Galera Announces Primary Endpoint Met Statistical Significance in Corrected Topline Efficacy Data of Phase 3 ROMAN Trial of Avasopasem

December 14, 2021

Corrected topline Phase 3 ROMAN data demonstrate primary endpoint achieved statistical significance in reducing the incidence of radiotherapy-induced severe oral mucositis (p=0.045)

Topline results from single-arm Phase 2a trial of avasopasem in Europe in line with the ROMAN trial results

Company plans to discuss avasopasem data with the FDA in 2022

Company to host conference call and live audio webcast on Tuesday, December 14 at 8:30 a.m. ET

MALVERN, Pa., Dec. 14, 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 (RT) in cancer, today announced that corrected results from its Phase 3 ROMAN trial of avasopasem for the treatment of RT-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) achieved statistical significance on the primary endpoint of reduction in the incidence of SOM. Avasopasem has been granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for the reduction of SOM induced by RT.

The Company previously announced the Phase 3 ROMAN trial of avasopasem in SOM did not achieve statistical significance on the primary endpoint. Upon further analysis, an error by the contract research organization (CRO) was identified in the statistical program. Correction of this error resulted in improved p-values for the primary and secondary endpoints.

The corrected p-values are as follows:

- 16% relative reduction in the incidence of SOM in the avasopasem treatment group (54%) vs. placebo group (64%) (**p=0.045***) (previously reported as p=0.113) (primary endpoint)
- 56% relative reduction in the number of days of SOM in the avasopasem treatment group (8 days) vs. placebo group (18 days) (**p=0.002***) (previously reported as p=0.011) (secondary endpoint)
- 27% relative reduction in the severity (incidence of Grade 4 OM) of SOM in the avasopasem treatment group (24%) vs. placebo group (33%) (**p=0.052**) (previously reported as p=0.167) (secondary endpoint)

The Company also announced topline results from its single-arm Phase 2a EUSOM trial of avasopasem in Europe for RT-induced SOM in patients with HNC undergoing standard-of-care RT + cisplatin. This trial was conducted in 12 centers across six countries in Europe and enrolled 38 patients, of which 33 completed full treatment. Avasopasem appeared to be generally well tolerated. In EUSOM, the incidence of SOM was 54.5% and the median number of days of SOM was 9 days, in line with the ROMAN trial in which the incidence was 54% and the median duration was 8 days.

“Given the high unmet medical need for patients with head and neck cancer who develop radiotherapy-induced severe oral mucositis, we are gratified that the Phase 3 ROMAN trial achieved statistical significance on the primary endpoint after the correction of the statistical programming error,” said Mel Sorensen, M.D., President and CEO of Galera. “ROMAN is our second randomized trial conducted in patients with head and neck cancer to achieve statistical significance and demonstrate improved clinical benefit. As we continue to analyze the full data set and evaluate our resources, we look forward to meeting with the FDA in 2022 to discuss whether the results from this single Phase 3 trial together with the randomized Phase 2b trial could support an NDA submission.”

Approximately 42,000 HNC patients undergo standard-of-care RT every year in the U.S. and are at risk of experiencing SOM, painful mouth sores that impact the ability to eat and drink. In market research, both radiation oncologists and patients cite SOM as the most burdensome RT toxicity in HNC treatment. Currently, there are no FDA approved drugs to reduce the incidence or duration of SOM in solid tumors.

Continued Dr. Sorensen, “In parallel, our anti-cancer therapeutic trials in lung and pancreatic cancer, which we refer to as the GRECO-1 and GRECO-2 trials, respectively, are currently enrolling, and we look forward to reporting initial data from our GRECO-1 trial in the first half of 2022. Both trials combine our second dismutase mimetic candidate, rucosopasem, with stereotactic body radiation therapy (SBRT) with the goal of augmenting the anti-cancer efficacy of SBRT.”

Conference Call

Galera will host a conference call and live audio webcast on Tuesday, December 14 at 8:30 a.m. ET to discuss the ROMAN Phase 3 data, including additional analyses from the full data set, and provide a general business update. The webcast will be accessible from the Investors page of Galera's website, investors.galeratx.com, and an archived version of the webcast will be available in the News & Events section of the Investors page of Galera's website for 30 days following the event.

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: expectations surrounding the continued advancement of our product pipeline, including timing of a meeting with the U.S. Food and Drug Administration to discuss avasopasem data; the potential safety and efficacy of Galera's product candidates and their regulatory and clinical development, including the interpretation of the safety and efficacy results from the Phase 3 ROMAN trial and the EUSOM trial; whether the results from the Phase 3 ROMAN trial together with the randomized Phase 2b trial could support an NDA submission; timing of enrollment in the Company's anti-cancer therapeutic trials in lung and pancreatic cancer, which the Company refers to as GRECO-1 and GRECO-2, respectively; timing of reporting initial data from the Company's GRECO-1 trial; and the Company's ability to achieve its goal of transforming radiotherapy in cancer treatment with its selective dismutase mimetics. 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) and rucosopasem manganese (GC4711); 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, 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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* Statistical significance per statistical analysis plan for the Phase 3 ROMAN trial