

G1 Therapeutics Announces Initiation of Two Phase 1b/2a Trials of CDK4/6 Inhibitor G1T28 in Small-Cell Lung Cancer

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- *Trials will assess G1T28 as a bone marrow and immune system chemoprotectant in newly diagnosed and previously treated patients with small-cell lung cancer*
- *G1T28 was well-tolerated and demonstrated robust, reversible, G1 cell cycle arrest of bone marrow stem cells in a Phase 1a trial*

RESEARCH PARK TRIANGLE, NC, August 11, 2015 – G1 Therapeutics, Inc., a clinical-stage oncology company, announced today that it has initiated two Phase 1b/2a trials of the CDK4/6 inhibitor G1T28 in patients with small-cell lung cancer (SCLC). G1T28 is an intravenous (IV) therapy being studied as a bone marrow and immune system chemoprotectant in patients with SCLC who are receiving chemotherapy. The two Phase 1b/2a trials consist of an 80-patient randomized first-line study (02 Study) and a 40-patient single-arm second / third-line study (03 Study).

"More than 300,000 patients per year are treated with chemotherapy for CDK4/6-independent tumors in the U.S. alone, but there are no approved therapies that protect a patient's bone marrow and immune system from the toxicity it causes," said Raj Malik, MD, Chief Medical Officer of G1 Therapeutics. "In a Phase 1a trial, G1T28 demonstrated a robust, reversible, G1 cell cycle arrest of bone marrow stem cells and displayed an ideal profile for use as an IV chemoprotectant. These Phase 1b/2a proof-of-concept trials will evaluate G1T28's ability to provide multi-lineage bone marrow and immune system protection in newly diagnosed and previously treated patients with SCLC."

"G1T28 is a first-in-class approach that could change the oncology treatment paradigm by mitigating myelosuppression and improving tumor responses and health outcomes. We are thrilled to have the first patient dosed and to assess these potential benefits," said Mark Velleca, Chief Executive Officer of G1 Therapeutics. "We believe that G1T28 could obviate the need for hematopoietic growth factors and has the potential to become part of emerging treatment regimens that combine chemotherapy with immune system modulation."

Details on the 02 Study and 03 Study are as follows:

02 Study: G1T28 in Combination with Etoposide and Carboplatin in Extensive-Stage SCLC

This multi-center, randomized, placebo-controlled, study will investigate the potential clinical benefit of G1T28 when administered IV just prior to standard doses of carboplatin and etoposide as a first-line treatment for patients with newly diagnosed extensive-stage SCLC. The study will enroll approximately 80 patients. Outcome measurements include assessment of hematologic parameters and toxicities, infections, chemotherapy dose reductions, utilization of growth factors and blood transfusions, and assessment of anti-tumor activity. For additional study details, including enrollment criteria, please visit: <https://clinicaltrials.gov/ct2/show/NCT02499770?term=g1t28&rank=1>.

03 Study: G1T28 in Patients with Previously Treated Extensive-Stage SCLC Receiving Topotecan Chemotherapy

This multi-center single-arm study will investigate the potential clinical benefit of G1T28 when administered IV just prior to standard doses of topotecan in patients previously treated for extensive-stage SCLC. The study will enroll approximately 40 patients. Outcome measurements include assessment of hematologic parameters and toxicities, infections, chemotherapy dose reductions, utilization of growth factors and blood transfusions, and assessment of anti-tumor activity. For additional study details, including enrollment criteria, please visit: <https://clinicaltrials.gov/ct2/show/NCT02514447?term=g1t28&rank=2>.

G1T28 Phase 1a Trial Results

G1T28 demonstrated robust, transient G1 cell-cycle arrest of hematopoietic stem and progenitor cells in a first-in-human Phase 1a trial. The compound was well-tolerated with no dose-limiting toxicities or serious adverse events, displayed an

ideal pharmacokinetic / pharmacodynamic profile for use as an IV chemoprotectant, and identified the dose for subsequent trials in SCLC. G1T28 Phase 1a data were presented at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting.

About G1 Therapeutics, Inc.

G1 Therapeutics, Inc. is a privately held clinical-stage pharmaceutical company based in Research Triangle Park, NC that focuses on the discovery and development of novel, small-molecule therapies to address significant unmet needs in oncology. The company is leveraging its proprietary kinase drug discovery platform to advance a pipeline of best-in-class compounds and first-in-class drug candidates that address two markets: CDK4/6 antineoplastics and protection of the bone marrow and immune system from damage by chemotherapy (chemoprotection).

Visit www.g1therapeutics.com for more information.

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