Galera Announces Oral Presentation at 2022 American Society of Clinical Oncology (ASCO) Annual Meeting Detailing Results from Phase 3 ROMAN Trial of Avasopasem

May 26, 2022

Avasopasem produced clinically meaningful, statistically significant reduction of severe oral mucositis (SOM) in patients with locally advanced head and neck cancer receiving radiotherapy

Company on track to submit NDA to U.S. FDA for avasopasem by end of 2022

MALVERN, Pa., May 26, 2022 (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 data from its Phase 3 ROMAN trial of avasopasem for severe oral mucositis will be highlighted in an oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting on Friday, June 3, 2022 from 2:45 p.m. – 5:45 p.m. CDT during the Head and Neck Cancer session. Topline data was announced in December 2021. Abstracts are currently available in the ASCO digital program.

“We are pleased that our Phase 3 trial of avasopasem was selected for an oral presentation at ASCO, where details of the clinically meaningful and statistically significant results will be shared,” said Mel Sorensen, M.D., Galera’s President and CEO. “Our research shows that radiation oncologists and patients cite SOM as the most burdensome radiotherapy toxicity in head and neck cancer treatment, and there are currently no FDA-approved drugs to reduce the incidence or duration of SOM in solid tumors. Avasopasem has been granted Breakthrough Therapy and Fast Track Designations by the U.S. FDA for the reduction of SOM induced by radiotherapy, and we look forward to submitting a New Drug Application to the FDA by year end in order to bring this potential treatment to patients as quickly as possible.”

Results from the 455-patient Phase 3 trial demonstrated a meaningful reduction in patients’ SOM burden across multiple endpoints, with statistically significant reductions on the primary endpoint of incidence of SOM and the secondary endpoint of number of days of SOM, more than halving the median number of days a patient suffered SOM. Exploratory analyses, such as time to SOM onset and SOM incidence at various landmarks of radiotherapy delivered, also demonstrated clinical benefit of avasopasem in reducing the burden of SOM. Avasopasem also appeared to be generally well tolerated compared to placebo. These results are consistent with those from the positive 223-patient Phase 2b trial (Anderson, J Clin Oncol, 2019) that was the basis for Breakthrough Therapy Designation.

Additionally, Galera’s Phase 2 GRECO-2 study of rucosopasem (GC4711) in combination with stereotactic body radiation therapy in pancreatic cancer will be presented at the ASCO Annual Meeting in a *Trials in Progress* poster session on Saturday, June 4, 2022, from 8:00 a.m. – 11:00 a.m. CDT. The primary endpoint of this trial is overall survival.

About Severe Oral Mucositis (SOM)
Approximately 42,000 patients with head and neck cancer undergo standard-of-care radiotherapy every year in the U.S. and are at risk of experiencing SOM. In patients with head and neck cancer, radiotherapy is a mainstay of treatment. Approximately 70 percent of patients receiving radiotherapy for head and neck cancer develop SOM, defined by the inability to eat solid food or drink liquids. The impact on patients who develop SOM is substantial, particularly when hospitalization and/or surgical placement of PEG tubes to maintain nutrition and hydration are required. SOM can adversely affect cancer treatment outcomes by causing interruptions in radiotherapy, which may compromise the otherwise good prognosis for tumor control in many of these patients. There is currently no drug approved to prevent or treat SOM for these patients.

About Avasopasem
Avasopasem manganese (avasopasem, or GC4419) is a selective small molecule dismutase mimetic in development for the reduction of radiation-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) and for the reduction of radiation-induced esophagitis in patients with lung cancer. The FDA has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy, with or without systemic therapy.

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 selective dismutase mimetic product candidate avasopasem manganese (GC4419, also referred to as avasopasem) is being evaluated for radiotherapy-induced toxicities. The Company’s second product candidate, rucosopasem manganese (GC4711, also referred to as rucosopasem), 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: the potential of Galera's product candidates to transform radiotherapy in cancer; the expectations surrounding the continued advancement of Galera's product pipeline; the potential safety and efficacy of Galera's product candidates and their regulatory and clinical development; and the timing of the submission of an NDA for avasopasem for the treatment of radiotherapy-induced SOM in patients with locally advanced head and neck cancer with the FDA and the potential for approval; and the expectations surrounding the progress of the Phase 2b trial of rucosopasem (GC 4711) in patients with locally advance pancreatic 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 (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, 2021 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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