G1 Therapeutics Initiates Three Drug Development Programs in Breast Cancer

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- *Phase 2 trial of trilaciclib in triple-negative breast cancer*
- *Phase 1b/2a trial of G1T38 in estrogen receptor-positive breast cancer*
- *Oral SERD (G1T48) in IND-enabling studies; Phase 1 trial planned for 4Q17*

RESEARCH TRIANGLE PARK, NC – January 10, 2017 – G1 Therapeutics, Inc., a clinical-stage oncology company, announced today the expansion of its pipeline of novel cancer therapies with the initiation of three development programs in breast cancer. G1 is enrolling a Phase 2 study of its intravenous CDK4/6 inhibitor trilaciclib for the treatment of triple-negative breast cancer (TNBC), and a Phase 1b/2a study of its oral CDK4/6 inhibitor G1T38 for the treatment of estrogen receptor-positive, HER2-negative (ER+, HER2-) breast cancer. In addition, G1 is advancing G1T48, its oral selective estrogen receptor degrader (SERD) with the goal of commencing a Phase 1 trial in the fourth quarter of 2017.

"Our CDK4/6 inhibitors have generated compelling clinical data, and we are thrilled to expand our pipeline to breast cancer, an area of significant need that still lacks adequate treatment options," said Raj Malik, MD, Chief Medical Officer of G1 Therapeutics. "We also recognize the strong scientific rationale and clinical validation for combining a SERD and a CDK4/6 inhibitor, and look forward to evaluating G1T48 and G1T38 as a potential best-in-class combination therapy for breast cancer patients."

"The expansion of our pipeline into breast cancer is the next step in our goal of building a fully integrated oncology company with novel products that address multiple indications," added Mark Velleca, MD, PhD, Chief Executive Officer of G1 Therapeutics.

Details of the clinical studies are as follows:

> **Phase 2 study of trilaciclib for the treatment of TNBC**
> This multi-center, randomized, open-label study will investigate the clinical benefit of trilaciclib combined with gemcitabine / carboplatin as a first- or second-line treatment for patients with metastatic TNBC. The study will enroll approximately 90 patients in the U.S. and Europe.
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> For additional information, please visit ClinicalTrials.gov: NCT02978716.
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> **Phase 1b/2a study of G1T38 for the treatment of ER+, HER2- breast cancer**
> This multi-center, open-label, dose-escalation / expansion study will investigate the clinical benefit of G1T38 in combination with Faslodex® as a potential treatment for patients with ER+, HER2- breast cancer after endocrine therapy failure. The study will enroll approximately 80 patients in Europe.
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> For additional information, please visit ClinicalTrials.gov: NCT02983071.

About Trilaciclib (G1T28)
Trilaciclib is a potential first-in-class short-acting CDK4/6 inhibitor in development to preserve hematopoietic stem cells and enhance immune system function during chemotherapy. Trilaciclib is administered intravenously prior to chemotherapy and has the potential to significantly improve treatment outcomes.
Trilaciclib is being evaluated in three Phase 2 clinical trials: a study in newly diagnosed, treatment-naive small-cell lung cancer patients (NCT02499770), a study in previously treated small-cell lung cancer patients (NCT02514447), and a study in patients with triple-negative breast cancer (NCT02978716).

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 ER+, HER2- breast cancer (NCT02983071).

About G1T48
G1T48 is a proprietary, orally available, selective estrogen receptor degrader (SERD). In preclinical studies, G1T48 has been shown to be more potent than Faslodex® and to have superior anti-tumor efficacy versus other SERDs in development. G1T48 is currently in IND-enabling studies, and is on track for Phase 1 clinical development in the fourth quarter of 2017.

About G1 Therapeutics, Inc.
G1 Therapeutics is a clinical-stage biopharmaceutical company developing novel, small-molecule therapies that address significant unmet needs in the treatment of cancer. The company is advancing a pipeline of potential best-in-class and first-in-class drug candidates in multiple oncology indications. G1 is privately held and based in Research Triangle Park, NC.

Visit www.g1therapeutics.com for more information.

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