Galera Announces Updated Data from its Randomized, Multicenter, Placebo-Controlled Trial in Patients with Pancreatic Cancer

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Near double the median overall survival observed in patients receiving Galera's dismutase mimetic + SBRT versus placebo + SBRT, showing strong therapeutic potential

Improvements versus placebo also observed in local tumor control, time to metastases and progression-free survival

Data support Company's 160 patient Phase 2b pancreatic cancer trial, GRECO-2

MALVERN, Pa., April 28, 2021 (GLOBE NEWSWIRE) -- Galera Therapeutics, Inc. (Nasdaq: GRTX), 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, today announced updated results from its Phase 1/2 pilot trial of GC4419, versus placebo, in patients with locally advanced pancreatic cancer (LAPC) who are undergoing stereotactic body radiation therapy (SBRT). The updated results, as of this data analysis, include a minimum follow up of six months on all 42 patients and were consistent with the positive results reported with a minimum follow up of three months. The Company plans to report final results from the trial after a minimum of one year of follow up, expected during the second half of 2021.

"The data from this trial continue to impress, showing consistent and durable benefits across multiple measures, including the most important for the patient, overall survival," said Mel Sorensen, M.D., President and CEO of Galera. "These encouraging results informed the design of our Phase 2b GRECO-2 trial and underscore our excitement about the potential to make a meaningful difference for patients with this tough diagnosis."

As of this data analysis, median overall survival in the treatment arm was nearly twice as long as observed in the placebo arm, 20.1 months compared to 10.9 months, respectively. 29% of patients in the treatment arm achieved a 30% or greater response (partial response) compared to 11% of patients in the placebo arm. Positive results were also observed in local tumor control, time to metastases and progression-free survival. As previously reported, GC4419 was well tolerated as of this data analysis, with similar rates of adverse events in the treatment and placebo arms.

"There are limited treatment options for patients with locally advanced pancreatic cancer and we are continually looking for innovative approaches," said Sarah Hoffe, M.D., Section Head of GI Radiation Oncology at H. Lee Moffitt Cancer Center and Research Institute. "These pancreatic data are exciting and speak to the potential emergence of an entirely novel class of cancer therapeutics for patients."

Galera's selective dismutase mimetic product candidates are small molecules being developed to protect normal cells and sensitize cancer cells to radiotherapy. The Phase 1/2 pilot trial is a randomized, double-blind, multicenter, placebo-controlled trial in 42 patients diagnosed with LAPC evaluating the safety and efficacy of SBRT and the dismutase mimetic GC4419 compared to SBRT and placebo. Patients were randomized (1:1) to receive GC4419 or placebo by intravenous infusion one hour prior to SBRT.

The data from this trial support GRECO-2, a multicenter, randomized, double-blind, placebo-controlled Phase 2b trial to evaluate GC4711, Galera's second dismutase mimetic product candidate, combined with SBRT in patients with LAPC. The primary endpoint of the Phase 2b trial is overall survival. The Company expects to initiate patient dosing in GRECO-2 in the first half of 2021, and the trial is expected to enroll approximately 160 patients.

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 avasopasem in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer (LAPC) has completed enrollment and reported 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. Galera also intends to initiate the GRECO-2 Phase 2b trial of GC4711 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; the potential, safety, efficacy, and regulatory and clinical development of Galera's product candidates; and plans and timing for the commencement of and the release of data from Galera's 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 or maintain 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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