



Galera Therapeutics Announces Interim Data from Pilot Phase 1/2 Trial of GC4419 in Combination with Stereotactic Body Radiation Therapy Showed Improved Overall Survival in Patients with Locally Advanced Pancreatic Cancer

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Initial results from pilot Phase 1/2 clinical trial in patients with locally advanced pancreatic cancer presented during virtual ASTRO Annual Meeting

First trial to evaluate anti-cancer activity of one of Galera's dismutase mimetics in combination with SBRT

Management will host a live audio webcast at 4:30 p.m. EDT

MALVERN, Pa., Oct. 27, 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 interim data from the full patient population (n=42) in its Phase 1/2 clinical trial of avasopasem manganese (GC4419) in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer (LAPC). The data were presented today during the late-breaker special session of the 2020 American Society for Radiation Oncology (ASTRO) virtual Annual Meeting.

GC4419 is an investigational, highly selective small molecule superoxide dismutase mimetic designed to rapidly and selectively convert superoxide to hydrogen peroxide and oxygen. The randomized, double-blind, multicenter, placebo-controlled pilot dose escalation Phase 1/2 trial was designed to evaluate the safety and efficacy of GC4419 in combination with SBRT, compared with SBRT and placebo, in patients with LAPC. The trial assessed safety and efficacy of SBRT when combined with GC4419 or placebo. After completion of induction chemotherapy, patients were randomized (1:1) to receive five-fraction SBRT and 90 mg of GC4419 or placebo control by intravenous infusion one hour prior to each SBRT fraction.

In the interim analysis of the intent-to-treat population (n=42), median overall survival (OS) had not been reached at the data cutoff (date of August 24, 2020) in the GC4419 arm, compared to 38.7 weeks (HR=0.4; 95% CI: 0.12-1.11; p=0.06) in the placebo arm. Six-to-eight weeks post-SBRT, patients underwent protocol-specified evaluation for resection, and seven underwent resection. Of the patients in the GC4419 arm who were surgically resected (n=5), all achieved clear / negative margins (R0), one achieved pathological complete response (pCR) and four achieved pathological partial response (pPR), compared to one R0 and pPR of the two surgically resected patients in the placebo arm. No statistically significant differences in progression-free survival (PFS) were observed between GC4419 and placebo (HR=0.6; 95% CI: 0.23-1.56; p=0.29). However, patients were censored for PFS at the date of surgical resection or due to short interval follow up. Toxicity was comparable across both treatment arms, with no significant differences in acute (<90 days) or late (91-365 days) Grade 3+ toxicity post-SBRT.

"The survival rate in pancreatic cancer is dismal. Our goals for treatment are to extend survival and improve the potential for surgical resection, as surgery remains the only potentially curative therapy for pancreatic cancer," said Sarah Hoffe, M.D., Section Head of GI Radiation Oncology and Senior Member at Moffitt Cancer Center, trial first author and investigator. "These interim data signal the potential of dismutase mimetics, when combined with SBRT, to prolong survival in patients with LAPC. Further study of dismutase mimetics to expand the utility of SBRT in pancreatic cancer treatment is warranted."

The interim data includes all patients followed for a minimum of three months and 19 for more than one year, with data through August 24, 2020. The Company plans to provide an additional update on this trial with at least one year of follow up on all patients in the second half of 2021.

"We're encouraged by the favorable overall survival benefit in this difficult-to-treat cancer observed in the interim data in this trial, which is the first trial evaluating the anti-cancer activity of one of Galera's dismutase mimetics in combination with SBRT," said Mel Sorensen, M.D., President and CEO of Galera. "Galera's dismutase mimetics are designed to improve radiation therapy by both increasing therapeutic anti-tumor efficacy at higher doses of radiation and by protecting normal cells, and we look forward to advancing the development of this potential combination therapy and expanding into other cancers to improve outcomes for patients undergoing radiotherapy for the treatment of cancer."

The Company plans to leverage observations from this pilot trial to further develop GC4711, its second superoxide dismutase mimetic clinical candidate, specifically for use in combination with SBRT, and anticipates initiating a follow-on Phase 2 trial in pancreatic cancer with GC4711 in combination with SBRT in the first half of 2021. Galera recently announced it is also evaluating the anti-cancer activity of GC4711 in an ongoing Phase 1/2 trial in combination with SBRT in patients with non-small cell lung cancer (NSCLC).

The presentation is available for on-demand viewing for registered ASTRO attendees for the next 30 days.

Conference Call

Galera will host a live audio webcast at 4:30 p.m. EDT today accessible from the Investors page of Galera's website, investors.galeratx.com. An archived version of the webcast will be available in the News & Events section of the Investors page of Galera's website for 60 days following the

event.

About GC4419 (Avasopasem Manganese)

Galera's lead product candidate, avasopasem manganese, 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), which is not yet approved. Avasopasem 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 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 on radiation-induced OM in patients with locally advanced 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 produced a statistically significant reduction in duration of SOM from 19 days to 1.5 days (92 percent) in the 90 mg treatment arm. Avasopasem 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. The overall safety findings for avasopasem in the Phase 2b trial was similar to that of placebo and consistent with the known adverse effects of chemoradiation, with reductions of blood cell counts, particularly low lymphocyte counts, the most prominent adverse events. Adverse events considered attributable to avasopasem were limited to mild, transient postural light-headedness or decreased blood pressure. Patients were followed for two years after enrollment and showed no difference in tumor outcomes between active and control, consistent with expectations for combinations with intensity-modulated radiation therapy (IMRT)/cisplatin, suggesting that the efficacy of the chemoradiation therapy was not compromised.

Avasopasem 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) and in a Phase 2 trial in hospitalized patients who are critically ill with COVID-19 (NCT04555096, available at clinicaltrials.gov); and a pilot Phase 1/2 trial (NCT03340974, available at clinicaltrials.gov) of avasopasem in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer was completed.

The U.S. Food and Drug Administration granted Fast Track and Breakthrough Therapy designations to avasopasem 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 is being studied in the Phase 3 ROMAN trial to assess its ability to reduce the incidence and severity of SOM induced by radiotherapy in patients with locally advanced head and neck cancer (HNC), its lead indication. It is also being studied in a Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, a Phase 2a trial to assess its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer, and a Phase 2 trial in hospitalized patients who are critically ill with COVID-19. A pilot Phase 1/2 trial of avasopasem in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer was completed. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. Galera's second SOD mimetic product candidate, GC4711, is initially being developed to augment the anti-cancer efficacy of radiation and is currently being studied in a Phase 1/2 clinical trial in combination with SBRT in patients with non-small cell lung 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 the potential, safety, efficacy, and regulatory and clinical development of Galera's product candidates, including with respect to the pilot Phase 1/2 clinical trial of GC4419 in combination with SBRT for LAPC and related data readouts, as well as the development of GC4711; and Galera's participation in upcoming events and presentations. 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; results of earlier studies and trials may not be predictive of future trial results; interim, topline and preliminary data may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data; 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 for which we have not yet received such designations; 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 June 30, 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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