



Galera Therapeutics Announces Two-Year Tumor Outcomes Data for GC4419

Oct 08, 2019

Data reinforce potential of GC4419 to become a promising treatment for reducing the incidence of severe oral mucositis in patients with head and neck cancer

MALVERN, Penn. — October 8, 2019— Galera Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer, today announced final data from its two-year tumor outcomes follow up of patients with locally advanced squamous cell head and neck cancer treated with its lead product candidate, GC4419 (avasopasem manganese).

GC4419, a highly selective and potent small molecule dismutase mimetic, is being developed to reduce the incidence and severity of radiation-induced severe oral mucositis (SOM), its lead indication. SOM is a common, debilitating complication of radiotherapy in patients with head and neck cancer. There is currently no FDA-approved drug to treat SOM in patients with head and neck cancer.

As part of its Phase 2b clinical trial of GC4419 in patients with locally advanced head and neck cancer, Galera assessed tumor outcomes of the patients over a two-year period following radiotherapy. Patients in the trial received seven weeks of radiation therapy plus cisplatin, and were treated with either 30 mg or 90 mg of GC4419 or placebo by infusion on the days they received their radiation treatment. At both the one-year interim assessment and final two-year mark, tumor outcomes were maintained across all four measures – overall survival, progression-free survival, locoregional control and metastasis-free survival – in both GC4419 dose groups (30 mg and 90 mg) compared to placebo.

“We are pleased with these data, which demonstrated GC4419, when added to a standard radiotherapy regimen, maintained the efficacy of treatment for head and neck cancer and reduced debilitating radiation-induced oral mucositis,” said Mel Sorensen, M.D., President and CEO of Galera Therapeutics. “GC4419 achieved meaningful reductions in the duration, incidence and severity of SOM in the completed Phase 2b trial. These two-year tumor data further reinforce the potential of GC4419 to be a promising treatment to reduce radiation toxicities and complement standard radiotherapy regimens in head and neck cancer.”

Full results will be submitted for presentation at a future scientific meeting.

GC4419 is being evaluated in the ongoing pivotal ROMAN Phase 3 trial in patients with head and neck cancer, with topline data anticipated in the first half of 2021. GC4419 is also currently being studied in combination with stereotactic body radiation therapy for its anti-tumor effect in a pilot Phase 1b/2a trial of patients with locally advanced pancreatic cancer.

About GC4419 (Avasopasem Manganese)

Galera’s lead product candidate, GC4419 (avasopasem manganese), is a highly selective and potent small molecule dismutase mimetic that is being developed for the reduction of SOM in patients with head and neck cancer. GC4419 is designed to rapidly convert superoxide to hydrogen peroxide, reducing mucosal damage and thereby the incidence and severity of mucositis. Left untreated, elevated superoxide can damage noncancerous tissues and lead to debilitating side effects, including oral mucositis, which can limit the anti-tumor efficacy of radiation therapy.

GC4419 is being studied in the Phase 3 ROMAN clinical trial of patients with locally advanced head and neck cancer, its lead indication, for its ability to reduce the duration, incidence and severity of radiation-induced severe oral mucositis. In Galera’s 223-patient, double blind, randomized, placebo-controlled Phase 2b clinical trial, GC4419 demonstrated the ability to reduce the median duration of severe oral mucositis (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, and GC4419 was well tolerated in the trial when added to a standard radiotherapy regimen. GC4419 is also currently being studied in combination with SBRT for its anti-tumor effect in a pilot Phase 1b/2a trial of patients with locally advanced pancreatic cancer. In addition, in multiple preclinical studies, GC4419 demonstrated an increased tumor response to radiation therapy while preventing toxicity in normal tissue.

The U.S. Food and Drug Administration granted Breakthrough Therapy and Fast Track designations to GC4419 for the reduction of the duration, incidence and severity of SOM induced by radiotherapy in patients with head and neck cancer.

About Galera Therapeutics

Galera Therapeutics, Inc. is a privately held, clinical-stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. Galera’s lead product candidate is GC4419 (avasopasem manganese), a highly selective and potent small molecule dismutase mimetic that is designed to rapidly convert superoxide to hydrogen peroxide. GC4419 is being studied in the Phase 3 ROMAN trial for its ability to reduce the duration, incidence and severity of radiation-induced severe oral mucositis in patients with locally advanced head and neck cancer, its lead indication. The FDA granted Fast Track and Breakthrough Therapy designations to GC4419 for the reduction of the duration, incidence and severity of severe oral mucositis induced by radiotherapy. 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