



Galera Therapeutics Announces Preclinical Data Demonstrating Potential of GC4419 to Improve Effectiveness of Radiation While Preventing Normal Tissue Toxicity

Posters presented at 2018 American Association for Cancer Research Annual Meeting

MALVERN, Penn. — Apr. 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 preclinical data on GC4419, a highly selective and potent small molecule dismutase mimetic, were presented during poster sessions at the 2018 American Association for Cancer Research (AACR) Annual Meeting in Chicago.

“New therapies that enhance the efficacy of radiation on cancer cells while actually decreasing toxicity to normal tissue are desperately needed to improve therapeutic outcomes in cancer. We are encouraged that the data presented at AACR demonstrate our lead candidate, GC4419, has these properties, underscoring its potential to become an important part of cancer radiotherapy,” said Mel Sorensen, M.D., President and CEO of Galera. “We look forward to building upon positive results from our Phase 2b clinical trial of GC4419 in head and neck cancer with data like this, and with the Phase 1/2 trial of GC4419 in combination with stereotactic body radiation therapy in patients with locally advanced pancreatic cancer, which is underway at The University of Texas MD Anderson Cancer Center.”

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

The studies from The University of Texas Southwestern Medical Center covered in this poster highlight that GC4419 can both significantly reduce the normal tissue toxicity of even high-dose radiation and increase tumor response to radiotherapy. Specifically, either pretreatment or mitigation with GC4419 significantly reduced pulmonary fibrosis in focally irradiated (54 Gy single dose) mice, similar to the reduction in severe oral mucositis seen in Galera’s clinical and pre-clinical studies. Separately, mice with H1299, A549, and HCC827 lung tumor xenografts were treated with GC4419 prior to irradiating the tumors with a single 18 Gy dose. Tumor growth in all three tumor types was significantly delayed ($p = 0.0022$), with the majority of mice apparently tumor-free at study end. Similar enhancements in tumor radiation response were seen with syngeneic lung (LLC) and breast (4T1) tumor models. Subsequent Tumor Cure Dose (TCD50) assays demonstrated that GC4419 enhanced the efficacy of radiation by a factor of 1.67.

GC4419 enhances the response of non-small cell lung carcinoma cell lines to cisplatin and cisplatin plus radiation through a ROS-mediated pathway

These studies from The University of Texas Southwestern Medical Center report that GC4419 synergistically decreased clonogenic survival in H460 and H1299 cells treated with either cisplatin or

cisplatin plus radiation. Consistent with the mechanism in combination with radiation alone, GC4419 was found to reduce intracellular superoxide, increase intracellular hydrogen peroxide, and induce early apoptosis. H1299CAT cells were used to demonstrate that this enhancement of cisplatin and cisplatin plus radiation cancer cell killing is also due to elevation of H₂O₂. The results are particularly intriguing given that the combination of cisplatin and radiotherapy is the primary treatment modality in GC4419's phase 2b trial 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 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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