



Galera Therapeutics Announces Presentation of Data from Phase 2b Clinical Trial of Avasopasem Manganese at 2019 NCCN Annual Conference

Mar 21, 2019

Data to be published in the Journal of the National Comprehensive Cancer Network

MALVERN, Penn. — March 21, 2019— 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, today announced data from its Phase 2b clinical trial of lead product candidate avasopasem manganese for the treatment of severe oral mucositis (SOM) in patients with head and neck cancer will be presented at the 2019 National Comprehensive Cancer Network (NCCN) Annual Conference. The meeting will take place March 21-23, 2019, at the Rosen Shingle Creek in Orlando, Fla.

Details of the presentation are as follows:

Title: Reducing the duration, incidence and severity of mucosal injury due to cancer radiation therapy (RT); positive randomized Phase 2b trial results with GC4419 (avasopasem manganese), a small molecule superoxide (SO) dismutase (SOD) mimetic

Session: General Poster Session Two

Date/Time: Friday, March 22, 2019, 12:25-1:40 p.m. EDT

Presenter: Jon T. Holmlund, M.D., Chief Medical Officer, Galera

As one of the top five scoring abstracts, the data will also be shared in an oral presentation during a breakfast session from 7-8 a.m. EDT on Saturday, March 23, 2019, and published in the *Journal of the National Comprehensive Cancer Network* print and online editions.

The 2019 NCCN Annual Conference: Improving the Quality, Effectiveness, and Efficiency of Cancer Care™, brings together cancer researchers, providers and other care professionals to share the latest cancer therapies and provide updates on selected NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the data upon which the NCCN Guidelines® are based, and quality initiatives in oncology. For more information, visit <https://www.nccn.org/professionals/meetings/default.aspx>.

About Avasopasem Manganese

Avasopasem manganese (GC4419) is a highly selective and potent small molecule dismutase mimetic that closely mimics the activity of human superoxide dismutase enzymes. It 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.

Avasopasem manganese is being studied in the Phase 3 ROMAN trial of patients with head and neck cancer, its lead indication, for its ability to reduce the incidence and severity of radiation-induced severe oral mucositis. In Galera's 223-patient, double blind, randomized, placebo-controlled Phase 2b clinical trial, avasopasem manganese demonstrated the 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. Avasopasem manganese is also 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. In addition, in multiple preclinical studies, it 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 and Fast Track designations to avasopasem manganese for the reduction of 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 avasopasem manganese (GC4419), a highly selective and potent small molecule superoxide dismutase enzyme mimetic that rapidly converts superoxide to hydrogen peroxide and oxygen. Avasopasem manganese is being studied in the Phase 3 ROMAN trial for its ability to reduce the incidence and severity of radiation-induced severe oral mucositis in patients with head and neck cancer, its lead indication. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem manganese. In September 2018, Galera announced a financing of \$150 million which permits the company to advance avasopasem manganese through Phase 3 and to New Drug Application submission. Galera is headquartered in

Malvern, PA. For more information, visit www.galeratx.com.

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