Galera Announces Completion of Enrollment in Pivotal 455-Patient Phase 3 Trial of Avasopasem for Severe Oral Mucositis

June 28, 2021

Topline data expected in the second half of 2021

Triggers $37.5M milestone payment from Blackstone Life Sciences

MALVERN, Pa., June 28, 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 completion of enrollment in its pivotal Phase 3 ROMAN trial of avasopasem manganese (avasopasem) for the treatment of severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) undergoing standard-of-care radiotherapy. This achievement has triggered a $37.5 million milestone payment from funds managed by Blackstone Life Sciences to Galera under the amended royalty agreement.

“We are extremely pleased to announce completion of enrollment of the pivotal ROMAN trial, laying the groundwork for the potential regulatory approval and commercialization of avasopasem, our lead dismutase mimetic product candidate,” said Mel Sorensen, M.D., Galera’s President and CEO. “About 65% of patients diagnosed with HNC will receive standard-of-care chemoradiotherapy and approximately 70% of those patients will develop SOM. Radiation oncologists describe SOM — which can lead to the inability to eat and drink in addition to causing severe pain — as the most burdensome toxicity patients can face. With no approved product to treat SOM, we are eager to report results in the second half of 2021 for this potentially transformative therapy.”

The ROMAN trial is a randomized, double-blind, placebo-controlled trial in 455 patients designed to evaluate the ability of avasopasem to reduce radiation-induced SOM in 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. The primary endpoint of the trial is the reduction in the incidence of SOM through the radiotherapy period. Secondary endpoints include the reduction in the severity of SOM and the number of days patients experience SOM.

The FDA has granted Fast Track and Breakthrough Therapy Designation to avasopasem for the reduction of SOM induced by radiotherapy, with or without systemic therapy.

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

Galera’s lead product candidate is avasopasem manganese (avasopasem, or GC4419), 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). In addition to the ongoing pivotal Phase 3 ROMAN trial evaluating avasopasem in SOM patients with locally advanced HNC, the Company is conducting a Phase 2a trial of avasopasem assessing its ability to reduce the incidence of radiation-induced esophagitis in patients with lung cancer as well as a Phase 1/2 trial assessing its anti-tumor effect when used in combination with stereotactic body radiation therapy in patients with locally advanced pancreatic cancer. The FDA has granted Fast Track and Breakthrough Therapy Designation 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 lead product candidate is avasopasem manganese (avasopasem, or GC4419), a selective small molecule dismutase mimetic in late-stage development to reduce the incidence and severity of radiotherapy-induced severe oral mucositis (SOM) in patients with head and neck cancer. Avasopasem is also in development for radiotherapy-induced 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 our growth and the continued advancement of our product pipeline, including plans for reporting topline data from the ROMAN trial in the second half of 2021, potential FDA regulatory approval and the commercial launch of avasopasem; the potential, safety, efficacy, and regulatory and clinical development of Galera's product candidates, including whether avasopasem could be a potentially transformative therapy for the treatment of SOM; and expected payments from Blackstone, including the receipt of the $37.5 million triggered upon completion of enrollment of the ROMAN trial. 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 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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