



## Galera Announces Presentation of Phase 3 ROMAN Long-term Follow-up Data at 2022 American Society for Radiation Oncology (ASTRO) Annual Meeting

Oct 26, 2022

*Tumor outcomes and overall survival maintained in patients with HNC at one-year*

*Cisplatin-related chronic kidney disease reduced by 50% in avasopasem patients compared to placebo at one-year*

*Meta-analysis of ROMAN and GT-201 (Phase 2b) supports efficacy across trials and key SOM endpoints*

*Company remains on track to submit NDA to the U.S. FDA for avasopasem for radiotherapy-induced severe oral mucositis by end of 2022*

MALVERN, Pa., Oct. 26, 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 the presentation of one-year tumor and renal function outcomes data from its Phase 3 ROMAN trial of avasopasem manganese 90 mg for radiotherapy-induced severe oral mucositis (SOM), as well as topline results from a recently completed meta-analysis of the ROMAN and GT-201 SOM trial results, at the 2022 American Society for Radiation Oncology (ASTRO) Annual Meeting. Final data from its Phase 2 AESOP trial of avasopasem for radiotherapy-induced esophagitis were also presented today in a separate session. In addition, poster presentations during ASTRO highlighted the completed Phase 2 EUSOM trial of avasopasem for SOM in Europe and the ongoing GRECO-1 trial of rucosopasem for non-small cell lung cancer. The presentations and posters are currently available in the [ASTRO digital program](#).

Highlights from the Phase 3 ROMAN data presented at ASTRO:

- After one-year follow-up, patients with locally advanced head and neck cancer treated with avasopasem in combination with the standard-of-care regimen (intensity-modulated radiation therapy (IMRT) + cisplatin) demonstrated comparable tumor outcomes and overall survival to patients in the placebo arm.
- Patients treated with avasopasem in combination with IMRT + cisplatin had a 10 percent incidence of chronic kidney disease (CKD) after one year of post treatment follow-up, compared to 20 percent of patients in the placebo arm ( $p=0.0043$ ). CKD (eGFR <60) is a known toxicity risk with cisplatin for these patients and the results highlight success on a predefined exploratory endpoint of renal function. The prospective exploration of this potential benefit of avasopasem was driven by published preclinical data and a post hoc assessment of patients from the GT-201 trial presented at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting.

"The ROMAN one-year follow-up data show that avasopasem can protect head and neck cancer patients from severe oral mucositis without affecting the treatment benefit of standard-of-care chemoradiotherapy," said Dr. Carryn Anderson, Clinical Associate Professor of Radiation Oncology at the University of Iowa. "Treatment with avasopasem also significantly reduced the likelihood of patients developing cisplatin-related chronic kidney disease compared to placebo at one-year follow-up, suggesting avasopasem can reduce cisplatin renal toxicities and greatly improve patient quality of life."

In addition to the ROMAN long-term endpoints, a meta-analysis of Galera's two randomized placebo-controlled trials (ROMAN and GT-201;  $n=551$ ) was included in Dr. Anderson's ASTRO presentation; these results reinforced that avasopasem therapy resulted in clinically meaningful reductions in radiotherapy-induced SOM, including a significant reduction in the incidence, duration, onset and severity of SOM compared to placebo.

"The data presented today affirm our belief that avasopasem is providing real benefit for patients with head and neck cancer undergoing the current standard of care," said Mel Sorensen, M.D., Galera's President and CEO. "We look forward to submitting the NDA to the FDA by the end of 2022 with the intention of bringing avasopasem to patients as the first FDA-approved drug for radiotherapy-induced SOM."

## **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 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, 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 (avasopasem, or GC4419) is being evaluated for radiotherapy-induced toxicities. 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. For more information, please visit [www.galeratx.com](http://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 severe oral mucositis (SOM) in patients with locally advanced head and neck cancer with the FDA; the ability of avasopasem to protect head and neck cancer patients from SOM without affecting the treatment benefit of standard-of-care chemoradiotherapy; the ability of avasopasem to reduce cisplatin renal toxicities and improve patient quality of life; 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; 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; the possibility of Galera's common stock being delisted from The Nasdaq Global Market; 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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