Galera Announces Presentation of Supplemental Analysis of Phase 3 ROMAN Trial at European Congress on Head and Neck Oncology

March 10, 2023

MALVERN, Pa., March 10, 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 the presentation of a net treatment benefit analysis of Phase 3 ROMAN results at the 10th European Congress on Head and Neck Oncology (ECHNO), taking place March 8-11, 2023, in Lisbon, Portugal. The analysis further demonstrates the overall impact of avasopasem manganese (avasopasem) in reducing the burden of severe oral mucositis (SOM). Galera's New Drug Application (NDA) in the U.S. for avasopasem is currently under U.S. Food and Drug Administration (FDA) priority review for radiotherapy (RT)-induced SOM in patients with head and neck cancer undergoing standard-of-care treatment.

"We are pleased to present at ECHNO the results of the Phase 3 ROMAN trial, including a net treatment benefit analysis submitted as part of Galera's NDA," said Mel Sorensen, M.D., President and Chief Executive Officer of Galera Therapeutics. "This analysis is particularly appropriate for SOM, where we believe that no single endpoint fully characterizes the potential impact of SOM on patient quality of life. We believe the results reinforce avasopasem's first-in-class potential to reduce SOM, a common and debilitating effect of radiotherapy in patients with head and neck cancer. As we work with the FDA on the potential to bring avasopasem to U.S. patients, we also look forward to discussions with European regulatory authorities on a path for patients in Europe."

Presentation Details:

Title: Net treatment benefit of avasopasem manganese for severe oral mucositis from the ROMAN trial
Abstract Number: 93
Presenter: Carryn M. Anderson, M.D., University of Iowa Hospitals & Clinics
Session Title: QOL in H&N Cancer Treatment
Session Date and Time: Friday, March 10th, 2023 | 9:00 a.m. GMT
Session Location: Auditorium I, Lisbon Congress Centre

The presentation is available on Galera's website at https://www.galeratx.com/our-pipeline/key-publications.

Results from two randomized, double-blind, placebo-controlled trials (Phase 3 ROMAN and Phase 2b GT-201) are the basis of the avasopasem NDA. The Company believes that the supplemental net treatment benefit analysis being presented at ECHNO further supports the avasopasem clinical benefit observed in those trials. It quantitatively demonstrates that the overall improvement in SOM is greater than that captured by any individual endpoint and that the improvement in each of the key SOM endpoints contributes to the benefit. The FDA accepted the filing and granted priority review to the NDA in February 2023, with a PDUFA target date of August 9, 2023. The FDA previously granted Breakthrough Therapy and Fast Track designations to avasopasem for the reduction of RT-induced SOM.

Head and neck cancers are a global problem, as is SOM caused by the standard-of-care RT. The Company intends for avasopasem to help patients beyond the U.S. and plans to meet with the European Medicines Agency (EMA) in 2023 to discuss the potential European registration pathway for avasopasem.

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. A New Drug Application (NDA) for avasopasem is currently under priority review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee (PDUFA) date of August 9, 2023 for radiotherapy-induced severe oral mucositis in patients with head and neck cancer undergoing standard-of-care treatment. The Company's second product candidate, rucosopasem manganese (rucosopasem, or 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.

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 interpretation of the results of the net treatment benefit analysis being presented at ECHNO; the potential to obtain approval by the U.S. Food and Drug Administration for avasopasem for the treatment of radiotherapy-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer at any time, including the anticipated PDUFA target date of August 9, 2023; the potential for avasopasem to be the first FDA-approved drug to reduce SOM in head and neck cancer patients undergoing standard-of-care treatment; the Company's plans to meet with the European Medicines Agency (EMA) to discuss the potential European registration pathway for avasopasem and the timing of that meeting; the Company's ability to provide avasopasem to patients with SOM outside the U.S.; 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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