Galera Therapeutics Announces Publication of GC4419 Data in the Journal of Clinical Oncology

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- GC4419 90 mg produced clinically meaningful reduction of severe oral mucositis duration, incidence and severity in Phase 2b clinical trial -

MALVERN, Pa., Dec. 05, 2019 (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 that full results from the 223-patient, randomized, double-blind Phase 2b clinical trial of lead candidate GC4419 (avasopasem manganese) in patients with locally advanced head and neck cancer have been published in the *Journal of Clinical Oncology*, a journal of the American Society of Clinical Oncology (ASCO).

Data in the paper, titled, “Phase IIb, Randomized, Double-Blind Trial of GC4419 Versus Placebo to Reduce Severe Oral Mucositis Due to Concurrent Radiotherapy and Cisplatin For Head and Neck Cancer,” demonstrated that adding a 90 mg dose of GC4419 to a standard radiotherapy regimen produced a significant reduction of severe oral mucositis (SOM) duration from 19 days to 1.5 days (92 percent), and improvement in SOM incidence through completion of radiation by 34 percent and improvement in oral mucositis (OM) severity (Grade 4 OM incidence) by 47 percent.

Carryn Anderson, M.D., Radiation Oncologist, University of Iowa Hospitals and Clinics, and lead investigator, said, “The clinically meaningful Phase 2b data highlight the potential of GC4419 to address a serious unmet need for a therapy to reduce the incidence and severity of radiation-induced severe oral mucositis, for which there is currently no FDA-approved drug. I look forward to the results of the pivotal ongoing ROMAN clinical trial which will potentially reinforce these promising findings.”

“We are pleased that our GC4419 Phase 2b data have been published in the preeminent peer-reviewed oncology journal. These data, like the data previously presented at ASCO, ASTRO and MASCC, reinforce GC4419’s potential to make a meaningful difference for head and neck cancer patients suffering from severe oral mucositis, a debilitating toxicity,” said Mel Sorensen, M.D., President and CEO of Galera. “Enrollment in our Phase 3 ROMAN clinical trial of GC4419 in patients with locally advanced head and neck cancer continues, and we anticipate reporting topline data in the first half of 2021.”

About GC4419 (Avasopasem Manganese)
Galera’s lead product candidate, GC4419 (avasopasem manganese), is a potent and highly selective small molecule dismutase mimetic that is being developed for the reduction of SOM. GC4419 is designed to rapidly convert superoxide to hydrogen peroxide, reducing mucosal damage and thereby the incidence and severity of mucositis. Left untreated, elevated superoxide can damage noncancerous tissues and lead to debilitating side effects, including oral mucositis, which can limit the anti-tumor efficacy of radiation therapy.

GC4419 is being studied in the Phase 3 ROMAN trial for its ability to reduce the incidence, severity and duration of SOM in patients with locally advanced head and neck cancer, its lead indication. In Galera’s 223-patient, double-blind, randomized, placebo-controlled Phase 2b clinical trial, GC4419 demonstrated the ability to reduce the duration of severe oral mucositis (SOM) from 19 days to 1.5 days (92 percent), the incidence of SOM through completion of radiation by 34 percent and the severity of patients’ OM by 47 percent, and GC4419 was well tolerated in the trial when added to a standard radiotherapy regimen. The two-year tumor outcomes follow up of patients enrolled in the trial also demonstrated that GC4419, when added to a standard radiotherapy regimen, maintained the efficacy of treatment, with tumor outcomes maintained across all four measures – overall survival, progression-free survival, locoregional control and metastasis-free survival – in both GC4419 dose groups (30 mg and 90 mg) compared to placebo. GC4419 is also currently being studied in combination with SBRT for its anti-tumor effect in a pilot Phase 1b/2a trial of patients with locally advanced pancreatic cancer. In addition, in multiple preclinical studies, GC4419 demonstrated an increased tumor response to radiation therapy while preventing toxicity in normal tissue.

The U.S. Food and Drug Administration granted Fast Track and Breakthrough Therapy designations to GC4419 for the reduction of the duration, incidence and severity of SOM induced by radiotherapy.

About Galera Therapeutics
Galera Therapeutics, Inc. is 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. Galera’s lead product candidate is GC4419 (avasopasem manganese), a potent and highly selective small molecule dismutase mimetic being developed for the reduction of severe oral mucositis (SOM). GC4419 is being studied in the Phase 3 ROMAN trial for its ability to reduce the incidence, severity and duration of SOM in patients with locally advanced head and neck cancer, its lead indication. The FDA granted Fast Track and Breakthrough Therapy designations to GC4419 for the reduction of the duration,

incidence and severity of SOM induced by radiotherapy. 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 expectations surrounding the potential, efficacy, and regulatory and clinical development of Galera's product candidates, and plans and timing for the release of data from Galera's clinical trials. 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 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; 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 prospectus filed with the U.S. Securities and Exchange Commission (SEC) pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, on November 8, 2019, 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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