Galera Announces Results of Phase 3 ROMAN Trial of Avasopasem for Radiotherapy-Induced Severe Oral Mucositis

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Primary endpoint of reduction in incidence of severe oral mucositis (SOM) not met

Trial demonstrated relative reduction in all key SOM endpoints, including more than halving the median duration

Avasopasem was generally well tolerated compared to placebo

MALVERN, Pa., Oct. 19, 2021 (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 results from the Phase 3 ROMAN trial of avasopasem manganese (avasopasem) for severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) undergoing standard-of-care radiotherapy. The trial did not meet its primary endpoint of reduction in the incidence of SOM. The Company is continuing to analyze the results.

“While the data, as in previous trials, showed reductions in the incidence, duration and severity of SOM, we are surprised and disappointed that the trial did not achieve statistical significance in its primary endpoint,” said Mel Sorensen, M.D., Galera’s President and CEO. “We would like to extend our heartfelt thanks to the patients who participated in this trial while they underwent radiotherapy for head and neck cancer. As we evaluate next steps for this program, we remain committed to our goal of transforming radiotherapy in cancer treatment with our selective dismutase mimetics.”

Key findings include:

- 16% relative reduction in the incidence of SOM in the avasopasem treatment group (54%) vs. placebo group (64%) (p=0.113) (primary endpoint)
- 56% relative reduction in the number of days of SOM in the avasopasem treatment group (8 days) vs. placebo group (18 days) (p=0.011) (secondary endpoint)
- 27% relative reduction in the severity (incidence of Grade 4 OM) of SOM in the avasopasem treatment group (24%) vs. placebo group (33%) (p=0.167) (secondary endpoint)
- Avasopasem was generally well tolerated with similar rates of adverse events in the active and placebo arms

Dr. Sorensen continued, “We continue to be excited about the potential of our second dismutase mimetic product candidate, GC4711, in clinical-stage development to augment the anti-cancer efficacy of stereotactic body radiation therapy (SBRT) in patients with non-small cell lung cancer (NSCLC) and locally advanced pancreatic cancer (LAPC). We recently initiated a Phase 2b trial of GC4711 in combination with SBRT in LAPC based on promising tumor and survival outcome benefits observed in a Phase 1/2 pilot trial. In addition, enrollment is ongoing in a Phase 1/2 trial of GC4711 in combination with SBRT in patients with NSCLC. We look forward to providing updates as these trials progress.”

The ROMAN trial is a randomized, double-blind, placebo-controlled trial in 455 patients with locally advanced HNC receiving seven weeks of standard-of-care radiotherapy plus cisplatin. Patients were randomized to one of the two treatment groups (3:2) to receive 90 mg of avasopasem or placebo by infusion on the days they receive their radiation treatment.

About Oral Mucositis
Oral mucositis is a side effect of radiation therapy characterized by severe pain, inflammation, ulceration and bleeding of the mouth. 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 severe oral mucositis (SOM), defined by the inability to eat solid food (Grade 3) or drink liquids (Grade 4). 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.

About Avasopasem
Avasopasem manganese (avasopasem, or GC4419) is a selective small molecule dismutase mimetic in development for the reduction of radiation-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) and for the reduction of radiation-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 the Phase 3 ROMAN Trial
The ROMAN trial is a randomized, double-blind, placebo-controlled trial designed to evaluate the ability of avasopasem to reduce the incidence and severity of radiation-induced SOM in patients with locally advanced head and neck cancer, receiving seven weeks of radiotherapy plus cisplatin. For more information, please visit https://clinicaltrials.gov/ct2/show/NCT03689712.

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 technology consists of selective small molecule dismutase mimetics that are in late-stage development in patients with cancer. Avasopasem is in development for radiotherapy-induced toxicities, including SOM in patients with head and neck cancer and esophagitis in patients with lung cancer. Avasopasem has been granted FDA Fast Track and Breakthrough Therapy designations for the reduction of SOM induced by radiotherapy, with or without systemic therapy. Galera's second dismutase mimetic product candidate, 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.

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: expectations surrounding the continued advancement of our product pipeline; the potential safety and efficacy of Galera's product candidates and their regulatory and clinical development, including the interpretation of the safety and efficacy results from the Phase 3 ROMAN trial and expectations surrounding the progress of the Phase 2b trial of GC4711 in patients with LAPC and the Phase 1/2 trial of GC4711 in patients with NSCLC; the Company's ability to achieve its goal of transforming radiotherapy in cancer treatment with its selective dismutase mimetics; and the potential of GC4711 to augment the anti-cancer efficacy of SBRT in patients with NSCLC and LAPC. 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; 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, 2020 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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