Galera Therapeutics Announces Presentation of One-year Follow-up Data From a Phase 1b/2a Study of GC4419 in the Reduction of Severe Oral Mucositis

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Data Presented at the American Society of Radiation Oncology Annual Meeting

MALVERN, PA – September 27, 2016 – Galera Therapeutics, Inc., a clinical-stage biotechnology company developing new treatments for cancer patients, today announced the presentation of final data, including one-year tumor control, from a Phase 1b/2a clinical trial of GC4419, an investigational drug candidate for the reduction of severe chemoradiation-induced oral mucositis (OM), in an oral presentation at the American Society of Radiation Oncology (ASTRO) Annual Meeting. The OM efficacy data from this study in head and neck cancer patients were previously presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June and demonstrated marked reductions in the incidence, severity and duration of severe OM when compared to historical experience.

The new one-year tumor control follow-up data presented today in Boston, Massachusetts further shows that local and distant tumor control, progression-free survival and overall survival compared well with historical experience for patients receiving chemoradiation for head and neck cancers.

This Phase 1b/2a trial assessed the safety and pharmacokinetics of GC4419, administered intravenously prior to each dose of standard intensity modulated radiotherapy (IMRT) and cisplatin therapy, in 46 head and neck cancer patients. The study demonstrated that, compared to historic controls, GC4419 delayed the onset, reduced the incidence, shortened the duration and reduced the intensity of severe OM (defined as WHO Grades 3 and 4 OM). Furthermore, only 4.3% of patients required breaks in IMRT of 5 consecutive fractions or more, as opposed to published rates of 15% in historical studies. In combination, GC4419 had a safety profile consistent with the underlying IMRT and cisplatin regimen.

Now with a full one year of follow-up in all consenting patients (44/46), investigators further report that the overall 1-year local-regional control, the 1-year distant metastasis-free rate and the 1-year overall survival were each 93%. The 1-year progression-free survival was 84%. These rates compare favorably with historic controls.

“We are encouraged to see that after one year of follow-up, tumor control in these patients appears to be maintained,” said J. Mel Sorensen, MD, President and CEO of Galera. “These findings support the continuing development of GC4419, now in a randomized double-blinded Phase 2 trial for this patient population. As radiation oncologists know well, severe OM is a debilitating side effect that can result in treatment interruptions of potentially life-saving chemoradiation therapy. We look forward to advancing our clinical development program for GC4419, as well as our pipeline of orally active dismutase mimetics.”

About Oral Mucositis (OM)
Oral mucositis 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 is designed to convert superoxide to hydrogen peroxide and oxygen. 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 preclinical models. 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 to reduce the incidence, severity and duration of severe OM in patients receiving radiation and chemotherapy for the treatment of 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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