Data from Galera Therapeutics' 223-Patient Phase 2b Clinical Trial of GC4419 Presented at MASCC/ISOO 2018 Annual Meeting

June 29, 2018

GC4419 demonstrated clinically significant reduction in duration and incidence of severe oral mucositis (SOM) in patients with head and neck cancer

Trial investigator Dr. Carryn Anderson honored with Steven M. Grunberg Memorial Award for excellence in cancer research

MALVERN, Penn. — June 29, 2018— Galera Therapeutics, Inc., a clinical-stage biotechnology company focused on the development of drugs targeting oxygen metabolic pathways with the potential to transform cancer radiotherapy, announced data from the Phase 2b clinical trial evaluating GC4419, a highly selective and potent small molecule dismutase mimetic, were presented today during an oral session at the Multinational Association of Supportive Care in Cancer (MASCC) and the International Society of Oral Oncology (ISOO) 2018 Annual Meeting in Vienna, Austria.

Trial investigator Carryn Anderson, M.D., Radiation Oncologist, University of Iowa Hospitals and Clinics, was awarded the MASCC Steven M. Grunberg Memorial Award, which recognizes the author of the highest-ranking abstract for excellent scientific achievement in supportive care in cancer. Dr. Anderson also delivered the Annual Steven M. Grunberg Memorial Lecture.

"I'm honored that my peers have recognized the clinically meaningful GC4419 data with this prestigious award," said Dr. Anderson. "GC4419 demonstrated the ability to significantly decrease the duration and incidence of severe oral mucositis, highlighting its potential to be an important new adjunct medication for head and neck cancer patients undergoing radiation therapy. There are currently no approved therapies to prevent or mitigate this common and painful side effect of cancer treatment."

"We're delighted that Dr. Anderson has been commended with the Steven M. Grunberg Memorial Award for the GC4419 data," said Mel Sorensen, M.D., President and CEO of Galera. "Earlier this month, our Phase 2b clinical trial data were also selected to be part of the Best of ASCO program. These distinctions from academia speak to the significance of the data and provide further validation of GC4419's promise to address a serious unmet need. We look forward to advancing GC4419 into the next phase of development."

About the GC4419 Phase 2b Data

The 223-patient, double blind, randomized, placebo-controlled trial evaluated the safety of GC4419 and its ability to reduce the duration of radiation-induced severe oral mucositis (SOM) in patients with locally advanced squamous cell head and neck cancer receiving seven weeks of radiation therapy plus cisplatin. Approximately 70 percent of patients receiving chemoradiotherapy develop SOM, as defined by the World Health Organization as Grade 3 or 4, which is the most debilitating side effect of the radiotherapy.

Patients in the trial were treated 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. GC4419 exhibited a safety profile comparable to placebo in the two treatment groups, and was well tolerated. In the trial's intent-to-treat population, the 90 mg dose of GC4419 met the primary endpoint, demonstrating a statistically significant ($p = 0.024$) 92 percent reduction in the median duration of SOM from 19 days to 1.5 days.

In the 90 mg arm, GC4419 also demonstrated a clinically meaningful effect in pre-specified secondary endpoints (incidence and severity of SOM). GC4419 achieved a 34 percent reduction through completion of radiation ($p = 0.009$), and a 36 percent reduction through 60 Gy of radiation ($p = 0.010$), in the overall incidence of SOM, and reduced the severity of patients' OM by 47 percent ($p = 0.045$).

About Oral Mucositis

Oral mucositis (OM) is a painful and problematic complication during cancer treatment, especially radiation therapy, caused by excessive superoxide generated during treatment that breaks down epithelial cells that line the mouth. Patients suffering from OM experience severe pain, inflammation, ulceration and bleeding of the mouth.

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 (SOM) as defined by the World Health Organization as Grade 3 or 4, which is the most debilitating side effect of the radiotherapy.

SOM can adversely affect cancer treatment outcomes by causing interruptions in radiotherapy, which may compromise the otherwise good prognosis for tumor control in many of these patients. SOM may also inhibit patients' ability to eat solid food or even drink liquids, and can cause 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. There is currently no drug approved to prevent or treat SOM in patients with head and neck cancer.

About GC4419

GC4419 is a highly selective and potent small molecule dismutase mimetic that closely mimics the activity of human superoxide dismutase enzymes. GC4419 works to reduce elevated levels of superoxide caused by radiation therapy by rapidly converting superoxide to hydrogen peroxide and oxygen. Left untreated, elevated superoxide can damage noncancerous tissues and lead to debilitating side effects, including oral mucositis (OM), which can limit the anti-tumor efficacy of radiation therapy. Conversion of elevated superoxide to hydrogen peroxide, which is selectively more toxic to

cancer cells, can also enhance the effect of radiation on tumors, particularly with stereotactic body radiation therapy (SBRT), which produces high levels of superoxide.

GC4419 has been studied in patients with head and neck cancer, GC4419's lead indication, for its ability to reduce the incidence and duration of radiation-induced severe oral mucositis (SOM). Results from Galera's 223-patient, double blind, randomized, placebo-controlled Phase 2b clinical trial demonstrated GC4419's ability to dramatically reduce the duration of SOM from 19 days to 1.5 days (92 percent), the incidence of SOM through completion of radiation by 34 percent and the severity of patients' OM by 47 percent, while demonstrating acceptable safety when added to a standard radiotherapy regimen. In addition, in multiple preclinical studies, GC4419 demonstrated an increased tumor response to radiation therapy while preventing toxicity in normal tissue.

The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to GC4419 for the reduction of the duration, incidence and severity of SOM induced by radiation therapy with or without systemic therapy. The FDA also granted Fast Track designation to GC4419 for the reduction of the severity and incidence of radiation and chemotherapy-induced OM.

About Galera Therapeutics

Galera Therapeutics, Inc. is a privately held, clinical-stage biotechnology company focused on discovering and developing novel therapeutics targeting oxygen metabolic pathways with the potential to transform how radiation therapy is used in patients with cancer. Galera's lead product candidate is GC4419, a highly selective and potent small molecule superoxide dismutase enzyme mimetic that rapidly converts superoxide to hydrogen peroxide and oxygen. GC4419 achieved positive results in a Phase 2b clinical trial, which demonstrated its ability to reduce the incidence and duration of radiation-induced severe oral mucositis in patients with head and neck cancer, its lead indication. The U.S. Food and Drug Administration granted Fast Track and Breakthrough Therapy designations to GC4419. Galera is headquartered in Malvern, PA. For more information, visit www.galeratx.com.

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