Science Translational Medicine Article Shows Galera's Selective Dismutase Mimetic Synergizes with Radiotherapy to Ablate Tumors

May 12, 2021

Describes mechanism which sensitizes cancer cells to radiotherapy

Supports recent results showing a near doubling of median overall survival observed in patients with pancreatic cancer by combining Galera's dismutase mimetic with radiation therapy

MALVERN, Pa., May 12, 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 in cancer, today announced that *Science Translational Medicine* has published a foundational preclinical article describing the synergy of avasopasem manganese, one of the Company's selective dismutase mimetics, with high fraction dose radiotherapy, such as stereotactic body radiation therapy (SBRT) or stereotactic ablative radiotherapy (SAbR), in killing tumors. The research, a collaboration between scientists at University of Texas Southwestern, University of Iowa and Galera, is part of the basis for two ongoing clinical trials with the Company's dismutase mimetics in combination with SBRT in pancreatic cancer and lung cancer. Galera recently reported clinical results from its placebo-controlled Phase 1/2 pilot trial, showing that the combination of its selective dismutase mimetic with SBRT nearly doubled the median overall survival of patients with locally advanced pancreatic cancer (LAPC).

"We are gratified to have these results published in *Science Translational Medicine* describing the strong scientific rationale which underpin the promising clinical data seen in our pancreatic cancer trial," said Mel Sorensen, M.D., President and CEO of Galera. "We thank our research collaborators who have helped us lay out the novel scientific basis for this potentially groundbreaking therapy for patients."

The publication, "Avasopasem manganese synergizes with hypofractionated radiation to ablate tumors through the generation of hydrogen peroxide," reports from preclinical cell and tumor models that the selective dismutase mimetic — by converting superoxide produced as a byproduct of radiotherapy into hydrogen peroxide — increased cancer cell killing with radiation. The synergy between the mimetic and radiotherapy increased with larger daily doses ("fractions") of radiation. Moreover, in the range of fraction sizes typical of SBRT, the combination ablated many of the tumors. In addition, as previously published, the authors report that by removing the superoxide, the dismutase mimetics protected normal cells from radiation toxicity. These two separate benefits of the dismutase mimetics with radiotherapy act through the differential responses to superoxide and hydrogen peroxide by normal cells and cancer cells and are at the core of Galera's clinical programs.

Consistent with today's publication, Galera recently reported updated clinical results from a randomized, placebo-controlled Phase 1/2 pilot trial in which a near doubling of median overall survival was observed in patients with LAPC treated with a dismutase mimetic combined with SBRT versus placebo plus SBRT. Final results from this trial are expected in the second half of 2021. Building on the pilot trial, the Company expects to open the randomized Phase 2b GRECO-2 trial of GC4711, its second dismutase mimetic product candidate, in combination with SBRT in patients with LAPC in the first half of this year. Galera's Phase 1/2 GRECO-1 trial of GC4711 is ongoing, testing its dismutase mimetic in combination with SBRT for patients with non-small cell lung cancer.

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 lead product candidate is avasopasem manganese (GC4419, also referred to as avasopasem), a selective small molecule dismutase mimetic initially being developed for the reduction of radiation-induced severe oral mucositis (SOM). Avasopasem is being studied in the Phase 3 ROMAN trial to assess its ability to reduce the incidence and severity of SOM induced by radiotherapy in patients with locally advanced head and neck cancer (HNC), its lead indication. It is also being studied in the EUSOM Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, the AESOP Phase 2a trial to assess its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer, and a Phase 2 trial in hospitalized patients who are critically ill with COVID-19. A pilot Phase 1/2 trial of avasopasem in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer (LAPC) has completed enrollment and reported updated results, with follow-up ongoing. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy, with or without systemic therapy. Galera's second dismutase mimetic product candidate, GC4711, is being developed specifically to augment the anti-cancer efficacy of SBRT, and is currently being studied in the GRECO-1 Phase 1/2 trial in combination with SBRT in patients with non-small cell lung cancer. Galera also intends to initiate the GRECO-2 Phase 2b trial of GC4711 in combination with SBRT in patients with LAPC. 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 our growth and the continued advancement of our product pipeline, including plans for the commercial launch of avasopasem; the potential, safety, efficacy, and regulatory and clinical development of Galera's product candidates; and plans and timing for the commencement of and the release of data from Galera's clinical trials. 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 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.

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
646-378-2960
zlockshin@soleburytrout.com