



Galera Therapeutics Completes Enrollment of Phase 1b/2a Clinical Trial of GC4419 in Combination with Radiotherapy for Locally Advanced Pancreatic Cancer

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Topline safety and efficacy data to be reported in the second half of 2020

MALVERN, Pa., July 13, 2020 (GLOBE NEWSWIRE) -- Galera Therapeutics, Inc. (Nasdaq: GRTX), a clinical-stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary small molecule therapeutics that have the potential to transform radiotherapy in cancer, today announced that it has completed patient enrollment in its pilot Phase 1b/2a safety and anti-cancer efficacy clinical trial of avasopasem manganese (GC4419) in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer (LAPC).

Galera's investigational, highly selective small molecule superoxide dismutase (SOD) mimetics are designed to rapidly and selectively convert superoxide to hydrogen peroxide and oxygen. These dismutase mimetics have potential anti-cancer synergy supported by positive results in multiple preclinical models. The randomized Phase 1b/2a trial is evaluating the safety, progression-free survival and overall response rate of GC4419 in combination with SBRT, compared with SBRT and placebo, in LAPC patients. The trial is also assessing safety and tolerability to determine the recommended dose of SBRT when combined with GC4419 or placebo.

"Pancreatic cancer has one of the poorest survival prognoses of common cancers and better treatments are urgently needed. Even when the disease is locally advanced, treatment options have limited impact on this difficult-to-treat cancer," said Mel Sorensen, M.D., President and CEO of Galera. "This pilot trial is the first to evaluate the anti-cancer effects of our dismutase mimetics in combination of SBRT in patients. We look forward to reporting topline data from this trial in the second half of 2020."

Additional information on the trial can be found on clinicaltrials.gov using the identifier NCT03340974.

About GC4419 (Avasopasem Manganese)

Galera's lead product candidate, avasopasem manganese, is an investigational, highly selective small molecule superoxide dismutase (SOD) mimetic that is initially being developed for the reduction of radiation-induced severe oral mucositis (SOM) which is not yet approved. Avasopasem 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 is currently being studied in the ROMAN trial, a randomized, double blind, placebo-controlled Phase 3 trial of approximately 450 patients (NCT03689712, available at clinicaltrials.gov) to investigate the effects of avasopasem 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 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 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. The overall adverse event profile of avasopasem in the Phase 2b trial was similar to that of placebo and consistent with the known adverse effects of chemoradiation, with reductions of blood cell counts, particularly low lymphocyte counts, the most prominent adverse effects. Adverse events considered attributable to avasopasem were limited to mild, transient postural light-headedness or decreased blood pressure. Patients were followed for two years after enrollment and showed no difference in tumor outcomes between active and control, consistent with expectations for combinations with intensity-modulated radiation therapy (IMRT)/cisplatin, suggesting that the efficacy of the chemoradiation therapy was not compromised.

Avasopasem is also currently being studied in a Phase 2a trial for its potential to reduce the incidence of radiation-induced esophagitis in patients with lung cancer (NCT04225026, available at clinicaltrials.gov); and 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 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 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. It is also being studied in a Phase 2a trial for its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer and in a pilot Phase 1/2 trial in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. Galera is developing a second product candidate, GC4711, for SBRT which successfully completed Phase 1 trials 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 the potential, efficacy, and regulatory and clinical development of Galera's product candidates, and plans and timing for the release of data from clinical trials. 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 (GC4419); 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; the impact of the COVID-19 pandemic on Galera's business and operations, including preclinical studies and clinical trials, and general economic conditions; 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 quarterly period ended March 31, 2020 filed with the U.S. Securities and Exchange Commission (SEC), Annual Report on Form 10-K for the year ended December 31, 2019 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.

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