Galera Therapeutics Announces Fast Track Designation of GC4419 for Prevention of Oral Mucositis

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Enrolls First Patients in Late-Stage Trial of GC4419 in Head and Neck Cancer Patients

MALVERN, PA – January 7, 2016 – Galera Therapeutics, Inc., today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for GC4419, an investigational drug candidate, for the reduction of severity and incidence of radiation and chemotherapy induced oral mucositis (OM). Galera also announced today that it has begun enrolling patients in a Phase 2b study of GC4419 for the reduction of OM in head and neck cancer (HNC) patients.

The FDA Fast Track process is designed to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. This designation provides for more frequent consultation between the FDA and the sponsor, as well as the potential "rolling review" of completed sections of the New Drug Application (NDA), and potential eligibility for accelerated approval and priority review.

Based on Phase 1b/2a trial results of GC4419 in HNC patients receiving chemoradiation therapy, Galera has begun enrolling patients in a double-blind, randomized Phase 2b clinical trial to prevent OM in this setting. This study will investigate the ability of doses of 30 mg and 90 mg GC4419 administered before each radiation therapy fraction to reduce the incidence, duration and intensity of severe OM, and is expected to enroll 200 patients at approximately 55 U.S. sites.

"These are important milestones for Galera as the Fast Track designation validates the immediate need for treatments for OM, and the potential of GC4419 to address this unmet need," said J. Mel Sorensen, MD, Chief Executive Officer of Galera. "Coupled with our recently initiated Phase 2b trial of GC4419, Fast Track offers the possibility to accelerate bringing this critical advance to HNC patients. If successful, GC4419 will not only reduce pain and suffering for HNC patients, but also improve their cancer treatment outcomes."

About Oral Mucositis (OM)
OM is a common debilitating side effect of radiation treatment in HNC patients. Severe OM, defined by the World Health Organization as Grade 3 or 4 OM, occurs in 60 to 80 percent of HNC patients who receive radiation therapy. Importantly, severe OM may result in interruptions in radiation treatment, which can compromise the otherwise good prognosis for tumor control in many of these patients. In addition, patients suffer significant pain, may develop serious infections, and may be unable to eat solid food or even drink liquids. 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 is required. There is currently no drug approved to prevent or treat severe OM in head and neck cancer patients.

About Galera Therapeutics, Inc.
Galera Therapeutics, Inc. is a clinical-stage biotechnology company, headquartered in Malvern, PA, focused on the development of breakthrough drugs targeting oxygen metabolic pathways. The Company's lead compounds are highly selective small molecule dismutase mimetics that closely mimic the activity of the human superoxide dismutase enzymes. While the biology of the superoxide dismutase family suggests a broad range of potential applications, Galera is initially focusing its development on the prevention of radiation-induced toxicity, including mucositis, and the treatment of cancer.

For more information, visit www.galeratx.com.

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