Galera Announces Topline Results from Phase 2a AESOP Trial of Avasopasem for Chemoradiotherapy-Induced Esophagitis

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Incidence of Grade 3 esophagitis substantially reduced in patients treated with avasopasem compared to literature

No Grade 4 or 5 esophagitis in patients treated with avasopasem

MALVERN, Pa, May 02, 2022 (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 topline results from the six-week, Phase 2a, open-label, single-arm AESOP trial of avasopasem evaluating its ability to reduce the incidence of severe acute radiation-induced esophagitis in patients with lung cancer receiving concurrent chemoradiotherapy.

The multicenter Phase 2a trial enrolled 39 patients (62 screened) with unresectable Stage 3A/3B or post-operative Stage 2B non-small cell (NSCLC) or limited-stage small cell (SCLC) lung cancers. Thirty-five patients completed treatment with 60 gray of intensity-modulated radiation therapy (IMRT) plus chemotherapy over six weeks. Of these 35 patients, 29 received at least five weeks of 90 mg of avasopasem on the days they underwent IMRT. These 29 patients were evaluated as the pre-specified per protocol population. Patients enrolled in this trial were considered at high risk for developing esophagitis due to the amount of radiation planned to be delivered to the esophagus.[1] Patients were assessed and classified according to NCI-CTCAE criteria.[2]

Incidence of esophagitis by grade and timepoint in the AESOP trial (per protocol, n=29):

	Weeks of IMRT					
	1	**2**	**3**	**4**	**5**	**6**
Grade 2	-	10%	17%	38%	48%	45%
Grade 3	-	-	3%	-	-	3%
Grade 4 or 5	-	-	-	-	-	-
Grading Scale for Esophagitis per NCI Criteria						
Grade 1	Asymptomatic; clinical or diagnostic observations only; intervention not indicated					
Grade 2	Symptomatic; altered eating/swallowing; oral supplements indicated					
Grade 3	Severely altered eating/swallowing; tube feeding, TPN, or hospitalization indicated					
Grade 4	Life-threatening consequences; urgent operative intervention indicated					
Grade 5	Death					

Only two of the 29 patients (7%) experienced Grade 3 esophagitis at any time, with neither patient experiencing Grade 3 for more than one week. No patients experienced Grade 4 or 5 esophagitis at any point during the trial. These data compare favorably to the literature in which approximately 20-30 percent of these patients experienced Grade 3 or 4 esophagitis.[3] Avasopasem was generally well tolerated. The adverse events experienced are comparable to those expected with chemoradiotherapy.

“These encouraging results demonstrate avasopasem’s potential to meaningfully reduce radiotherapy-induced Grade 3 or worse esophagitis,” said Mel Sorensen, M.D., Galera’s President and CEO. “Patients with lung cancer undergoing chemoradiotherapy are at high risk of severe and potentially life-threatening esophagitis, including an inability to eat or swallow, severe pain, ulceration, infection, bleeding and weight loss, and there are no established drug therapies. Following the positive Phase 3 results of avasopasem in radiotherapy-induced severe oral mucositis (SOM), we believe these results in esophagitis support the safety and efficacy of avasopasem as a potential therapy to prevent the most severe forms of radiotherapy-induced toxicities.”

Approximately 50,000 lung cancer patients undergo standard-of-care chemoradiotherapy every year in the U.S. and are at risk of developing esophagitis.

About Radiotherapy-Induced Esophagitis
Radiotherapy-induced esophagitis is a common and debilitating adverse effect that develops in patients receiving radiotherapy, most commonly for lung, esophageal, breast or head and neck cancers or for lymphoma. Radiotherapy-induced esophagitis is inflammation, edema, erythema, and erosion of the mucosal surface of the esophagus caused by radiotherapy. Esophagitis can be life-threatening, and symptoms include an inability to swallow, severe pain, ulceration, infection, bleeding and weight loss and may require hospitalization. There are currently no FDA-approved drugs and

no established guidelines for the treatment of radiotherapy-induced esophagitis.

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 2a AESOP Trial
The AESOP trial is an open-label, multicenter trial designed to evaluate the ability of avasopasem to reduce the incidence of radiotherapy-induced esophagitis in patients receiving chemoradiotherapy for unresectable Stage 3A/3B or post-operative Stage 2B non-small cell lung cancer, or small cell lung cancer treatable with chemoradiotherapy. For more information, please visit https://clinicaltrials.gov/ct2/show/NCT04225026.

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 selective dismutase mimetic product candidate avasopasem manganese (GC4419, also referred to as avasopasem) is being evaluated for radiotherapy-induced toxicities. The Company's second product candidate, rucosopasem manganese (GC4711, also referred to as rucosopasem), 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: the potential of Galera's product candidates to transform radiotherapy in cancer; the potential safety of those product candidates; and the ability of avasopasem to reduce or prevent the incidence of severe acute radiation-induced esophagitis in patients with lung cancer receiving chemoradiotherapy. 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, 2021 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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[1] Palma, DA. (2013). *Int J Radiation Oncol Biol Phys*, Vol. 87 (4), 690-696.

[2] NCI Common Toxicity Criteria 5.0.

[3] LAMP Study. Belani, CP et al. (2005). *J Clin Oncol*, 23:5883-5891 (carboplatin + paclitaxel chemo); RTOG 9410. Curran, WJ et al. (2011). *J Natl Cancer Inst*, 103:1452–1460 (cisplatin + vinblastine).