Galera Therapeutics Announces Dosing of First Patient in the Phase 1/2 GRECO-1 Clinical Trial of GC4711 in Combination with SBRT for Non-Small Cell Lung Cancer

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Trial Supported in Part by NIH SBIR Grant

MALVERN, Pa., Oct. 22, 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 that the first patient has been dosed in the Phase 1/2 GRECO-1 clinical trial of GC4711 in combination with stereotactic body radiation therapy (SBRT) in patients with non-small cell lung cancer (NSCLC).

GC4711, Galera's second clinical candidate, is a highly selective small molecule superoxide dismutase (SOD) mimetic that is designed to rapidly convert superoxide to hydrogen peroxide and is being developed specifically for use in combination with SBRT. In preclinical studies, GC4711, when added to an SBRT regimen, increased the anti-cancer efficacy of radiotherapy and protected normal lung tissue.

The trial is supported in part by a recently awarded Small Business Innovation Research (SBIR) grant from the National Cancer Institute (NCI) of the National Institutes of Health (NIH) for the investigation of Galera's dismutase mimetics in combination with SBRT for the treatment of lung cancer. The grant was awarded by the NCI of the NIH under award number 4R44CA206795-02.

"SBRT holds promise to deliver more efficient, targeted and potent radiotherapy to improve cancer outcomes. This trial builds on the pilot trial in combination with SBRT in patients with locally advanced pancreatic cancer and we are eager to embark on our exploration of the potential of Galera's GC4711 to enhance the anti-cancer efficacy of SBRT," said Mel Sorensen, M.D., President and CEO of Galera. "We're grateful for the support provided by the SBIR grant, which further recognizes the potential of this combination."

Following a safety run-in cohort, up to 66 NSCLC patients with locally advanced disease will receive GC4711 with SBRT or placebo with SBRT over five consecutive weekdays in the randomized, double-blind, placebo-controlled Phase 2 portion of the GRECO-1 trial. The goals of this trial are to assess the effects of GC4711 in combination with SBRT on tumor outcomes and lung injury.

Additional information on the trial can be found on clinicaltrials.gov using the identifier NCT04476797.

About GC4711

Galera's product candidate, GC4711, is an investigational, highly selective small molecule superoxide dismutase (SOD) mimetic in development specifically for use in combination with stereotactic body radiation therapy (SBRT). GC4711 is designed to rapidly convert superoxide to hydrogen peroxide and is being developed to synergize with SBRT to exploit cancer cells' increased sensitivity to hydrogen peroxide to promote cancer cell death. In preclinical studies, GC4711, when added to an SBRT regimen, increased the anti-cancer efficacy of radiotherapy at current doses. GC4711 successfully completed Phase 1a clinical trials in healthy volunteers, and is currently being studied in a Phase 1/2 trial in combination with SBRT in patients with non-small cell lung cancer (NSCLC).

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 to assess 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 to assess 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. Enrollment has also been completed in a pilot Phase 1/2 trial of avasopasem 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's second SOD mimetic product candidate, GC4711, is initially being developed to augment the anti-cancer efficacy of radiation and is currently being studied in a Phase 1/2 clinical trial in combination with SBRT in patients with non-small cell lung cancer. 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, safety, efficacy, and regulatory and clinical development of Galera's product candidates, including with respect to the Phase 1/2 GRECO-1 clinical trial. 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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