



Galera Therapeutics Completes Enrollment in Phase 2b Clinical Trial with Lead Compound GC4419 for Treatment of Oral Mucositis

June 15, 2017

Company expects to report topline results in 4Q 2017

MALVERN, PA, June 15, 2017 — Galera Therapeutics, Inc. announced today that it has completed enrollment in its phase 2b clinical trial evaluating the efficacy, safety and tolerability of GC4419 as a treatment for reducing the incidence and duration of oral mucositis (OM) in head and neck cancer patients receiving chemoradiation therapy. GC4419 is a novel dismutase mimetic designed to prevent the damaging effects of radiation in normal tissue by rapidly converting superoxide to hydrogen peroxide.

"We are pleased with the rapid enrollment as well as investigator and patient enthusiasm for this trial," said J. Mel Sorensen, M.D., Galera Therapeutics President and Chief Executive Officer. "This trial is intended to identify a safe and effective dose of GC4419 and, if positive, will guide the design of our phase 3 clinical program."

The phase 2b clinical trial is a double blind, randomized, controlled trial of 223 head and neck cancer patients treated with either 30mg or 90mg of GC4419 or placebo infusion on the days they receive their radiation treatment. The primary outcome measure is the duration of severe OM (defined as World Health Organization Grade 3 or 4) experienced by patients receiving 7 weeks of radiation therapy plus cisplatin. Secondary endpoints include incidence of severe OM.

About Oral Mucositis (OM)

Oral mucositis is a common, debilitating side effect of radiation therapy (RT) in head and neck cancer (HNC) patients that can also adversely affect cancer treatment outcomes. Severe OM, defined by the World Health Organization as Grade 3 or 4 OM, occurs in 60 to 80 percent of HNC patients receiving radiation therapy. In addition, patients with severe OM suffer significant pain, may be unable to eat solid food or even drink liquids, and may develop serious infections. Further, the costs of managing these side effects are substantial, particularly when hospitalization and/or surgical placement of feeding tubes to maintain nutrition and hydration are required. Importantly, severe OM may result in interruptions in RT, which can compromise the otherwise good prognosis for tumor control in many of these patients. There is currently no FDA-approved drug to prevent or treat severe OM in head and neck cancer patients.

About GC4419

GC4419 is Galera's first-in-class, small molecule dismutase mimetic with the potential to transform radiation therapy through the rapid, selective, conversion of superoxide to hydrogen peroxide and oxygen. In preclinical studies, GC4419 has been shown to reduce the damaging effects of superoxide on normal tissue, while acting to inhibit tumor growth alone and in combination with multiple cancer treatments. For example, GC4419 was highly effective in reducing the damaging effects of radiation to normal tissue, while also potentiating the effectiveness of radiation on tumors, in multiple animal models. In September 2016, Galera presented results from a Phase 1b/2a clinical trial where GC4419 was generally safe and well tolerated and dramatically reduced the duration and incidence of severe OM versus historical control. At one year follow-up in this trial, there was no evidence of tumor protection with GC4419 when compared to historical control. In January 2016, the company announced the initiation of a randomized, double-blind, placebo controlled phase 2b trial assessing 30mg or 90mg of GC4419 or placebo infusions to reduce the duration and incidence of severe OM in HNC patients receiving chemoradiation. Top-line results from the trial are expected in 4Q 2017.

About Galera Therapeutics, Inc.

Galera Therapeutics, Inc. is a clinical-stage biotechnology company headquartered in Malvern, Pennsylvania, focused on the development of breakthrough drugs targeting oxygen metabolic pathways with the potential to transform how radiation therapy is used in cancer patients. The Company's lead clinical candidate, GC4419, is a highly selective small molecule dismutase mimetic that closely mimics the activity of the human superoxide dismutase enzymes. While the biology of the superoxide dismutase family suggests a broad range of potential applications, GC4419 is initially focused on reducing the side effects of RT. GC4419 is currently being studied in head and neck cancer patients to reduce the duration and incidence of oral mucositis. For more information, visit www.galeratx.com.

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