Galera Therapeutics Announces Dosing of First Patient in Phase 1/2 Pancreatic Cancer Clinical Trial of GC4419

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First Clinical Trial Evaluating Anti-Tumor Effect of GC4419 in Combination with Radiation

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 the first patient with locally advanced pancreatic cancer (LAPC) has been dosed in a Phase 1/2 clinical trial of lead candidate GC4419, a highly selective and potent small molecule dismutase mimetic, at The University of Texas MD Anderson Cancer Center in Houston, Texas.

Pancreatic cancer is the fourth-leading cause of cancer-related death in the United States, with more than 55,000 patients diagnosed annually. Although its five-year overall survival rate is approximately less than 5 percent, it has the potential to improve to more than 25 percent following successful surgical resection, according to the American Cancer Society. Unfortunately, fewer than 10 percent of patients have resectable tumors at diagnosis. A goal of treatment for patients with LAPC is to use a combination of aggressive chemotherapy and radiation to shrink the unresectable tumor and improve the possibility of resectability.

Preclinical data demonstrate GC4419 has the potential to improve the effectiveness of radiation on cancer cells while preventing toxicity in normal tissue. GC4419 leverages Galera's dismutase mimetic platform to rapidly convert the superoxide generated by radiation therapy into hydrogen peroxide, which is lethal to cancer cells in high concentrations. The most profound effects are seen when combining GC4419 with targeted, high doses of radiation like that used in stereotactic body radiation therapy (SBRT). This is because the amount of hydrogen peroxide created by the conversion of superoxide increases as the dose of radiation increases when combined with GC4419, producing a magnified anti-tumor effect.

"Our recently completed 223-patient Phase 2b trial of GC4419 in head and neck cancer demonstrated GC4419's ability to limit radiation-induced healthy tissue damage by reducing the duration, incidence and severity of radiation and chemotherapy-induced oral mucositis," said Mel Sorensen, M.D., President and CEO of Galera. "We seek to build upon these results with this anti-tumor trial in LAPC and generate robust data to demonstrate GC4419's potential to change the management of radiation therapy by both protecting normal tissue and improving the effectiveness of radiation, making more surgical resections possible."

The adaptive, Phase 1/2 dose escalation trial will evaluate the safety and anti-tumor effect (i.e. tumor response and improvement in resectability) of GC4419 in combination with SBRT, compared with SBRT alone, in LAPC patients. The trial, which will enroll 48 patients, will also assess safety and tolerability to determine the maximum tolerated dose of SBRT when combined with GC4419 or placebo.

"GC4419 offers the potential to create two opportunities to improve radiation therapy – by synergistic anti-tumor efficacy and by protecting healthy cells at higher doses of radiation," said Jon T. Holmlund, M.D., Chief Medical Officer of Galera. "This trial will indicate whether SBRT and GC4419 can offer a powerful combination therapy that may improve the survival for LAPC patients by making inoperable tumors operable, which may have important implications for the treatment of pancreatic and other cancers."

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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