Galera Therapeutics Announces Presentation of Data from Phase 2b Clinical Trial of GC4419 at 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

May 16, 2018

Data demonstrate GC4419 reduced duration, incidence and severity of radiation-induced severe oral mucositis in patients with head and neck cancer
Abstract selected for 2018 Best of ASCO program

MALVERN, Penn. — May 16, 2018— Galera Therapeutics, Inc., a clinical-stage biotechnology company developing drugs targeting oxygen metabolic pathways with the potential to transform cancer radiotherapy, today announced that data from its Phase 2b clinical trial of GC4419 for severe oral mucositis in patients with head and neck cancer will be presented during an oral abstract session at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting, to be held June 1-5, 2018 in Chicago. GC4419 is a highly selective and potent small molecule dismutase mimetic that rapidly converts superoxide to hydrogen peroxide and oxygen.

Presentation details are as follows:

Title: Results of a randomized, placebo (PBO) controlled, double-blind P2b trial of GC4419 (avasopasem manganese) to reduce duration, incidence and severity and delay onset of severe radiation-related oral mucositis (SOM) in patients (pts) with locally advanced squamous cell cancer of the oral cavity (OC) or oropharynx (OP)

Abstract Number: 6006

Oral Abstract Session: Head and Neck Cancer

Date / Time / Location: June 3, 2018 / 10-10:12 a.m. CDT / McCormick Place E451

Presenter: Carryn M. Anderson, MD, Radiation Oncologist, University of Iowa Hospitals and Clinics

The abstract has also been selected for inclusion in the 2018 Best of ASCO program, which aims to increase global access to cutting-edge science by condensing highlights from ASCO's Annual Meeting into a two-day program to be held this summer.

For information about the 2018 ASCO Annual Meeting, please visit https://am.asco.org/.

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 duration, incidence and severity 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 duration, incidence and severity 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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