Galera Receives Complete Response Letter from U.S. FDA for Avasopasem Manganese

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The Company remains committed to its goal of bringing avasopasem to patients and intends to meet with FDA as soon as possible to discuss potential next steps

Galera will take actions to extend its cash runway and continue enrolling its rucosopasem clinical trials

Conference call tomorrow, August 10, 2023 at 8:30 a.m. ET

MALVERN, Pa., Aug. 09, 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 it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the Company's New Drug Application (NDA) for avasopasem manganese (avasopasem) for radiotherapy-induced severe oral mucositis (SOM) in patients with head and neck cancer undergoing standard-of-care treatment.

In the CRL, the FDA communicated that the results from the Phase 3 ROMAN trial together with the supporting data from the GT-201 trial are not sufficiently persuasive to establish substantial evidence of avasopasem's effectiveness and safety for reducing severe oral mucositis in patients with head and neck cancer. FDA stated that results from an additional clinical trial will be required for resubmission.

The Company intends to request a Type A meeting with the FDA to understand the FDA's rationale for its decision and discuss next steps to support an NDA resubmission seeking approval of avasopasem. The Company will also explore strategic alternatives, including partnering, for the continued development of avasopasem and rucosopasem.

"This response from the FDA is deeply disappointing for Galera and for patients who suffer from severe oral mucositis," said Mel Sorensen, M.D., Galera's President and CEO. "We continue to believe in avasopasem's potential to bring a meaningful benefit to these patients, who currently have no FDA-approved drugs for this debilitating condition."

Restructuring and Financial Update

"As we explore a potential approval path for avasopasem, we are taking decisive actions to extend our cash runway," continued Dr. Sorensen. "Unfortunately, this necessitates reducing our workforce by approximately 70%. We are grateful for the many contributions our talented team has made over the years and their commitment to avasopasem."

Galera's restructuring plan includes a wind-down of commercial readiness efforts and headcount reductions across several departments. The Company will focus resources to define the path forward for avasopasem and to progress the ongoing clinical trials for rucosopasem. Rucosopasem is the Company's second product candidate in development to augment the anti-cancer efficacy of stereotactic body radiation therapy (SBRT) for patients with non-small cell lung cancer and locally advanced pancreatic cancer.

"We will continue our focus on completing enrollment of our rucosopasem GRECO trials," continued Dr. Sorensen. "Our GRECO-2 trial is a 220-patient trial in locally advanced pancreatic cancer intended to build upon the positive results observed in our placebo-controlled pilot trial, where we saw meaningful improvements in multiple endpoints including overall survival and tumor outcomes. There is an urgent need for novel therapies to extend survival in patients with pancreatic cancer, and we believe rucosopasem's unique mechanism of action in combination with SBRT could offer a transformative treatment option."

Galera estimates that its balance of cash, cash equivalents and marketable securities as of June 30, 2023 was $38.8 million. This figure is preliminary and is subject to completion of the Company's financial closing procedures. The Company plans to file its Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 on August 14, 2023. The Company now expects that its current cash will be sufficient to support operations into the second quarter of 2024.

The NDA submission for avasopasem included data from a total of 678 patients enrolled in two randomized, double-blind, placebo-controlled trials (Phase 3 ROMAN and Phase 2b GT-201). The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. The NDA was accepted for priority review, which is granted to applications for therapies that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions compared to available therapies.

Conference Call and Webcast
Galera will host a conference call and live audio webcast tomorrow, August 10, 2023 at 8:30 a.m. ET. The conference call dial-in numbers are (877) 869-3847 (domestic) or +1(201) 689-8261 (international). The live audio webcast of the event will be accessible from the Investors page of Galera's website, investors.galeratx.com. The webcast replay will be available shortly after conclusion of the event for 90 days.

About Avasopasem
Avasopasem manganese (avasopasem) is a selective dismutase mimetic in development for the reduction of radiotherapy-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) and for the reduction of radiotherapy-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.

About Rucosopasem
Rucosopasem manganese (rucosopasem) is a next-generation selective dismutase mimetic in development to increase the anti-cancer efficacy of stereotactic body radiation therapy (SBRT), a type of high fraction dose radiotherapy, in patients with non-small cell lung cancer and locally advanced pancreatic cancer. The FDA has granted orphan drug designation to rucosopasem for the treatment of pancreatic cancer.

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 Company's intention to request and hold a Type A meeting with the FDA in order to understand the FDA's rationale for its decision and discuss next steps to support an NDA resubmission seeking approval of avasopasem; the Company's ability to resubmit the NDA; the Company's plans to take actions, and the potential for those actions, to extend its cash runway; the Company's intention to pursue strategic alternatives; the enrollment of the rucosopasem GRECO trials; 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 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 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 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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