



Galera Therapeutics Presents Structure and Synthesis of GC4419 at American Chemical Society Annual Meeting

August 20, 2018

Presentation selected as part of The Halpern Legacy Symposium and press program

Phase 3 trial of GC4419 for treatment of severe oral mucositis in patients with head and neck cancer expected to initiate in fourth quarter 2018

MALVERN, Penn. — Aug. 20, 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 that Co-Founder and Chief Scientific Officer Dennis Riley, Ph.D., will deliver an oral presentation as part of The Halpern Legacy Symposium today at the 256th National Meeting & Exposition of the American Chemical Society (ACS) in Boston.

The presentation will detail the chemical design and development of Galera's lead candidate GC4419, a highly selective and potent small molecule dismutase mimetic, for use as a pharmaceutical agent to reduce the undesired side effects of radiation therapy for the treatment of cancer.

Dr. Riley and his team designed GC4419, the synthetic enzyme which mimics the function of the naturally occurring superoxide dismutase enzymes that convert superoxide to molecular oxygen and hydrogen peroxide. GC4419's molecular structure is based on a 15-membered macrocyclic ring complex of manganese(II) and GC4419's GMP synthesis yields a molecule with >99.8 percent chemical purity. The molecule is selective, stable *in vivo* and does not react with other oxygen species, and its low molecular weight contributes to its ability to access a cell's cytosol and mitochondria.

"The ability to develop a low-molecular-weight synthetic enzyme that harnesses the power of dismutase mimetics to function as a radiation response modifier, with efficient chemical synthesis and stability, offers a new paradigm for drug design," said Dr. Riley. "We're pleased to present for the first time publicly on the discovery and structure of GC4419, and honored to have been selected to present as part of The Halpern Legacy Symposium."

By rapidly converting superoxide to oxygen and hydrogen peroxide, GC4419 works to reduce elevated levels of superoxide caused by radiation, which can damage noncancerous tissues and lead to serious side effects, including oral mucositis. Results from a Phase 2b trial demonstrated GC4419's ability to reduce the incidence and duration of radiation-induced severe oral mucositis (SOM) in patients with head and neck cancer, its lead indication. SOM is one of the most common and debilitating side effects of radiotherapy and there are currently no approved therapies to prevent or treat it.

Conversion of superoxide to hydrogen peroxide, which is much more toxic to cancer cells than normal cells, may also enhance the effect of radiation on tumors, particularly with stereotactic body radiation therapy (SBRT), which uses higher doses of radiation and thus produces higher levels of superoxide. GC4419 is 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.

"The design of GC4419 forms the foundation of the drug's highly differentiated approach and potential to change the management of radiation therapy to address serious unmet medical needs in a number of indications," said Mel Sorensen, M.D., President and CEO of Galera. "We look forward to continued evaluation of the promise of GC4419, and plan to initiate a Phase 3 trial of GC4419 for the treatment of SOM in patients with head and neck cancer later this year."

Dr. Riley's presentation will also be included in the ACS press program.

The American Chemical Society, the world's largest scientific society, is a not-for-profit organization chartered by the U.S. Congress. ACS is a global leader in providing access to chemistry-related information and research through its multiple databases, peer-reviewed journals and scientific conferences. ACS does not conduct research, but publishes and publicizes peer-reviewed scientific studies. Its main offices are in Washington, D.C., and Columbus, Ohio.

For more information and to view the abstracts, visit www.acs.org/content/acs/en/meetings/national-meeting.html.

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 incidence and duration 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 incidence and duration 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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