Galera Therapeutics Announces Avasopasem Manganese (GC4419) Maintained Anti-Cancer Benefit of Chemoradiotherapy for Head and Neck Cancer While Substantially Reducing Radiation-Induced Severe Oral Mucositis

Feb 27, 2020

Tumor outcomes results from two-year follow-up of patients with head and neck cancer treated in Phase 2b clinical trial of avasopasem manganese to be presented at the 2020 Multidisciplinary Head and Neck Cancers Symposium

MALVERN, Pa., Feb. 27, 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 full tumor outcomes results from the two-year follow-up of patients with head and neck cancer treated with avasopasem manganese (GC4419), Galera's lead product candidate for severe oral mucositis (SOM), in a Phase 2b clinical trial. The results will be presented February 28, 2020, during a late-breaking oral presentation at the 2020 Multidisciplinary Head and Neck Cancers Symposium in Scottsdale, Ariz.

"There is currently no drug to prevent or treat SOM, one of the most common and disruptive side effects of radiation therapy that severely impacts both a patient's quality of life and treatment experience," said Mel Sorensen, M.D., President and CEO of Galera Therapeutics. "Avasopasem manganese's efficacy and tumor outcomes in SOM underscore its potential to complement a standard radiation therapy regimen and change the standard of care for the reduction of SOM in patients with head and neck cancer receiving radiotherapy. We look forward to the continued evaluation of avasopasem manganese for the treatment of SOM in our ongoing Phase 3 ROMAN trial, as well as for other radiation-induced toxicities, such as esophagitis in lung cancer in our ongoing Phase 2a trial."

Avasopasem manganese is a highly selective small molecule superoxide dismutase (SOD) mimetic initially being developed for the reduction of radiation-induced SOM defined by the World Health Organization as Grade 3 or 4, a common side effect characterized by significant pain and the inability to eat solid food or drink liquids. Galera's completed Phase 2b clinical trial evaluated avasopasem manganese in patients with locally advanced head and neck cancer. Patients in the trial received seven weeks of radiation therapy plus cisplatin, and were treated with either 30 mg or 90 mg of avasopasem manganese or placebo by infusion on the days they received their radiation treatment.

As part of the trial, Galera assessed tumor outcomes of the patients over a two-year period following radiation therapy. At both the one-year interim assessment and final two-year mark, tumor outcomes were maintained in both avasopasem manganese dose groups compared to placebo. Specifically, outcomes for the 90 mg dose group, the dose currently being evaluated in the ongoing Phase 3 ROMAN trial, were comparable to placebo across all four measures – overall survival, progression-free survival, locoregional control and metastasis-free survival.

"Radiation-induced toxicities like SOM are prevalent and debilitating complications of cancer treatment," said Carryn Anderson, M.D., Radiation Oncologist, University of Iowa Hospitals and Clinics, and lead investigator. "SOM in head and neck cancer patients, in particular, may be associated with dose reductions and / or radiation treatment breaks which can limit the antitumor efficacy of radiation therapy and impede successful tumor management. The tumor outcomes resulting from treatment with avasopasem manganese were consistent with expectations for concurrent intensity-modulated radiation therapy (IMRT)/cisplatin in patients with head and neck cancer and demonstrate avasopasem manganese's potential to mitigate this devastating side effect while maintaining radiation efficacy."

Trial results previously disclosed also demonstrated that adding a 90 mg dose of avasopasem manganese to a standard radiotherapy regimen produced a statistically significant reduction in duration of SOM from 19 days to 1.5 days (92 percent), and clinically meaningful reductions in SOM incidence through completion of radiation by 34 percent and in the severity of oral mucositis (OM) (incidence of Grade 4 OM) by 47 percent.

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, 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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding expectations surrounding the potential, efficacy, and regulatory and clinical development of Galera's product candidates, including the Phase 3 ROMAN trial and the Phase 2a clinical trial of avasopasem manganese to reduce the incidence of radiation-induced esophagitis in patients with lung cancer. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause Galera's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: Galera's limited operating history; anticipating continued losses for the foreseeable future; needing substantial funding and the ability to raise capital; Galera's dependence on avasopasem manganese; uncertainties inherent in the conduct of clinical trials; difficulties or delays enrolling patients in clinical trials; the FDA's acceptance of data from clinical trials outside the United States; undesirable side effects from Galera's product candidates; risks relating to the regulatory approval process; failure to capitalize on more profitable product candidates or indications; ability to receive Breakthrough Therapy Designation or Fast Track Designation for product candidates; failure to obtain regulatory approval of product candidates in the United States or other jurisdictions; ongoing regulatory obligations and continued regulatory review; risks related to commercialization; risks related to competition; ability to retain key employees and manage growth; risks related to intellectual property; inability to maintain collaborations or the failure of these collaborations; Galera's reliance on third parties; the possibility of system failures or security breaches; liability related to the privacy of health information obtained from clinical trials and product liability lawsuits; unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives; environmental, health and safety laws and regulations; risks related to ownership of Galera's common stock; and significant costs as a result of operating as a public company. These and other important factors discussed under the caption "Risk Factors" in Galera's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 filed with the U.S. Securities and Exchange Commission (SEC) and Galera's other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any forward-looking statements speak only as of the date of this press release and are based on information available to Galera as of the date of this release, and Galera assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contacts:
Christopher Degnan
Galera Therapeutics, Inc.
610-725-1500
cdegnan@galeratx.com

Chiara Russo
Solebury Trout
617-221-9197
crusso@soleburytrout.com

Media Contact:
Heather Anderson
6 Degrees
919-827-5539
handerson@6degreespr.com

Source: Galera Therapeutics