Galera Therapeutics Announces Dosing of First Patient in Phase 2a Clinical Trial of Avasopasem Manganese (GC4419) in Second Indication

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-- Evaluates avasopasem manganese's ability to reduce the incidence of radiation-induced esophagitis in patients with lung cancer --

-- Marks expansion of lead product candidate avasopasem manganese into second radiation toxicity indication --

MALVERN, Pa., Jan. 07, 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 Phase 2a clinical trial of lead product candidate avasopasem manganese (GC4419) to evaluate its ability to reduce the incidence of radiation-induced esophagitis in patients with lung cancer.

The open-label, multi-center trial will evaluate the efficacy of avasopasem manganese, a highly selective small molecule superoxide dismutase (SOD) mimetic, in reducing the incidence of severe (Grade 2 or worse on the NCI Common Terminology Criteria for Adverse Events scale) acute radiation-induced esophagitis in patients with lung cancer receiving chemoradiotherapy. Approximately 60 adult patients with pathologically confirmed unresectable Stage 3A/3B or post-operative Stage 2B non-small cell (NSCLC) or limited-stage small cell (SCLC) lung cancers will be enrolled at approximately 10 sites. Patients in the trial will receive 90 mg of avasopasem manganese by infusion on the days they receive their radiation therapy.

"Radiation-induced esophagitis is a common, debilitating side effect that can delay or prevent curative cancer treatment, and no FDA-approved therapies to treat it currently exist," said Lawrence Berk, M.D., Ph.D., Professor of Radiation Oncology at the University of South Florida and lead investigator of the Phase 2a trial. "The initiation of this trial is a critical step toward addressing this urgent unmet need for a treatment option. The results of the Phase 2b trial of avasopasem manganese which demonstrated its ability to reduce the incidence of radiation-induced severe oral mucositis – another debilitating radiotherapy side effect – in patients with head and neck cancer support the further evaluation of avasopasem manganese for the treatment of other related radiation toxicities like esophagitis."

There are approximately 230,000 new lung cancer patients diagnosed annually in the United States, and approximately 50,000 of those are treated with radiation therapy. Esophagitis, or mucositis of the esophagus, is a common and painful complication of radiation therapy for lung cancer. Symptoms can be life-threatening and include an inability to swallow, severe pain, ulceration, infection, bleeding and weight loss, and may require hospitalization.

"We're pleased to expand the evaluation of avasopasem manganese into a second radiation toxicity, esophagitis, in patients with lung cancer," said Mel Sorensen, M.D., President and CEO of Galera. "Galera is committed to improving the quality of life for patients suffering from cancer. This trial will broaden our understanding of the utility of avasopasem manganese in the treatment of radiotherapy toxicities beyond our first indication, radiation-induced severe oral mucositis in patients with head and neck cancer."

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.

GC4419 is currently being studied in the ROMAN trial, a randomized, double blind, placebo-controlled Phase 3 trial with 365 patients (NCT03689712 available at clinicaltrials.gov) to determine the efficacy and safety of avasopasem manganese in patients with locally advanced head and neck cancer and radiation-induced OM. In Galera's 223-patient, double-blind, randomized, placebo-controlled Phase 2b clinical trial in patients with locally advanced head and neck cancer receiving concurrent radiation therapy, avasopasem manganese significantly reduced the duration of SOM by 92 percent (from 19 days to 1.5 days in the 90 mg treatment arm). The incidence of SOM and the incidence of Grade 4 OM were also significantly reduced (by 34 percent and 47 percent, respectively, in the 90 mg treatment arm) in patients treated with avasopasem manganese. 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 the duration, incidence and severity 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, severity and duration of radiation-induced SOM in patients with locally advanced head and neck cancer being treated with radiotherapy, its lead indication. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem manganese for the reduction of the duration, incidence and severity 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 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.

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