Galera Therapeutics Announces Dosing of First Patient in a Randomized, Double-Blind Pilot Phase 2 Clinical Trial of GC4419 for COVID-19

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Trial to enroll up to 50 hospitalized adults critically ill with COVID-19

Company continues to advance its three ongoing trials evaluating the potential of GC4419 to address radiation toxicities and improve the anti-cancer effect of radiation

MALVERN, Pa., Sept. 16, 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 the first patient has been dosed in a pilot Phase 2 clinical trial of lead product candidate avasopasem manganese (GC4419) to evaluate its ability to improve 28-day mortality in hospitalized patients who are critically ill with COVID-19. GC4419 is an investigational, highly selective small molecule superoxide dismutase (SOD) mimetic designed to rapidly and selectively convert superoxide to hydrogen peroxide and oxygen.

“The unprecedented medical need of this pandemic has prompted many companies in our industry to test the potential utility of their technology to help fight this infection,” said Mel Sorensen, M.D., President and CEO of Galera. “Our corporate mission continues to be that of transforming radiotherapy, and we remain focused on progressing our ongoing trials, most notably, our Phase 3 ROMAN trial for the reduction of radiation-induced severe oral mucositis in patients with head and neck cancer, as well as our Phase 2 anti-cancer trial in locally advanced pancreatic cancer in combination with stereotactic body radiation therapy. We look forward to exploring the potential of GC4419 in patients who are critically ill with COVID-19 while maintaining a disciplined approach to our resource allocation in support of this trial.”

The randomized, double-blind, placebo-controlled Phase 2 trial is designed to assess the safety and efficacy of GC4419 in improving 28-day mortality, compared to placebo. The trial will enroll up to 50 hospitalized adult patients critically ill with COVID-19 at several sites across the U.S. Patients in the trial will receive 90 mg of GC4419 or placebo by infusion twice daily for seven days. The trial will also collect additional data related to the requirement for intensive care, mechanical ventilation, and organ function.

“Superoxide is reported in internal and published data to play a causative role in the progression of the hyperinflammatory phase of this infection, sometimes referred to as cytokine storm. Galera’s dismutase mimetics have shown the ability in preclinical models to protect the lungs and other organs from damage caused by excessive and prolonged superoxide production,” said Dennis Riley, Ph.D., Chief Scientific Officer of Galera. “Based upon the guidance of experts in pulmonary disease and viral infections, we have worked with the FDA to initiate this trial having recognized the importance of potentially contributing to the care of those affected by COVID-19.”

Multiple preclinical models suggest that by removing superoxide, GC4419 can potentially break the hyperinflammatory cycle, and reduce acute inflammatory lung injury and acute respiratory distress syndrome (ARDS). In preclinical models, GC4419 has shown it can prevent superoxide damage to the lungs by radiation therapy and other injuries. Other preclinical models also suggest that removing superoxide to inhibit the hyperinflammatory cycle might reduce COVID-19 damage to other organs and the related hypotension.

For additional information about the trial, visit www.galeratx.com.

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 locally advanced 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 in a Phase 2 trial in hospitalized patients who are critically ill with COVID-19; and avasopasem completed enrollment 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 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 (HNC), its lead indication. It is also being studied in a Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, a Phase 2a trial for its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer, and a Phase 2 trial in hospitalized patients who are critically ill with COVID-19; and avasopasem completed enrollment 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 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, including with respect to the Phase 2 clinical trial of avasopasem manganese (GC4419) for COVID-19. 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 June 30, 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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