



## Quantum Leap Healthcare Collaborative and G1 Therapeutics Announce the Selection of Trilaciclib in the I-SPY 2 TRIAL for Breast Cancer

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SAN FRANCISCO and RESEARCH TRIANGLE PARK, N.C., Jan. 14, 2020 (GLOBE NEWSWIRE) -- Quantum Leap Healthcare Collaborative™ (QLHC) and G1 Therapeutics, Inc. (Nasdaq: [GTHX](#)) announced today a collaboration to evaluate trilaciclib, an investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy, in a new randomized, investigational treatment arm for the ongoing I-SPY 2 TRIAL™ for neoadjuvant treatment of locally advanced breast cancer.

"The I-SPY 2 TRIAL is designed to evaluate agents with the goal of accelerating the pace of promising effective and potentially less toxic treatments to patients who are most likely to benefit quickly. We are excited to include trilaciclib in I-SPY 2, with the goal of determining whether adding trilaciclib to neoadjuvant chemotherapy-based treatment, either with or without an immune checkpoint inhibitor, increases the probability that the tumor will disappear prior to surgery, signaling a much better outcome and survival. The study will also measure how much chemotherapy lowers red and white blood cell levels (myelosuppression) to assess whether trilaciclib reduces any of these negative side effects, which have a significant impact on patient care and quality of life," stated Dr. Laura J. Esserman, M.D., MBA, Principal Investigator of I-SPY 2 and Director of the Carol Franc Buck Breast Care Center at the UCSF Helen Diller Family Comprehensive Cancer Center. "As with other arms, the I-SPY 2 TRIAL has the ability to evaluate the drug across an array of biomarker signatures to learn the chance of how it will benefit patients and predict success in a confirmatory phase 3 trial."

"The I-SPY 2 program is recognized as a leading breast cancer research initiative, and we are excited about the opportunity to evaluate the potential of trilaciclib to improve outcomes for a range of breast cancer subtypes. In our Phase 2 trial of women with triple-negative breast cancer, patients who received trilaciclib plus chemotherapy showed significant improvement in overall survival and reductions in the rate of red blood cell transfusions versus patients treated with chemotherapy alone," said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D at G1. "The I-SPY 2 study will allow us to evaluate trilaciclib for the first time in combination with several broadly-used chemotherapy classes. It will provide important data regarding which patients may benefit from treatment with trilaciclib and inform our future development plans."

The I-SPY 2 TRIAL, sponsored by QLHC, is a standing Phase 2 randomized, controlled, multicenter platform with an innovative Bayesian adaptive randomization design aimed to rapidly screen and identify promising new treatments in specific subgroups of adults with newly-diagnosed, high-risk (high likelihood of recurrence), locally-advanced breast cancer (Stage II/III). G1 Therapeutics will provide funding and trilaciclib and QLHC will be responsible for running the trial.

Trilaciclib will be evaluated across all high-risk, early-stage breast cancer subtypes (including HR+, HER2+ and triple-negative breast cancer). All patients will receive standard neoadjuvant treatment, including chemotherapy (and anti-HER2 Mab for HER2+ disease) prior to surgical resection of breast tissue. Patients in two arms of the study will also receive an anti-PD-1 immunotherapy in combination with paclitaxel prior to surgery. Biomarker data to evaluate the impact of trilaciclib on the tumor immune microenvironment, as well as pre-specified endpoints to evaluate anti-tumor efficacy and myelopreservation will be collected.

### About Trilaciclib

Trilaciclib is a first-in-class investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy. Based on results from three randomized trials in patients with small cell lung cancer, trilaciclib has received Breakthrough Therapy Designation, and G1 Therapeutics expects to submit marketing applications in the U.S. and Europe for myelopreservation in small cell lung cancer in 2020. In a randomized trial of women with metastatic triple-negative breast cancer, trilaciclib improved overall survival when administered in combination with chemotherapy compared with chemotherapy alone. In 2020, the company plans to initiate a Phase 3 clinical trial in colorectal cancer and begin a neoadjuvant trial in breast cancer as part of the I-SPY 2 TRIAL.

### About the I-SPY TRIALS

The I-SPY 2 TRIAL (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis) was designed to rapidly screen promising experimental treatments and identify those most effective in specific patient subgroups based on molecular characteristics (biomarker signatures). The trial is a unique collaborative effort by a consortium that includes the Food and Drug Administration (FDA), industry, patient advocates, philanthropic sponsors, and clinicians from more than 20 major U.S. cancer research centers. Under the terms of the collaboration agreement, Quantum Leap Healthcare Collaborative is the trial sponsor and manages all study operations. For more information, visit [www.ispytrials.org](http://www.ispytrials.org).

### About Quantum Leap Healthcare Collaborative

Quantum Leap Healthcare Collaborative (QLHC) is a 501c(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Our mission is to integrate high-impact research with clinical processes and systems technology, resulting in improved data management and information systems, greater access to clinical trial matching and sponsorship, and greater benefit to providers, patients, and researchers. Quantum Leap provides operational, financial, and regulatory oversight to I-SPY. For more information, visit [www.quantumleaphealth.org](http://www.quantumleaphealth.org).

### About G1 Therapeutics

G1 Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development and delivery of innovative therapies that improve the lives of those affected by cancer. The company is advancing three clinical-stage programs. [Trilaciclib](#) is a first-in-class therapy designed to improve outcomes for patients being treated with chemotherapy. Trilaciclib has received Breakthrough Therapy Designation from the FDA; a rolling NDA submission for small cell lung cancer is expected to be completed in the second quarter of 2020. [Rintodestrant \(formerly G1T48\)](#) is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. [Lerociclib](#) is a differentiated oral CDK4/6 inhibitor designed to enable more effective combination treatment strategies.

G1 Therapeutics is based in Research Triangle Park, N.C. For additional information, please visit [www.g1therapeutics.com](http://www.g1therapeutics.com) and follow us on Twitter [@G1Therapeutics](https://twitter.com/G1Therapeutics).

### **Company 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, those relating to lerociclib's differentiated safety and tolerability profile over other marketed CDK4/6 inhibitors, the therapeutic potential of trilaciclib and the timing of marketing applications in the U.S. and Europe for trilaciclib in SCLC, whether adding trilaciclib to neoadjuvant chemotherapy-based treatment, either with or without a checkpoint inhibitor, will increase the probability of pathologic complete response, and whether the I-SPY 2 TRIAL will provide important data regarding which patients may benefit from treatment with trilaciclib and inform future development plans, and 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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