Galera Therapeutics Reports Statistically Significant Results in a 223-Patient Phase 2b Trial of GC4419 for Severe Oral Mucositis in Patients with Head and Neck Cancer

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• Achieved primary endpoint against placebo (p=0.024) demonstrating a statistically significant and clinically meaningful reduction of 92 percent in the duration of severe oral mucositis (SOM)

Secondary Endpoints Consistent with Primary Endpoint

• GC4419 reduced the incidence of SOM through completion of radiotherapy by 34 percent (p=0.009)

• GC4419 also achieved a 36 percent reduction in the overall incidence of SOM through 60 Gy of radiation (p=0.010)

• GC4419 reduced the incidence of debilitating Grade 4 oral mucositis (OM) by 47 percent (p=0.045)

MALVERN, PA, December 18, 2017 (GLOBE NEWSWIRE) — Galera Therapeutics, Inc. today reported positive results from its Phase 2b clinical trial for its lead drug candidate, GC4419 for severe oral mucositis (SOM) in patients with head and neck cancer receiving chemoradiation. In the intent-to-treat population, the 90 milligram (mg) dose of GC4419 met its primary endpoint, demonstrating a highly significant (p=0.024), clinically meaningful and dose-dependent reduction in the duration of SOM as defined by the World Health Organization as Grade 3 or 4. In the pre-specified secondary endpoints, GC4419 demonstrated a consistent effect across all efficacy measures.

“We are excited by these results and believe these are robust data in this patient population. Up to 70 percent of patients with head and neck cancer receiving radiotherapy experience severe oral mucositis, and GC4419 has the potential to become an important treatment in a therapeutic area that has not seen meaningful innovation,” said J. Mel Sorensen, M.D., Galera Therapeutics, President and Chief Executive Officer. “The results of this trial validate the superoxide dismutase mimetic mechanism of action of GC4419, demonstrating its role in reducing the side effects of radiation therapy. We look forward to discussing the results of this trial and our next steps with the FDA.”

The 223-patient, double blind, randomized, placebo-controlled trial treated patients with head and neck cancer with either 30 mg or 90 mg of GC4419 or placebo by infusion on the days they received their radiation treatment. Patients were randomized to one of the three treatment groups (1:1:1) and the trial recruited patients in both the United States and Canada. The primary outcome measure was the duration of SOM experienced by patients scheduled to receive seven weeks of radiation therapy plus cisplatin.

GC4419 was well tolerated and the frequency of treatment-related side effects was comparable across all treatment arms in the trial.

“Oral mucositis is a common and debilitating side effect of chemoradiation to treat head and neck cancer. Oral mucositis can severely and negatively impact quality of life, treatment outcomes and recovery, as many patients are unable to eat or drink for several weeks,” said Carryn Anderson, M.D., Head and Neck Radiation Oncologist, University of Iowa. “New treatment options are urgently needed to reduce or eliminate this problem, and the Phase 2b data on GC4419 suggests a new approach to mitigate oral mucositis in patients with head and neck cancer by preventing the damaging effects of radiation in normal tissue.”

About Oral Mucositis

In the United States, more than 50 percent of patients with cancer receive radiotherapy at some time in their treatment. In patients with head and neck cancer, radiotherapy is a mainstay of treatment and approximately 70 percent of patients receiving chemoradiotherapy develop severe oral mucositis as defined by the World Health Organization as Grade 3 or 4, which is the most debilitating side effect of the radiotherapy. Oral mucositis can also adversely affect cancer treatment outcomes. 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 PEG tubes to maintain nutrition and hydration are required. Importantly, severe OM may result in interruptions in radiotherapy, 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 patients with head and neck cancer.

About Galera Therapeutics

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, including an anti-cancer effect, GC4419 is initially focused on reducing the side effects of radiotherapy. The U.S. Food and Drug Administration granted Fast Track

designation to GC4419 for the reduction and incidence of radiotherapy induced oral mucositis in patients with head and neck cancer. For more information, visit www.galeratx.com.