Galera Therapeutics Receives FDA Breakthrough Therapy Designation for GC4419 for the Reduction of Severe Oral Mucositis

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Designation Based on Positive Results of Phase 2b Trial of GC4419

Severe Oral Mucositis Affects 70 Percent of Head & Neck Cancer Patients Receiving Radiotherapy

MALVERN, Penn. — Feb. 28, 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 the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to lead candidate GC4419, a highly selective and potent small molecule dismutase mimetic, for the reduction of the duration, incidence and severity of severe oral mucositis (SOM) induced by radiation therapy with or without systemic therapy.

Approximately 70 percent of patients with head and neck cancer receiving radiotherapy develop SOM, a painful complication caused by excessive superoxide generated during treatment that breaks down epithelial cells in the mouth. By leveraging Galera's dismutase mimetic platform to rapidly convert the superoxide generated by radiation therapy into hydrogen peroxide, GC4419 is thought to reduce the duration, incidence and severity of radiation-induced SOM. There is currently no drug approved to prevent or treat SOM in patients with head and neck cancer.

According to the FDA, Breakthrough Therapy designation is designed to expedite the development and review of a therapy intended to treat a serious condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. The designation provides intensive FDA guidance on an efficient drug development program, an organizational commitment to expedite the FDA development and review, and the potential eligibility, based on supporting clinical data, for rolling and priority review of the marketing application.

"Breakthrough Therapy designation from the FDA further validates the meaningful efficacy and safety results GC4419 demonstrated in our recent Phase 2b clinical trial and highlights the urgent need for a treatment option for severe oral mucositis," said Mel Sorensen, M.D., President and CEO of Galera. "We look forward to working closely with the FDA on the continued development of GC4419 for the reduction of SOM in patients in order to efficiently advance the clinical program and ultimately bring GC4419 to patients in need."

Breakthrough Therapy designation for GC4419 was granted based on the data from Galera's 223-patient, double blind, randomized, placebo-controlled Phase 2b clinical trial in patients with head and neck cancer. In the trial, GC4419 reduced 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.

GC4419 has also received Fast Track designation from the FDA for the reduction of the severity and incidence of radiation and chemotherapy-induced OM.

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 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 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 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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