G1 Therapeutics Presents Updated Data from Phase 1b/2a Trial of Oral CDK4/6 Inhibitor Lerociclib at 2019 San Antonio Breast Cancer Symposium (SABCS)

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RESEARCH TRIANGLE PARK, N.C. and SAN ANTONIO, Dec. 11, 2019 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today reported additional data from the Phase 1b/2a clinical trial investigating its oral CDK4/6 inhibitor lerociclib in combination with fulvestrant for the treatment of estrogen receptor-positive, HER2-negative (ER+, HER2-) breast cancer. Updated findings presented during a poster session (P1-19-17) at the 2019 San Antonio Breast Cancer Symposium (SABCS) showed lerociclib, dosed without a drug holiday, has a differentiated safety and tolerability profile than observed in clinical trials with currently marketed CDK4/6 inhibitors. Preliminary efficacy findings were consistent with other CDK4/6 inhibitors used in combination with fulvestrant.

The Phase 1b/2a trial is designed to evaluate the safety, tolerability and efficacy of lerociclib administered continuously in combination with fulvestrant as a treatment for ER+, HER2- breast cancer and identify the dose and schedule for future trials of lerociclib. Further investigation is ongoing, with longer-duration efficacy data required to determine the dose for future study in a Phase 3 clinical trial. The company expects to share an update in 2020.

“We designed lerociclib to improve upon the clinical profiles of currently available CDK4/6 inhibitors,” said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. “The findings from this trial showed that twice-daily dosing of lerociclib with fulvestrant was well tolerated, with 150 mg demonstrating less neutropenia and gastrointestinal side effects. We look forward to evaluating the mature efficacy data for the 150 mg and 200 mg cohorts as we prepare to advance lerociclib into pivotal development.”

About the Lerociclib Trial
Patients enrolled in the Phase 1a/2b clinical trial are women of any menopausal status with locally advanced or metastatic ER+, HER2- breast cancer who had progressed during or within 12 months after adjuvant therapy or progressed during or within two months after endocrine therapy for advanced or metastatic disease. As of October 7, 2019, 110 trial participants received lerociclib at doses ranging from 200-650 mg once daily (QD) and 100-250 mg twice daily (BID). Fulvestrant 500 mg was administered on Day 1, 15, 29, and then once monthly, per standard of care. Preliminary findings were announced in June 2018 (press release here).

Updated Findings

- Continuous lerociclib dosing with fulvestrant was well tolerated, with BID dosing having a differentiated safety profile
  -- Low rates of Grade 4 neutropenia support continuous lerociclib dosing without a drug holiday
  -- BID dosing demonstrated an improved safety and tolerability profile compared with QD dosing, with lower rates of gastrointestinal adverse events (AEs)
  -- Low rates of lerociclib-related stomatitis and alopecia were observed across all dose levels in both dosing schedules
- Coadministration of fulvestrant had minimal impact on the pharmacokinetics (PK) of lerociclib
- The efficacy data were consistent with those from other CDK4/6 inhibitors used in combination with fulvestrant
  -- The combination of lerociclib and fulvestrant was active, with a 65.2% clinical benefit rate and a median progression-free survival (PFS) of 15 months observed across the entire study; median PFS was 12.8 months for all QD dose levels combined and not reached for all BID dose levels combined

The poster presented at SABCS is available on the G1 website here.

About Lerociclib
Lerociclib is a differentiated oral CDK4/6 inhibitor being developed for use in combination with other targeted therapies in certain types of breast and lung cancer. Preliminary clinical data in estrogen receptor-positive, HER2-negative (ER+, HER2-) breast cancer have demonstrated proof-of-concept of the differentiated clinical profile of lerociclib versus currently marketed CDK4/6 inhibitors, with improved tolerability and less neutropenia. Neutropenia is one of the main toxicities associated with CDK4/6 inhibition. Current treatments require frequent blood testing for neutropenia. Less monitoring would mean fewer office visits and blood draws, improving the experience for patients and reducing the burden on physician offices and costs to the healthcare system.

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 will begin in 4Q19 and is expected to be completed in the second quarter of 2020. Lerociclib is a differentiated oral CDK4/6 inhibitor designed to enable more effective combination treatment strategies. G1T48 is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. G1 Therapeutics also has an active discovery program focused on cyclin-dependent kinase targets.

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 news release include, but are not limited to, those relating to lerociclib's differentiated safety and tolerability profile over other marketed CDK4/6 inhibitors, whether lerociclib's preliminary efficacy findings will continue to be consistent with other CDK4/6 inhibitors, lerociclib's potential advancement into pivotal trials and the therapeutic potential of trilaciclib and the timing of marketing applications in the U.S. and Europe for trilaciclib in SCLC, 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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