# Galera Announces Receipt of Type A Meeting Minutes and Strategic Update

Oct 31, 2023

*FDA confirms need for new trial for avasopasem for severe oral mucositis (SOM)*

*GRECO-2 trial did not pass futility analysis; Company will discontinue both GRECO trials*

*Company reviewing potential strategic alternatives to maximize shareholder value*

MALVERN, Pa., Oct. 31, 2023 (GLOBE NEWSWIRE) -- Galera Therapeutics, Inc. (Nasdaq: GRTX), a clinical-stage biopharmaceutical company focused on developing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer, today announced that it has received official meeting minutes from the Type A meeting with the United States Food and Drug Administration (FDA) held September 28, 2023 in which the FDA reiterated the need for an additional Phase 3 trial of avasopasem manganese (avasopasem) for radiotherapy-induced SOM. The Company also decided to halt the Phase 2b GRECO-2 trial of rucosopasem manganese (rucosopasem) in patients with locally advanced pancreatic cancer (LAPC) and the Phase 1/2 GRECO-1 trial of rucosopasem in patients with non-small cell lung cancer (NCSLC), following a futility analysis of the GRECO-2 trial. The Company believes this decision will enable the Company to conserve cash while it continues to assess potential strategic alternatives with the goal of maximizing shareholder value.

In the Type A Meeting minutes, the FDA reiterated that results from an additional Phase 3 trial will be required to support resubmission of the Company's New Drug Application (NDA) for avasopasem in radiotherapy-induced SOM.

"We are disappointed that the FDA did not find the data from our Phase 2b GT-201 and Phase 3 ROMAN trials sufficient for the approval of the NDA for avasopasem," said Mel Sorensen, M.D., Galera's President and CEO. "After discussing the data with the FDA, it is clear that their position is another Phase 3 trial is required."

To optimize the Company's resources, it conducted a futility analysis of the GRECO-2 trial to assess the likelihood of a successful outcome. The analysis indicated that the trial was unlikely to succeed as designed. GRECO-2 is a randomized, double-blind, placebo-controlled Phase 2b trial evaluating rucosopasem or placebo in combination with SBRT in patients with LAPC. Overall survival is the trial's primary endpoint. The trial was designed to enroll 220 patients with final analysis at 120 events (deaths). The trial has enrolled 177 patients to date, and the futility analysis was conducted based on 35 deaths with a data cutoff of October 9, 2023.

Dr. Sorensen continued, "In light of our current resources and the results of the futility analysis, we have made the difficult decision to discontinue both GRECO trials. We will analyze the data collected to date to determine next steps for the asset, and we thank the patients and providers who participated in both trials."

The Company has engaged Stifel, Nicolaus & Company, Inc. to assist in reviewing strategic alternatives for the Company and its portfolio of dismutase mimetics with the goal of maximizing value for its shareholders. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction. If the Company is unable to undertake any strategic alternative, it may be required to cease operations altogether.

Galera estimates that its balance of cash, cash equivalents and short-term investments as of September 30, 2023 was $28.4 million. This figure is preliminary and is subject to completion of the Company's financial closing procedures. The Company plans to file its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 on November 14, 2023.

**About Galera Therapeutics**

Galera Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing 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 (avasopasem) is being developed for radiation-induced toxicities. The FDA has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of severe oral mucositis induced by radiotherapy. The Company's second product candidate, rucosopasem manganese (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. Rucosopasem was granted orphan drug designation and orphan medicinal product designation by the FDA and EMA, respectively, for the treatment of pancreatic cancer. 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: the expectations surrounding the continued advancement of Galera's product pipeline; the potential safety and efficacy of Galera's product candidates and their regulatory and clinical development; Galera's intention to pursue strategic alternatives and the ability

of any such strategic alternative to provide shareholder value; the expected financial and operational impacts of Galera's decision to discontinue the Phase 2b GRECO-2 trial and the Phase 1/2 GRECO-1 trial; Galera's estimated balance of cash, cash equivalents and short-term investments as of September 30, 2023; and Galera'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; substantial doubt regarding Galera's ability to continue as a going concern; 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; 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; environmental, health and safety laws and regulations; Galera's recent reduction in force undertaken to significantly reduce our ongoing operating expenses may not result in our intended outcomes and may yield unintended consequences and additional costs; Galera may not be able to enter into any desired strategic alternative or partnership on a timely basis, on acceptable terms, or at all; if Galera is unable to secure additional funding or enter into any desired strategic alternative or partnership, it may need to cease operations; risks related to ownership of Galera's common stock; the possibility of Galera's common stock being delisted from The Nasdaq Global Market; 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, 2022 and Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023 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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