



## **Galera Therapeutics Announces Presentation of Data from Phase 2b Clinical Trial of GC4419 at MASCC/ISOO 2018 Annual Meeting**

June 12, 2018

### **Abstract receives Steven M. Grunberg Memorial Award for excellence in cancer research**

**MALVERN, Penn. — June 12, 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, today announced data from its Phase 2b clinical trial of lead product candidate GC4419 for the treatment of severe oral mucositis (SOM) in patients with head and neck cancer will be presented during an oral presentation at the Multinational Association of Supportive Care in Cancer (MASCC) and the International Society of Oral Oncology (ISOO) 2018 Annual Meeting. The meeting will take place June 28-30, 2018, at the Messe Wien Exhibition & Congress Center in Vienna, Austria.

Details of the presentation are as follows:

#### **Presentation Number:** PS037

**Title:** GC4419, a small molecule superoxide dismutase (SOD) mimetic: Randomized trial to reduce chemoradiotherapy (CRT)-induced oral mucositis (OM) in oral cavity (OC)/oropharyngeal (OP) carcinoma (OCC) patients

**Session:** Parallel Session 10: Regimen Related Oral Mucosal Injury – New Age Anti-Cancer Therapies

**Date/Time:** Friday, June 29, 2018, 2:10-3:40 p.m. CEST

**Presenter:** Carryn M. Anderson, M.D., Radiation Oncologist, University of Iowa Hospitals and Clinics

Dr. Anderson will receive the MASCC Steven M. Grunberg Memorial Award and deliver the Annual Steven M. Grunberg Memorial Lecture during the meeting. The award recognizes the author of the highest-ranking abstract for excellent scientific achievement in supportive care in cancer.

MASCC/ISOO 2018 takes a multidisciplinary approach to topics in supportive cancer care. Each year, the MASCC/ISOO Annual Meeting serves as a forum for sharing new knowledge about the symptoms and complications of cancer and its treatments. MASCC and ISOO are dedicated to multidisciplinary research and education of all health professionals who care for people with cancer. Visit [www.mascc.org/meeting](http://www.mascc.org/meeting) for more information.

#### **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 median 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 incidence of the most severe OM by 47 percent, while demonstrating acceptable safety when added to a standard chemoradiotherapy 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](http://www.galeratx.com).

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