Galera Therapeutics Announces Avasopasem Manganese Improved Markers of Chronic Kidney Disease in Patients Receiving Cisplatin

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Retrospective analysis of patients with head and neck cancer treated in Phase 2b clinical trial of avasopasem manganese presented at ASCO 2020 Virtual Scientific Program

MALVERN, Penn., May 29, 2020 (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 new data from a retrospective analysis of pre- and post-treatment markers of kidney function of patients treated with lead candidate avasopasem manganese in its Phase 2b trial for the reduction of chemoradiation-induced severe oral mucositis (SOM). The data are featured in an American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program poster presentation now available for on-demand viewing in ASCO's virtual program.

Avasopasem is a highly selective small molecule superoxide dismutase (SOD) mimetic initially being developed for the reduction of radiation-induced toxicity severe oral mucositis (SOM). Galera's completed Phase 2b clinical trial evaluated avasopasem in patients with locally advanced head and neck cancer. Patients in the trial received seven weeks of concurrent radiation therapy and cisplatin, the current standard of care for head and neck cancer patients, plus either 30 mg or 90 mg of avasopasem or placebo.

Each year in the United States, approximately 65,000 patients are diagnosed with head and neck cancer, according to the American Cancer Society, and nephrotoxicity from cisplatin-based chemotherapy occurs in up to 68 percent of head and neck cancer patients treated.

The retrospective analysis evaluated changes in kidney function markers in a subset of 52 Phase 2b trial participants and 7 matched comparator patients who all received high dose (100 mg/m^2) cisplatin once every three weeks. Post-treatment kidney function markers indicated patients who received 90 mg avasopasem had significantly less cisplatin-induced chronic kidney disease (CKD) compared to placebo.

"Cisplatin, which is commonly used as part of the treatment regimen for patients with head and neck cancer, is associated with robust survival outcomes, but its use can be limited due to nephrotoxicity. There is a serious and unmet need for therapies to prevent or minimize kidney injury associated with cisplatin in order to sustain the survival benefit and ensure clinicians are able to optimize the clinical utility of chemotherapies, including platinum agents, for the up to 40 percent of head and neck cancer patients that develop a loco-regional recurrence," said Bryan Allen, M.D., Ph.D., Radiation Oncologist, University of Iowa Hospitals & Clinics. "The effect of avasopasem on markers of chronic kidney disease is an exciting preliminary finding and warrants continued study."

Specifically, treatment with 90 mg avasopasem demonstrated statistically significant improvements ($p<0.05$) in return of kidney function to normal ranges after chemoradiotherapy, as measured by serum creatinine (sCr) levels between three and 24 months, estimated glomerular filtration rate (eGFR) between three and 24 months, and blood urea nitrogen (BUN) levels at three, six and 18 months, compared to placebo. A significant reduction ($p<0.05$) in the incidence of CKD at 12 months (GFR categories G3a-G5), compared to placebo, was also observed.

"This new analysis demonstrating an improvement in markers of kidney function following cisplatin therapy further strengthens the body of evidence for the potential of avasopasem to be an important part of the treatment armamentarium for cancer," said Mel Sorensen, M.D., President and CEO of Galera. "We look forward to the continued evaluation of the potential of avasopasem in the reduction of chemoradiation-induced toxicities in our ongoing Phase 3 ROMAN trial for the treatment of SOM in head and neck cancer and our Phase 2a trial for the treatment of esophagitis in lung cancer."

About Avasopasem Manganese (GC4419)

Galera's lead product candidate, avasopasem manganese (GC4419), is an investigational, highly selective small molecule superoxide dismutase (SOD) mimetic that is initially being developed for the reduction of radiation-induced severe oral mucositis (SOM). Avasopasem manganese is designed to rapidly and selectively convert superoxide to hydrogen peroxide and oxygen, protecting normal tissue from damage associated with radiation therapy. Left untreated, elevated superoxide can damage noncancerous tissues and lead to debilitating side effects, including oral mucositis (OM), which can limit the anti-tumor efficacy of radiation therapy.

Avasopasem manganese is currently being studied in the ROMAN trial, a randomized, double blind, placebo-controlled Phase 3 trial of approximately 450 patients (NCT03689712 available at clinicaltrials.gov) to investigate the effects of avasopasem manganese on radiation-induced OM in patients

with head and neck cancer. In Galera's 223-patient, double-blind, randomized, placebo-controlled Phase 2b trial in patients with locally advanced head and neck cancer receiving concurrent radiation therapy, avasopasem manganese produced a statistically significant reduction in duration of severe oral mucositis (SOM) from 19 days to 1.5 days (92 percent) in the 90 mg treatment arm. Avasopasem manganese also demonstrated clinically meaningful reductions in SOM incidence through completion of radiation by 34 percent and in the severity of OM (incidence of Grade 4 OM) by 47 percent in the 90 mg treatment arm. No significant safety signals were observed, demonstrating avasopasem manganese was well tolerated when added to a standard radiotherapy regimen. The two-year tumor outcomes follow-up of patients enrolled in the trial were consistent with expectations for intensity-modulated radiation therapy (IMRT)/cisplatin alone suggesting that radiation efficacy was maintained.

Avasopasem manganese is also currently being studied in a Phase 2a trial for its potential to reduce the incidence of radiation-induced esophagitis in patients with lung cancer (NCT04225026 available at clinicaltrials.gov), as well as in a pilot Phase 1/2 trial (NCT03340974 available at clinicaltrials.gov) in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer.

The U.S. Food and Drug Administration granted Fast Track and Breakthrough Therapy designations to avasopasem manganese for the reduction 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 avasopasem manganese (GC4419), a highly selective small molecule superoxide dismutase (SOD) mimetic initially being developed for the reduction of radiation-induced severe oral mucositis (SOM). Avasopasem manganese is being studied in the Phase 3 ROMAN trial for its ability to reduce the incidence and severity of SOM induced by radiotherapy in patients with locally advanced head and neck cancer, its lead indication, and in the Phase 2a trial for its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem manganese for the reduction of SOM induced by radiotherapy. Galera is developing a second product candidate, GC4711, which successfully completed Phase 1 trials in healthy volunteers. 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 our beliefs about clinical data, and the potential, efficacy, and regulatory and clinical development of Galera's product candidates. 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020 filed with the U.S. Securities and Exchange Commission (SEC), Annual Report on Form 10-K for the year ended December 31, 2019 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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