Galera Announces Final Results from Pancreatic Cancer Trial Showing Improvements on all Efficacy Parameters

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Improvements observed in overall survival, progression-free survival, local tumor control, time to metastases, and tumor response rate

Hazard ratios better than 0.5 on all survival and tumor outcome endpoints

Combination with SBRT was well tolerated in the active and placebo arms

Results reinforce rationale for GRECO-2, Galera's ongoing 160-patient Phase 2b pancreatic cancer trial

MALVERN, Pa., Sept. 08, 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 final results from its Phase 1/2 pilot trial of its dismutase mimetic, GC4419, versus placebo, in patients with unresectable or borderline resectable locally advanced pancreatic cancer (LAPC), who are undergoing stereotactic body radiation therapy (SBRT). The results include a minimum of one year of follow up on all 42 patients enrolled in the trial.

In this proof-of-concept trial, improvements were observed in overall survival (HR=0.48; 95% CI: 0.20-1.14; p=0.090), progression-free survival (HR=0.46; 95% CI: 0.22-0.98; p=0.040), local tumor control (HR=0.30; 95% CI: 0.08-1.10; p=0.055) and time to distant metastases (HR=0.39; 95% CI: 0.16-0.93; p=0.028). 46% of patients in the active arm were alive at last follow-up (11 out of 24) compared to 33% in the placebo arm (6 out of 18). As previously reported, 29% of patients in the active arm achieved a 30% or greater decrease in primary tumor size (partial response) compared to 11% of patients in the placebo arm. GC4419 was well tolerated, with similar rates of early and late adverse events in the active and placebo arms. For more information related to this trial, please see the Company's updated corporate presentation on the Investors page of Galera's website at investors.galeratx.com.

"We are very pleased with the survival and tumor outcome benefits observed in the final analysis of this proof-of-concept trial," said Mel Sorensen, M.D., President and CEO of Galera. "The improvements across multiple efficacy parameters, together with the safety data, are encouraging and underpin the rationale for our 160-patient blinded, randomized GRECO-2 trial of GC4711 with SBRT in pancreatic cancer, where the primary endpoint is overall survival. These are exciting times for Galera as we also look forward to announcing topline data from our ROMAN Phase 3 trial for the reduction of severe oral mucositis in patients with head and neck cancer later this year."

"We are excited to see the final results from this trial and enthusiastic to participate in the Phase 2b GRECO-2 trial," said Sarah Hoffe, M.D., Section Head of GI Radiation Oncology at H. Lee Moffitt Cancer Center and Research Institute. "These observed overall survival rates are particularly encouraging in pancreatic cancer, as this patient population faces a difficult diagnosis with high rates of distant metastasis and low rates of cure."

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 was 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.

GRECO-2 is a randomized, double-blind, placebo-controlled Phase 2b trial evaluating Galera's second dismutase mimetic product candidate, GC4711, compared to placebo in patients with LAPC undergoing SBRT. The trial was initiated in May 2021 and is expected to enroll approximately 160 patients. The primary endpoint of the trial is overall survival. Secondary endpoints include progression-free survival, local tumor control, time to distant metastases and surgical resection rate, in addition to safety.

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 (avasopasem, or GC4419), a selective small molecule dismutase mimetic in late-stage development to reduce the incidence and severity of radiotherapy-induced severe oral mucositis (SOM) in patients with head and neck cancer. Avasopasem is also in development for radiotherapy-induced esophagitis in patients with lung cancer. Avasopasem has been granted FDA Fast Track and Breakthrough Therapy designations for the reduction of SOM induced by radiotherapy, with or without systemic therapy. Galera's second dismutase mimetic product candidate, GC4711, is in

clinical-stage development to augment the anti-cancer efficacy of stereotactic body radiation therapy in patients with non-small cell lung cancer and locally advanced pancreatic 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: 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, including the interpretation of the safety and efficacy results from the Phase 1/2 LAPC pilot trial and whether such results underpin the rationale for the ongoing GRECO-2 trial; 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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