Data from Galera Therapeutics' Phase 2b Clinical Trial of Avasopasem Manganese (GC4419) Presented at ASTRO Annual Meeting

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MALVERN, Penn. — October 23, 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 its Phase 2b clinical trial evaluating avasopasem manganese (GC4419), a highly selective and potent small molecule dismutase mimetic, in patients with locally advanced squamous cell head and neck cancer were presented today during a scientific session at the American Society for Radiation Oncology Annual Meeting in San Antonio, Tex.

Avasopasem manganese demonstrated statistically significant reductions in the duration, incidence and severity of severe oral mucositis (SOM) in patients with head and neck cancer, its lead indication. The presentation, "A Randomized, Placebo (PBO) Controlled, Double-blind Phase 2b Trial of GC4419 (avasopasem manganese) to Reduce Severe Radiation-related Oral Mucositis (SOM) in Patients (pts) with Locally Advanced Squamous Cell Cancer of the Oral Cavity (OC) or Oropharynx (OP)," was given by trial investigator Carryn Anderson, M.D., Radiation Oncologist, University of Iowa Hospitals and Clinics.

"Approximately 70 percent of patients receiving chemoradiotherapy for head and neck cancer develop severe oral mucositis, and there is currently no drug approved to prevent or treat it. These positive Phase 2b data have been presented at multiple scientific meetings, which reinforces both the strength of the results and the urgency for a treatment to address this pervasive and unmet need," said Mel Sorensen, M.D., President and CEO of Galera. "We are pleased to have initiated our pivotal ROMAN trial of avasopasem manganese in patients with head and neck cancer earlier this month, which seeks to confirm the efficacy seen in this Phase 2b trial."

Additional non-clinical data were presented in a poster discussion, "The Radioprotector GC4419 Ameliorates Radiation Induced Lung Fibrosis While Enhancing the Response of Non-Small Cell Lung Cancer Tumors to High Dose per Fraction Radiation Exposures," by Michael Story, Ph.D., UT Southwestern Medical Center, on October 22. These data highlighted a reduction in normal organ damage and a significant increase in tumor response to radiation therapy with avasopasem managanese. Galera sponsored this research.

For more information and to view the abstracts, please visit https://www.astro.org/Meetings-and-Education/Live-Meetings/2018/2018-Annual-Meeting.

About the Avasopasem Manganese Phase 2b Data

The 223-patient, double blind, randomized, placebo-controlled trial evaluated the safety of avasopasem manganese and its ability to reduce the duration of radiation-induced SOM in patients with locally advanced squamous cell head and neck cancer receiving seven weeks of radiation therapy plus cisplatin.

Patients in the trial were treated with either 30 mg or 90 mg of avasopasem manganese 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. Avasopasem manganese 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 avasopasem manganese 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, avasopasem manganese also demonstrated a clinically meaningful effect in pre-specified secondary endpoints (incidence and severity of SOM). Avasopasem manganese 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 Avasopasem Manganese

Avasopasem manganese (GC4419) is a highly selective and potent small molecule dismutase mimetic that closely mimics the activity of human superoxide dismutase enzymes. It 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.

Avasopasem manganese is being studied in the Phase 3 ROMAN trial of patients with head and neck cancer, its lead indication, for its ability to reduce the incidence and severity of radiation-induced severe oral mucositis. In Galera's 223-patient, double blind, randomized, placebo-controlled Phase 2b clinical trial, avasopasem manganese demonstrated the 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. Avasopasem manganese is also currently being studied in combination with SBRT for its anti-tumor effect in a Phase 1/2 trial of patients with locally advanced pancreatic cancer. In addition, in multiple preclinical studies, it 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 and Fast Track designations to avasopasem manganese for the reduction of SOM in patients with head and neck cancer.

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 radiotherapy develop 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 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 avasopasem manganese (GC4419), a highly selective and potent small molecule superoxide dismutase enzyme mimetic that rapidly converts superoxide to hydrogen peroxide and oxygen. Avasopasem manganese is being studied in the Phase 3 ROMAN trial for its ability to reduce the incidence and severity of radiation-induced severe oral mucositis in patients with head and neck cancer, its lead indication. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem manganese. In September 2018, Galera announced a financing of $150 million which permits the company to advance avasopasem manganese through Phase 3 and to New Drug Application submission. Galera is headquartered in Malvern, PA. For more information, visit www.galeratx.com.

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