibitor designed to preserve hematopoietic stem cell and immune system function (myelopreservation) during chemotherapy. G1T38 is a potential best-in-class oral CDK4/6 inhibitor for use in combination with other targeted therapies. G1 is also advancing G1T48, a potential best-in-class oral selective estrogen receptor degrader, or SERD, which is targeted for the treatment of ER+ breast cancer.

G1 is based in Research Triangle Park, NC. 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 news release include, but are not limited to, the therapeutic potential of trilaciclib, G1T38 and G1T48, and are based on G1 Therapeutics' 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 G1 Therapeutics'

actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in G1 Therapeutics' filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein and include, but are not limited to, the inherent uncertainties associated with developing new products or technologies and operating as a development-stage company; G1 Therapeutics' ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; G1 Therapeutics' ability to recruit and enroll patients in its studies; competition in the industry in which G1 Therapeutics operates; and market conditions. Except as required by law, G1 Therapeutics assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Contact:

Jeff Macdonald

Head of Investor Relations / Public Relations

917-371-0940

jmacdonald@g1therapeutics.com



G1 Therapeutics