Galera Therapeutics Announces Promising Innovative Medicines Designation from the United Kingdom's Medicines and Healthcare Products Regulatory Agency for GC4419 for the Reduction of Oral Mucositis in Head and Neck Cancer Patients

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MALVERN, PA, July 31, 2017 — Galera Therapeutics, Inc., a clinical stage biotechnology company announced today that GC4419 has received a Promising Innovative Medicines (PIM) designation in the United Kingdom (UK) by the Medicines and Healthcare Products Regulatory Agency (MHRA) for the reduction of the duration or incidence of radiation and chemotherapy induced severe oral mucositis in head and neck cancer patients. GC4419 is a novel dismutase mimetic designed to prevent the damaging effects of radiation in normal tissue by rapidly converting superoxide to hydrogen peroxide, and is currently in a 223 patient randomized, controlled phase 2b trial with top line results expected in 4Q 2017.

The PIM allowance is an early indication that a product is a promising candidate for the Early Access to Medicines Scheme (EAMS), intended for the treatment of a life-threatening or seriously debilitating condition with the potential to address an unmet need following an early review of the clinical data by the agency. A compound must meet the following criteria to obtain a PIM designation:

1. The condition should be life-threatening or seriously debilitating with a high unmet need;
2. The medicinal product is likely to offer a major advantage over methods currently used in the UK; and
3. The potential adverse effects of the medicinal product are likely to be outweighed by the benefits.

Such a designation is based on early clinical data and is a prerequisite to enter the EAMS scientific opinion assessment step.

"We are pleased that GC4419 has been granted a PIM designation, demonstrating the MHRA's commitment to facilitate the development of GC4419 as an important new therapy for head and neck cancer patients experiencing the debilitating side effect of severe oral mucositis," said J. Mel Sorensen, M.D., Galera Therapeutics President and Chief Executive Officer. "With a positive EAMS opinion, GC4419 could be available to patients prior to receiving marketing authorization in the UK."

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 drug approved 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 223 patient trial are expected in Q4 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.

Media Contact

Mike Beyer
Sam Brown Inc.
mikebeyer@sambrown.com
312-961-2502