Galera Schedules Type A Meeting with FDA to Discuss Next Steps for Avasopasem

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MALVERN, Pa., Sept. 18, 2023 (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 that a Type A Meeting has been scheduled for September 28, 2023 with the U.S. Food and Drug Administration (FDA) regarding the Complete Response Letter (CRL) received for the Company's New Drug Application (NDA) for avasopasem manganese (avasopasem). The FDA is expected to issue written meeting minutes approximately 30 days following the meeting.

"We look forward to further understanding the FDA's review of our NDA for avasopasem and the data from our two randomized placebo-controlled clinical trials," said Mel Sorensen, M.D., Galera's President and CEO. "We believe in avasopasem's potential to bring meaningful benefit to patients with head and neck cancer suffering from severe oral mucositis. With clarity on the perspective of the FDA reviewers from the meeting and subsequent minutes, we hope to identify necessary steps to bring avasopasem to these patients."

The Company intends to gain an understanding from the FDA of its evaluation of avasopasem for radiotherapy-induced severe oral mucositis (SOM) in patients with head and neck cancer undergoing standard-of-care treatment and next steps to support an NDA resubmission. The Type A Meeting is the highest priority classification of meeting that the FDA grants to NDA sponsors.

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 (avasopasem) is being developed for radiation-induced toxicities. The FDA has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of severe oral mucositis induced by radiotherapy. The Company's second product candidate, rucosopasem manganese (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. Rucosopasem was granted Orphan Drug Designation by the FDA for the treatment of pancreatic cancer. Galera is headquartered in Malvern, PA.

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 Company's ability to gain an understanding of, and get clarity on, FDA's evaluation of the NDA for avasopasem and next steps to support an NDA resubmission from the Type A meeting with the FDA scheduled for September 28, 2023; the timing of receipt from FDA of meeting minutes from the Type A meeting; the Company's ability to resubmit the NDA; and the Company's ability to achieve its goal of transforming radiotherapy in cancer treatment with its selective dismutase mimetics. 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; substantial doubt regarding Galera's ability to continue as a going concern; 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, 2022 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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