Galera Announces Plan to Submit Avasopasem NDA by Year End

May 16, 2022

After discussions with FDA, Company is on track to file an NDA for avasopasem for the treatment of radiotherapy-induced severe oral mucositis by end of 2022

MALVERN, Pa., May 16, 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 its intent to file a New Drug Application (NDA) for avasopasem manganese (avasopasem) for the treatment of radiotherapy-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer with the U.S. Food and Drug Administration (FDA) by the end of 2022.

“We are excited to take this next step after our productive interactions with the FDA,” said Mel Sorensen, M.D., Galera’s President and CEO. “The NDA will be based on the positive and clinically meaningful data from our Phase 3 ROMAN trial and our randomized Phase 2b trial. There are no FDA-approved treatments for radiotherapy-induced SOM, which affects over 40,000 patients with head and neck cancer undergoing radiotherapy in the U.S. alone, and we are enthusiastically working to bring this potential treatment to patients as quickly as possible.”

The FDA has already granted Breakthrough Therapy and Fast Track Designations to avasopasem for the reduction of SOM induced by radiotherapy. The Company looks forward to continuing to work with the FDA to bring this potential new treatment to patients with head and neck cancer receiving radiotherapy.

The Company also recently announced that detailed results from the ROMAN trial will be presented in an oral presentation at the upcoming 2022 American Society of Clinical Oncology (ASCO) Annual Meeting on Friday, June 3, 2022.

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 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; 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 approval and commercialization of avasopasem and the timing thereof. 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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