Galera Announces Results from Phase 1 Stage of GRECO-1 Trial of Rucosopasem with SBRT for NSCLC

June 29, 2022

Rucosopasem was safe and well tolerated

Early indications of anti-cancer activity and pulmonary function preservation

Enrollment ongoing in the randomized, double-blinded, placebo-controlled Phase 2 stage of this trial

MALVERN, Pa., June 29, 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 results from the open-label Phase 1 stage of the GRECO-1 trial of rucosopasem in combination with stereotactic body radiation therapy (SBRT) in patients with centrally located or large non-small cell lung cancer (NSCLC). Enrollment is ongoing in the randomized, double-blinded, placebo-controlled Phase 2 stage of the trial, with completion of enrollment anticipated in the second half of 2023.

“The initial results from the Phase 1 stage of GRECO-1 demonstrate a promising safety profile for the rucosopasem and SBRT combination in patients with NSCLC,” said Mel Sorensen, M.D., Galera’s President and CEO. “We are also encouraged by the initial signs of anti-tumor activity observed and the preliminary evidence for preservation of pulmonary function compared to historical literature evaluating pulmonary function in a similar patient population with SBRT alone. We look forward to seeing how the combination performs compared to SBRT alone in the ongoing Phase 2 stage of this trial.”

Key findings in this group of seven patients (median age = 72) include:

- Rucosopasem in combination with SBRT appeared well tolerated. The most frequent adverse events were fatigue, cough, and nausea, which are common in patients with lung cancer receiving radiotherapy.
- In-field partial responses or stable disease were seen in six of the seven patients at six months follow-up, including target tumor reductions in five patients of 61%, 58%, 33%, 29% and 27% from baseline.
- All seven patients are alive through a minimum of nine months of follow-up.
- Early evidence of protection of pulmonary function was observed compared to the literature. No Grade 2-4 (RTOG scale) declines in DLCO[1] were seen in any of the seven patients receiving rucosopasem compared to a prospective trial (n=127) evaluating pulmonary function after four to five fractions of lung SBRT, in which 7-12% of patients had Grade 2-4 decline in DLCO.[2]

GRECO-1 consists of two stages. The primary endpoint of this open-label Phase 1 stage was safety of 100 mg of rucosopasem administered intravenously over 15 minutes in combination with each of five SBRT treatments. Secondary endpoints include late toxicities through 12 months and anti-cancer efficacy through 24 months. Anti-cancer endpoints include overall and progression-free survival, as well as local tumor and distant metastasis control.

The Phase 2 stage of GRECO-1 is a randomized, double-blinded, placebo-controlled evaluation in up to 66 patients with large and/or central NSCLC tumors. Patients are being randomized in a 1:1 ratio to receive either 100 mg of rucosopasem or placebo before each fraction of SBRT. The primary endpoint of the Phase 2 stage of the trial is in-field (i.e., SBRT target) tumor response at six months post SBRT. Patients are also being followed for long-term anti-cancer endpoints and safety similar to the Phase 1 stage of the trial.

About Rucosopasem
Rucosopasem manganese (rucosopasem, or GC4711) is a selective dismutase mimetic in development to augment the anti-cancer efficacy of stereotactic body radiation therapy (SBRT). The molecule is currently being studied in a Phase 1/2 trial in combination with SBRT in patients with non-small cell lung cancer (NCT04476797) and a Phase 2b trial in combination with SBRT in patients with locally advanced pancreatic cancer (NCT04698915).

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 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 timing of enrollment in the randomized, double-blinded, placebo-controlled Phase 2 stage of the GRECO-1 trial; and the performance of the rucosopasem, SBRT combination compared to SBRT alone in the Phase 2 stage of the GRECO-1 trial and the results of the Phase 2 stage of the GRECO-1 trial. 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.

Investor Contacts:
Christopher Degnan
Galera Therapeutics, Inc.
610-725-1500
cdegnan@galeratx.com

William Windham
Solebury Trout
646-378-2946
wwindham@soleburytrout.com

Media Contact:
Zara Lockshin
Solebury Trout
330-417-6250
zlockshin@soleburytrout.com

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[1] Diffusing capacity of the lung for carbon monoxide; one standard measure of pulmonary function

[2] Stone B, Mangona VS, Johnson MD et.al. Changes in pulmonary function following image-guided stereotactic lung radiotherapy. J Thorac Oncol. 2015;10: 1762–1769