G1 Therapeutics and AstraZeneca Enter Clinical Trial Collaboration in Non-Small Cell Lung Cancer

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Phase 1b/2 study evaluating AstraZeneca's Tagrisso® and G1T38 in EGFR mutation-positive non-small cell lung cancer is expected to initiate in the first quarter of 2018

RESEARCH TRIANGLE PARK, N.C., Nov. 28, 2017 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (NASDAQ:GTHX), a clinical-stage oncology company, today announced a clinical trial collaboration with AstraZeneca to evaluate AstraZeneca's epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) Tagrisso® (osimertinib) in combination with G1's oral CDK4/6 inhibitor G1T38 for the treatment of EGFR mutation-positive non-small cell lung cancer (NSCLC).

Under the terms of the agreement, G1 will sponsor and conduct a Phase 1b/2 study in collaboration with AstraZeneca in patients with NSCLC who have experienced disease progression on first-line EGFR inhibitors and harbor the EGFR T790M mutation. After defining the recommended Phase 2 dose of G1T38 in combination with Tagrisso in the Phase 1b portion, the Phase 2 study is designed to randomize 108 patients (one-to-one) to G1T38 plus Tagrisso or Tagrisso monotherapy to assess progression free survival. G1 plans to initiate the trial in the first quarter of 2018.

"CDK4/6 inhibitors can enhance the efficacy of targeted therapies, and G1T38 has already shown encouraging preclinical and initial clinical data that support a potential best-in-class profile," said Mark Velleca, MD, PhD, Chief Executive Officer of G1 Therapeutics. "The addition of G1T38 to Tagrisso in EGFR mutation-positive non-small cell lung cancer has the potential to prolong the time to disease progression by overcoming resistance mechanisms. We look forward to collaborating with AstraZeneca to advance this compelling combination therapy to patients in need."

"Tagrisso's potential as a new first-line treatment of EGFR mutation-positive NSCLC has been shown in a global Phase 3 clinical trial earlier this year," said Susan Galbraith, Head of Oncology, AstraZeneca Research and Early Development. "We are delighted to explore how Tagrisso in combination with G1T38 could provide additional benefit to patients with EGFRm non-small cell lung cancer."

The financial terms of the non-exclusive collaboration have not been disclosed.

About Tagrisso

Tagrisso (osimertinib) is a third-generation, irreversible EGFR TKI designed to inhibit both EGFR-sensitizing and EGFR T790M-resistance mutations, with clinical activity against central nervous system (CNS) metastases. Tagrisso 40mg and 80mg once-daily oral tablets have been approved in more than 60 countries, including the U.S., EU, Japan and China, for patients with EGFR T790M mutation-positive advanced NSCLC. Tagrisso is also being investigated in the adjuvant setting and in combination with other treatments.

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. G1T38 was well-tolerated with no grade 3/4 adverse events in a Phase 1 study of 75 healthy subjects. G1T38 is currently being evaluated in combination with Faslodex® in a Phase 1b/2a study in patients with estrogen receptor-positive, HER2-negative (ER+, HER2-) breast cancer (NCT02983071). Preliminary Phase 1b data from the breast cancer study are expected to be presented at a medical meeting in the second quarter of 2018.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

For more information, please visit www.astrazeneca.com and follow us on Twitter @AstraZeneca.

About G1 Therapeutics

G1 Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery and development of novel therapeutics for the treatment of cancer. G1's two clinical assets, trilaciclib and G1T38, are CDK4/6 inhibitors, a validated and promising class of targets for anti-cancer therapeutics. Trilaciclib and G1T38 have broad therapeutic potential in many forms of cancer and may serve as the backbone of multiple combination regimens. In addition, G1 is advancing G1T48, a potential first/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, N.C. For more 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 the timing for initiation of additional trials of, patient enrollment in, and data readouts regarding, G1 Therapeutics' product candidates, 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's ability to complete clinical trials for, obtain approvals for, and commercialize any of its product candidates; G1's ability to recruit and enroll patients in our studies; competition in the industry in which we operate; 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.

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