G1 Therapeutics Provides Update on Phase 3 PRESERVE 2 Trial in Patients Receiving Trilaciclib Prior to First Line Chemotherapy in Metastatic Triple Negative Breast Cancer (mTNBC)

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- PRESERVE 2 Did Not Achieve Statistical Significance in the Primary Endpoint of Overall Survival (OS) in the Intent-to-Treat (ITT) Population -

- The Company Will Focus its Efforts on the Global Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Market -

- G1 is Sufficiently Funded to Achieve Anticipated Company Profitability in the Second Half of 2025 -

- Management to Host Webcast and Conference Call Today at 8:30 AM ET -

RESEARCH TRIANGLE PARK, N.C., June 24, 2024 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced topline results from the final OS analysis of its Phase 3 PRESERVE 2 trial evaluating the efficacy and safety of trilaciclib administered prior to chemotherapy (gemcitabine and carboplatin; GCb) in patients with metastatic TNBC.

The study did not demonstrate a statistically significant treatment effect in the ITT population (n=187) with a hazard ratio (HR) of 0.91 (p=0.884). The median OS in the trilaciclib plus GCb arm was 17.4 months compared to 17.8 months in the control arm. Median OS numerically favored the trilaciclib arm in both PD-L1 subgroups (positive and negative), though neither achieved statistical significance. Varying effects were observed across regions and patients who received different types of subsequent therapies; these findings will be evaluated further. The safety profile of trilaciclib with GCb observed in the trial was consistent with prior studies, and no new safety signals were identified. Consistent with other trilaciclib studies, evidence of myeloprotection was observed, including a reduction in the occurrence of severe neutropenia, which occurred in 8% of patients who received trilaciclib compared to 29% of patients in the control arm. The Company will submit the results of this trial to a future medical conference.

“The unexpected results from PRESERVE 2 underscore the challenge of developing new therapies for triple negative breast cancer,” said Jack Bailey, Chief Executive Officer of G1 Therapeutics. “We are disappointed that this trial did not deliver the benefit that we anticipated to people living with TNBC. We are also grateful to the patients who participated in this trial, their families, and their healthcare teams including the clinicians and their staff.”

Mr. Bailey continued, “We will now further our focus on both accelerating and expanding the growth of the ES-SCLC business to achieve anticipated company profitability in the second half of 2025 and evaluating other myeloprotection uses for trilaciclib. We are also pursuing ex-US partners to expand the use of COSELA® (trilaciclib) globally.”

Financial Guidance

G1 today reaffirmed its full year 2024 COSELA net revenue guidance and updated its cash runway guidance. G1's guidance is based on current expectations for continued sales growth of COSELA in the U.S. and achievement of its forecasts.

The Company expects to generate between $60 million and $70 million in COSELA net revenue in 2024. Additionally, G1 plans to wind down the Phase 3 PRESERVE 2 trial, discontinue the anticipated hiring of staff and investment for a 1L TNBC indication and make targeted headcount reductions outside of the existing commercial organization to streamline the Company. These efforts are expected to provide sufficient cash runway to achieve anticipated company profitability in the second half of 2025.

Webcast and Conference Call

G1 will host a webcast and conference call at 8:30 a.m. ET today to discuss PRESERVE 2. Please note the following process to access the call via telephone: To register and receive a dial in number and unique PIN to access the live conference call, please follow this link to register online. While not required, it is recommended to join 10 minutes prior to the start of the event. A live and archived webcast will be available on the Events & Presentations page of the Company’s website: www.g1therapeutics.com. The webcast will be archived on the same page for 90 days following the event.

About G1 Therapeutics
G1 Therapeutics, Inc. is a commercial-stage oncology biopharmaceutical company whose mission is to develop and deliver next-generation therapies that improve the lives of those affected by cancer, including the Company's first commercial product, COSELA® (trilaciclib). G1's goal is to provide innovative therapeutic advances for people living with cancer. G1 is based in Research Triangle Park, N.C. For additional information, please visit http://www.g1therapeutics.com and follow us on X (formerly known as Twitter) @G1Therapeutics and LinkedIn.

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," "could", "believe," "goal", "projections," "estimate," "intend," "indicate," "potential," "opportunity," "suggest," 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, expectations with respect to future performance and development and commercialization of our products, including our focus on ES-SCLC and ex-US partnering on COSELA (trilaciclib), our anticipated cash runway and profitability, and financial guidance for full year 2024. Each of these forward-looking statements involves significant risks and uncertainties that could cause the actual results to differ materially from those discussed in the forward-looking statements. 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 our filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein and include, but are not limited to, our dependence on the commercial success of COSELA (trilaciclib); the development and commercialization of new drug products is highly competitive; our ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; our 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 commercial-stage company; chemotherapy shortages and market conditions. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties. We caution readers not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Except as required by law, we assume 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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