Galera Therapeutics Announces Presentation at ASCO of Positive Results From Study of GC4419 for the Reduction of Severe Oral Mucositis

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MALVERN, PA – June 6, 2016 – Galera Therapeutics, Inc., a clinical-stage biotechnology company developing new treatments for cancer patients, today announced the presentation of data from a Phase 1b/2a clinical trial of GC4419, an investigational drug candidate for the reduction of chemoradiotherapy-induced oral mucositis (OM), at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL. Study results suggest that GC4419 may reduce the incidence, severity and duration of severe OM in patients receiving chemoradiation therapy for the treatment of head and neck cancer, particularly when GC4419 is administered for the duration of chemoradiation therapy.

The Phase 1b/2a trial assessed the safety and pharmacokinetics of GC4419, administered intravenously prior to each dose of intensity modulated radiotherapy (IMRT) and cisplatin therapy, in 43 patients evaluable for OM. Study endpoints also included assessments of the incidence, time to onset, duration, and severity of OM and initial tumor outcomes for several dosing schedules of GC4419. The study demonstrated that, compared to historic controls, GC4419 appeared to delay onset, shorten the duration and decrease the incidence of severe OM (defined as WHO Grades 3 and 4 OM). The data also showed that the effect of GC4419 was greater if the treatment was administered for the entire duration of IMRT, with larger reductions in all grades of OM experienced by patients receiving full therapy (6-7 weeks) compared to patients receiving partial therapy (3 weeks). For example, investigators reported that the cumulative overall incidence of Grade 4 OM was 25 percent in patients in the 3 week cohort, while patients receiving full therapy had 0 percent. The median duration of severe OM was 2.5 days in patients receiving full therapy, far shorter than the 3-4 week duration in matched historical controls. Patients who received partial therapy still experienced less than 25 percent of the duration of severe OM than reported for matched historical controls.

GC4419 had a safety profile consistent with the IMRT and cisplatin regimen. The most common adverse events were attributable to chemotherapy or head and neck cancer. The plasma half-life of GC4419 was approximately 1.5 hours, with minimal accumulation after repeated dosing. Only 4.3 percent of patients required breaks in IMRT of 5 consecutive fractions or more, as opposed to 15% in published reports of other studies of OM in comparable patients. Patients followed for up to 12 months after completion of IMRT have showed no evidence of tumor protection from GC4419 treatment, with follow-up ongoing.

“We are pleased to share the promising results of the Phase 1b/2a trial, which offer early insight into the potential safety profile and clinical benefit of GC4419 in reducing severe oral mucositis in patients with head and neck cancer,” said J. Mel Sorensen, MD, President and CEO of Galera. “These findings support the continued clinical development of GC4419, as well as our pipeline of breakthrough drugs targeting oxygen metabolic pathways. Enrollment in a randomized Phase 2 trial of GC4419 is currently underway. In addition, we are conducting IND-enabling work on orally active dismutase mimetics.”

About Oral Mucositis (OM)
OM is a common debilitating side effect of radiation treatment in head and neck cancer (HNC) patients. Severe OM, defined as Grade 3 or 4 OM on the World Health Organization Oral Mucositis Scale, 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 GC4419
GC4419 is a superoxide dismutase mimetic, a small molecule drug that selectively targets the superoxide pathway by supplementing the activity of the superoxide dismutase enzyme family to accelerate the conversion of superoxide to hydrogen peroxide. This mechanism is thought to block the large burst of superoxide induced by radiotherapy, the initiating step in the development of OM, and has been shown to be protective of normal tissue but not tumor. In preliminary clinical studies, GC4419 markedly delayed the onset, shortened the duration and decreased the incidence of severe OM when administered intravenously prior to each dose of intensity modulated radiotherapy (IMRT) and cisplatin. GC4419 has now entered randomized Phase 2 development for the reduction of severe OM associated with chemoradiotherapy in head and neck cancer.

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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