Galera Therapeutics Announces Presentation of Avasopasem Manganese Data at ASCO 2020 Virtual Scientific Program

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MALVERN, Penn., April 30, 2020 (GLOBE NEWSWIRE) -- Galera Therapeutics, Inc. (Nasdaq: GRTX), a clinical-stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer, today announced three abstracts regarding lead candidate avasopasem manganese (GC4419) were accepted for presentation at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program, taking place May 29-31, 2020. The titles of the abstracts are currently available in the ASCO digital program, with the full abstracts scheduled to be published on May 13, 2020, at 5 p.m. EDT. Presentations will be available for on-demand viewing on May 29, 2020, at 8 a.m. EDT.

Details of the presentations are as follows:

Abstract Number: TPS4670
Poster Number: 278
Title: Adaptive dose optimization trial of stereotactic body radiation therapy (SBRT) with or without GC4419 (avasopasem manganese) in pancreatic cancer
Session: Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary
Presenter: Elizabeth C. Moser, M.D., Ph.D., VP of Clinical Development, Galera

Abstract Number: 12071
Poster Number: 359
Title: Effects of GC4419 (avasopasem manganese) on chronic kidney disease in head and neck cancer patients treated with radiation and cisplatin
Session: Symptoms and Survivorship
Presenter: Emily J. Steinbach, Radiation Oncology, University of Iowa Hospitals and Clinics

Abstract Number: TPS6596
Poster Number: 257
Title: ROMAN: Reduction in oral mucositis with avasopasem manganese (GC4419)–phase III trial in patients receiving chemoradiotherapy for locally advanced, nonmetastatic head and neck cancer
Session: Head and Neck Cancer
Presenter: Jon T. Holmlund, M.D., Chief Medical Officer, Galera

About Avasopasem Manganese (GC4419)

Galera's lead product candidate, avasopasem manganese (GC4419), is a highly selective small molecule superoxide dismutase (SOD) mimetic that is initially being developed for the reduction of radiation-induced severe oral mucositis (SOM). Avasopasem manganese is designed to rapidly and selectively convert superoxide to hydrogen peroxide and oxygen, protecting normal tissue from damage associated with radiation therapy. 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.

Avasopasem manganese is currently being studied in the ROMAN trial, a randomized, double blind, placebo-controlled Phase 3 trial with approximately 365 patients (NCT03689712 available at clinicaltrials.gov) to investigate the effects of avasopasem manganese on radiation-induced OM in patients with head and neck cancer. In Galera's 223-patient, double-blind, randomized, placebo-controlled Phase 2b trial in patients with locally advanced head and neck cancer receiving concurrent radiation therapy, avasopasem manganese produced a statistically significant reduction in duration of severe oral mucositis (SOM) from 19 days to 1.5 days (92 percent) in the 90 mg treatment arm. Avasopasem manganese also demonstrated clinically meaningful reductions in SOM incidence through completion of radiation by 34 percent and in the severity of OM (incidence of Grade 4 OM) by 47 percent in the 90 mg treatment arm. No significant safety signals were observed demonstrating avasopasem manganese is well tolerated when added to a standard radiotherapy regimen. The two-year tumor outcomes follow-up of patients enrolled in the trial were consistent with expectations for intensity-modulated radiation therapy (IMRT)/cisplatin alone suggesting that radiation efficacy was maintained.

Avasopasem manganese is also currently being studied in a Phase 2a trial for its ability to reduce the incidence of radiation-induced esophagitis in patients with lung cancer (NCT04225026 available at clinicaltrials.gov), as well as in a pilot Phase 1/2 trial (NCT03340974 available at clinicaltrials.gov) in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer.

The U.S. Food and Drug Administration granted Fast Track and Breakthrough Therapy designations to avasopasem manganese for the reduction of SOM induced by radiotherapy.

About Galera Therapeutics

Galera Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. Galera's lead product candidate is avasopasem manganese (GC4419), a highly selective small molecule superoxide dismutase (SOD) mimetic initially being developed for the reduction of radiation-induced severe oral mucositis (SOM). Avasopasem manganese is being studied in the Phase 3 ROMAN trial for its ability to reduce the incidence and severity of SOM induced by radiotherapy in patients with locally advanced head and neck cancer, its lead indication, and in the Phase 2a trial for its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem manganese for the reduction of SOM induced by radiotherapy. Galera is developing a second product candidate, GC4711, which successfully completed a Phase 1 trial in healthy volunteers. Galera is headquartered in Malvern, PA. For more information, please visit www.galeratx.com.

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