



## Galera Presents Additional Chronic Kidney Disease Data from ROMAN Trial at 2023 ASCO Annual Meeting

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*As previously reported, avasopasem reduced cisplatin-related chronic kidney disease by 50% compared to placebo at one-year follow-up*

*Additional data demonstrated improved preservation of kidney function at month 3 through one year in avasopasem-treated patients*

*Based on ROMAN oral mucositis data, avasopasem NDA under FDA priority review for radiotherapy-induced SOM; PDUFA target date of August 9, 2023*

MALVERN, Pa., June 05, 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 presented data from the Phase 3 ROMAN trial demonstrating avasopasem manganese (avasopasem) improved preservation of kidney function and reduced cisplatin-related chronic kidney disease (CKD) in patients with head and neck cancer (HNC) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. Patients in the ROMAN trial received standard-of-care radiation therapy with concurrent cisplatin. These kidney results are in addition to the ROMAN data showing a significant reduction in severe oral mucositis (SOM) in these patients, which form the basis of the avasopasem New Drug Application (NDA) currently under priority review with the U.S. Food and Drug Administration (FDA).

"The demonstrated improvement in kidney function and reductions in cisplatin-related CKD following treatment suggest that avasopasem has the potential to significantly reduce known kidney toxicities associated with cisplatin and other platinum-based chemotherapies," said Mel Sorensen, M.D., Galera's President and CEO. "In addition to a reduction in reported renal toxicity adverse events during treatment, benefits to kidney function were observed soon after cessation of cisplatin therapy, with CKD reduced by 50 percent in the avasopasem treatment arm at one year, regardless of cisplatin dosing schedule. Our Phase 3 ROMAN trial demonstrated avasopasem's ability to reduce SOM, a debilitating toxicity induced by radiotherapy, and our NDA for this indication is currently under FDA priority review. The pre-specified exploratory analysis of CKD presented at ASCO suggests a potential additional protective clinical benefit for patients undergoing treatment with cisplatin in multiple cancers."

Highlights from the Phase 3 ROMAN data presented at ASCO:

- Avasopasem was associated with significant improvements in preservation of kidney function compared to placebo based on mean change in estimated Glomerular Filtration Rate (eGFR) compared to baseline, beginning by 3 months through the one-year end of follow-up
- Avasopasem was associated with a significant reduction in incidence of grade 3+ CKD according to KDIGO<sup>1</sup> criteria (eGFR <60 mL/min/1.73m<sup>2</sup>)
  - 10% of patients treated with avasopasem had grade 3+ CKD, compared to 20% of patients in the placebo arm at one-year follow-up (relative risk 0.55, p=0.0043)
- Reductions in CKD were consistent across cisplatin dosing schedules
- Avasopasem was associated with reduced incidence of cisplatin-related renal adverse events during treatment

This prospectively-defined exploratory analysis of the Phase 3 ROMAN trial included patients undergoing the standard-of-care regimen of intensity-modulated radiation therapy (IMRT) with concurrent cisplatin. The effect of avasopasem on kidney function was assessed throughout treatment and every three months for one year following seven weeks of therapy. Grade 3+ CKD was defined as eGFR <60 mL/min/1.73m<sup>2</sup>.

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

### About Avasopasem

Avasopasem manganese 90 mg (avasopasem, or GC4419) 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. Avasopasem is currently under FDA priority review for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment.

## **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, or GC4419) 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 (SOM) 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. 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 ability of avasopasem to improve preservation of kidney function and reduce cisplatin-related chronic kidney disease (CKD) in patients with head and neck 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; 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; 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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<sup>1</sup> Kidney Disease Improving Global Outcomes (KDIGO)