Galera Therapeutics Announces Dosing of First Patient in Pivotal Phase 3 'ROMAN' Clinical Trial of Avasopasem Manganese (GC4419)

Oct 15, 2018

Data from pivotal trial of avasopasem manganese for the reduction of severe oral mucositis in patients with head and neck cancer intended to support New Drug Application

MALVERN, Penn. — October 15, 2018 – Galera Therapeutics, Inc., a clinical-stage biotechnology company focused on the development of drugs targeting oxygen metabolic pathways with the potential to transform cancer radiotherapy, today announced the first patient has been dosed in a Phase 3 clinical trial of avasopasem manganese (GC4419) to reduce the incidence and severity of severe oral mucositis (SOM) in patients with head and neck cancer, its lead indication.

The trial, "ROMAN: **R**eduction in **O**ral **M**ucositis with **A**vasopasem ma**N**ganese (GC4419)—Phase 3 trial in Patients Receiving Chemoradiotherapy for Locally-Advanced, Non-Metastatic Head and Neck Cancer," is a randomized, double blind, placebo-controlled trial designed to evaluate the ability of avasopasem manganese to reduce the incidence and severity of radiation-induced SOM in adult patients with locally advanced, non-metastatic squamous cell head and neck cancer receiving seven weeks of radiation therapy plus cisplatin. In the United States, more than 50 percent of patients with cancer receive radiotherapy at some time in their treatment. In patients with head and neck cancer, radiotherapy is a mainstay of treatment. Approximately 70 percent of patients receiving radiotherapy develop SOM, as defined by the World Health Organization as Grade 3 or 4, which is the most debilitating side effect of the radiotherapy. There is currently no drug approved to prevent or treat SOM.

"This Phase 3 ROMAN trial of avasopasem manganese aims to confirm the statistically significant efficacy seen in our Phase 2b trial in a larger patient population, to ultimately support the submission of a New Drug Application to the U.S. Food and Drug Administration," said Jon T. Holmlund, M.D., Chief Medical Officer of Galera. "We are proud of our team for their incredible work getting this Phase 3 trial underway, bringing avasopasem manganese one step closer to addressing the urgent need for a treatment option for severe oral mucositis."

Patients in the pivotal trial will receive 90 mg of avasopasem manganese or placebo by infusion on the days they receive their radiation treatment. Patients will be randomized to one of the two treatment groups (3:2) and the trial will recruit approximately 335 patients across more than 70 trial sites in the U.S. and Canada. The primary endpoint will be the reduction in the incidence of SOM through treatment period, and the secondary endpoint will be the reduction in the severity of SOM. The trial will also assess the safety and tolerability of avasopasem manganese. Patients will be followed for tumor progression and overall survival.

"Our meetings with both the FDA and European Medicines Agency have been productive and have provided a clear path for the registration of avasopasem manganese," said Mel Sorensen, M.D., President and CEO of Galera. "We are pleased that avasopasem manganese has now entered the final stage of clinical development and look forward to collaborating with patients and their doctors in enrolling and completing this Phase 3 trial. We anticipate enrollment to take less than two years, and we will refine our timeline as the trial progresses."

About Avasopasem Manganese

Avasopasem manganese (GC4419) is a highly selective and potent small molecule dismutase mimetic that closely mimics the activity of human superoxide dismutase enzymes. It works to reduce elevated levels of superoxide caused by radiation therapy by rapidly converting superoxide to hydrogen peroxide and oxygen. Left untreated, elevated superoxide can damage noncancerous tissues and lead to debilitating side effects, including oral mucositis (OM), which can limit the anti-tumor efficacy of radiation therapy. Conversion of elevated superoxide to hydrogen peroxide, which is selectively more toxic to cancer cells, can also enhance the effect of radiation on tumors, particularly with stereotactic body radiation therapy (SBRT), which produces high levels of superoxide.

Avasopasem manganese is being studied in the Phase 3 ROMAN trial of patients with head and neck cancer, its lead indication, for its ability to reduce the incidence and severity of radiation-induced severe oral mucositis. In Galera's 223-patient, double blind, randomized, placebo-controlled Phase 2b clinical trial, avasopasem manganese demonstrated the ability to dramatically reduce the duration of SOM from 19 days to 1.5 days (92 percent), the incidence of SOM through completion of radiation by 34 percent and the severity of patients' OM by 47 percent, while demonstrating acceptable safety when added to a standard radiotherapy regimen. Avasopasem manganese is also currently being studied in combination with SBRT for its anti-tumor effect in a Phase 1/2 trial of patients with locally advanced pancreatic cancer. In addition, in multiple preclinical studies, it demonstrated an increased tumor response to radiation therapy while preventing toxicity in normal tissue.

The FDA granted Breakthrough Therapy designation to avasopasem manganese for the reduction of the duration, incidence and severity of SOM induced by radiation therapy with or without systemic therapy. The FDA also granted Fast Track designation to avasopasem manganese for the reduction of the severity and incidence of radiation and chemotherapy-induced OM.

About Oral Mucositis

Oral mucositis (OM) is a painful and problematic complication during cancer treatment, especially radiation therapy, caused by excessive superoxide generated during treatment that breaks down epithelial cells that line the mouth. Patients suffering from OM experience severe pain, inflammation, ulceration and bleeding of the mouth.

In the United States, more than 50 percent of patients with cancer receive radiotherapy at some time in their treatment. In patients with head and neck cancer, radiotherapy is a mainstay of treatment and approximately 70 percent of patients receiving radiotherapy develop severe oral mucositis (SOM) as defined by the World Health Organization as Grade 3 or 4, which is the most debilitating side effect of the radiotherapy.

SOM can adversely affect cancer treatment outcomes by causing interruptions in radiotherapy, which may compromise the otherwise good prognosis for tumor control in many of these patients. SOM may also inhibit patients' ability to eat solid food or even drink liquids, and can cause serious infections. Further, the costs of managing these side effects are substantial, particularly when hospitalization and/or surgical placement of PEG tubes to maintain nutrition and hydration are required. There is currently no drug approved to prevent or treat SOM in patients with head and neck cancer.

About Galera Therapeutics

Galera Therapeutics, Inc. is a privately held, clinical-stage biotechnology company focused on discovering and developing novel therapeutics targeting oxygen metabolic pathways with the potential to transform how radiation therapy is used in patients with cancer. Galera's lead product candidate is avasopasem manganese (GC4419), a highly selective and potent small molecule superoxide dismutase enzyme mimetic that rapidly converts superoxide to hydrogen peroxide and oxygen. Avasopasem manganese is being studied in the Phase 3 ROMAN trial for its ability to reduce the incidence and severity of radiation-induced severe oral mucositis in patients with head and neck cancer, its lead indication. The U.S. Food and Drug Administration granted Fast Track and Breakthrough Therapy designations to avasopasem manganese. In September 2018, Galera announced a financing of $150 million which permits the company to advance avasopasem manganese through Phase 3 and to New Drug Application submission. Galera is headquartered in Malvern, PA. For more information, visit www.galeratx.com.

###

Media Contact:
Heather Anderson
6 Degrees
980-938-0260
handerson@6degreespr.com