Galera Announces FDA Orphan Drug Designation Granted to Rucosopasem for Pancreatic Cancer

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Rucosopasem in clinical development to augment the anti-cancer efficacy of stereotactic body radiation therapy

MALVERN, Pa., May 18, 2023 (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 that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to Galera's second product candidate, rucosopasem manganese (rucosopasem), for the treatment of pancreatic cancer.

Rucosopasem is a next-generation selective dismutase mimetic in clinical development to augment the anti-cancer efficacy of stereotactic body radiation therapy (SBRT) in patients with pancreatic cancer and lung cancer. The Company is currently conducting the GRECO-2 Phase 2b randomized, double-blind, placebo-controlled 220-patient trial of rucosopasem in combination with SBRT in patients with locally advanced pancreatic cancer (LAPC).

"Orphan drug designation for rucosopasem highlights the urgent need for more treatment options to extend survival in patients with pancreatic cancer, which is the fourth leading cause of cancer death in the U.S.," said Mel Sorensen, M.D., Galera's President and CEO. "Following our announcement of encouraging survival results from our pilot proof-of-concept trial in patients with LAPC in 2021, we initiated the GRECO-2 trial, which is currently enrolling. We believe rucosopasem has the potential to improve the efficacy of SBRT for pancreatic cancer, and we anticipate topline data from GRECO-2 by the end of next year."

About Orphan Drug Designation
The U.S. Food and Drug Administration (FDA)'s orphan drug product program is designed to support the development of new drug candidates for the treatment of rare diseases (a condition with a prevalence of less than 200,000 in the U.S.). The FDA has authority to grant orphan drug status to a drug product intended to treat, diagnose or prevent a rare disease or condition. Orphan drug designation provides certain benefits, including market exclusivity upon regulatory approval, exemption of FDA application fees, and tax credits for qualified clinical trials.

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 (avasopasem, or GC4419) is being developed for radiation-induced toxicities. A New Drug Application (NDA) for avasopasem is currently under priority review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee (PDUFA) date of August 9, 2023 for radiotherapy-induced severe oral mucositis in patients with head and neck cancer undergoing standard-of-care treatment. The Company's second product candidate, rucosopasem manganese (rucosopasem, or GC4711), 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 by the U.S. FDA 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; the potential to obtain approval by the U.S. Food and Drug Administration for avasopasem for the treatment of radiotherapy-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer at any time, including the anticipated PDUFA target date of August 9, 2023; the expectations surrounding the progress of the randomized, placebo-controlled Phase 2b GRECO-2 trial of rucosopasem in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer and the timing of completion of enrollment of the trial and topline data readout therefrom; 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; 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 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, 2022 and Quarterly Report on Form 10-Q for the quarter ended March 31, 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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