Galera Announces First Patient Dosed with GC4711 in Phase 2b GRECO-2 Trial in Patients with Pancreatic Cancer

May 17, 2021

Initiation builds on positive overall survival and tumor control data from Phase 1/2 trial

Triggers $20M milestone payment from Blackstone Life Sciences

160-patient randomized, multicenter, placebo-controlled trial

MALVERN, Pa., May 17, 2021 (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 the randomized Phase 2b GRECO-2 trial of GC4711 in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer (LAPC). GC4711 is a selective small molecule dismutase mimetic being developed to increase the anti-cancer effect of radiation. Enrollment of the first patient in this trial has triggered a $20 million milestone payment from funds managed by Blackstone Life Sciences to Galera under the amended royalty agreement.

“We are excited to start this large Phase 2b trial in pancreatic cancer following the promising data from our initial trial in these patients, a placebo-controlled Phase 1/2 pilot trial, in which we saw a near doubling of overall survival in patients receiving a dismutase mimetic with SBRT,” said Mel Sorensen, M.D., President and CEO of Galera. “In addition, the $20 million milestone payment from Blackstone ensures we are well capitalized to advance this trial in addition to our programs in lung cancer and radiation-induced severe oral mucositis as we prepare for the potential regulatory approval and commercialization of avasopasem, our lead dismutase mimetic product candidate.”

GRECO-2 is a randomized, double-blind, placebo-controlled Phase 2b trial evaluating the effect of 100 mg of GC4711 or placebo in combination with SBRT on overall survival (OS), the trial’s primary endpoint, in patients with LAPC. Secondary endpoints include progression-free survival (PFS), locoregional control (LRC), time to distant metastases (TDM) and surgical resection, in addition to safety. The trial is expected to enroll approximately 160 patients.

“In the fight against pancreatic cancer, which has a 10% five-year survival rate and few treatment options, clinical trials are critical,” said Julie Fleshman, J.D., MBA, President and CEO of the Pancreatic Cancer Action Network (PanCAN). “Galera’s GRECO-2 study, as well as the other studies in our comprehensive database of pancreatic cancer clinical trials available in the U.S., investigates cutting edge research and has the potential to improve patient outcomes.”

Additional information on GRECO-2 can be found on clinicaltrials.gov using the identifier NCT04698915.

About GC4711

Galera’s selective dismutase mimetic product candidates, GC4711 and GC4419, are small molecules being developed to protect normal cells and sensitize cancer cells to radiotherapy. GC4711 is in development specifically to augment the anti-cancer efficacy of stereotactic body radiation therapy (SBRT). The molecule is currently being studied in a Phase 1/2 trial in combination with SBRT in patients with non-small cell lung cancer (NCT04476797) and a Phase 2b trial in combination with SBRT in patients with locally advanced pancreatic cancer (NCT04698915).

About Galera Therapeutics

Galera Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutic candidates that have the potential to transform radiotherapy in cancer. Galera’s lead product candidate is avasopasem manganese (GC4419, also referred to as avasopasem), a selective small molecule dismutase 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 the EUSOM Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, the AESOP 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. A pilot Phase 1/2 trial of GC4419 in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer (LAPC) has completed enrollment and reported updated results, with follow-up ongoing. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy.

Galera's second dismutase mimetic product candidate, GC4711, is being developed specifically to augment the anti-cancer efficacy of SBRT, and is currently being studied in the GRECO-1 Phase 1/2 trial in combination with SBRT in patients with non-small cell lung cancer and the GRECO-2 Phase 2b trial in combination with SBRT in patients with LAPC. 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 our growth and the continued advancement of our product pipeline, including plans for the commercial launch of avasopasem; the potential, safety, efficacy, and regulatory and clinical development of Galera's product candidates; and expected payments from Blackstone. 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 Annual Report on Form 10-K for the year ended December 31, 2020 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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