Galera Reports Second Quarter 2022 Financial Results and Recent Corporate Updates

August 9, 2022

Company on track to submit NDA to U.S. FDA for avasopasem by end of 2022

Phase 3 ROMAN trial data highlighted in an oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting

Phase 1 stage of GRECO-1 trial demonstrated rucosopasem in combination with SBRT was well tolerated with early indications of anti-cancer activity

Completion of enrollment in both GRECO-1 and GRECO-2 trials of rucosopasem in combination with SBRT expected in 2H 2023

MALVERN, Pa., Aug. 09, 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 financial results for the second quarter ended June 30, 2022 and provided recent corporate updates.

“During this past quarter, we made substantial progress in advancing our product candidates, avasopasem and rucosopasem, across all programs,” said Mel Sorensen, M.D., Galera’s President and CEO. “We continue to prepare for submission of an NDA for avasopasem for the treatment of radiotherapy-induced SOM and are on track to submit it by the end of the year. Further, data from our Phase 3 ROMAN trial were presented at multiple prestigious medical conferences, including ASCO, underscoring the significant unmet need for an FDA-approved treatment option for radiotherapy-induced SOM in patients with head and neck cancer. In addition, we recently announced data from the open-label Phase 1 stage of GRECO-1 investigating rucosopasem in combination with SBRT in patients with NSCLC and are pleased to report that rucosopasem seems to exhibit a favorable benefit-risk profile, with in-field partial responses or stable disease seen in six of the seven patients at six months follow-up.”

Recent Corporate Updates

Radiotherapy-Induced Toxicity Programs:

Severe Oral Mucositis (SOM)

- The Company remains on track to submit a New Drug Application (NDA) for avasopasem for the treatment of radiotherapy-induced SOM to the U.S. Food and Drug Administration (FDA) by the end of 2022.
- An oral presentation on Phase 3 ROMAN data of avasopasem for SOM was given at the 2022 ASCO Annual Meeting. Avasopasem produced a clinically meaningful reduction in patients’ SOM burden across multiple endpoints, with statistically significant reductions on the primary endpoint of incidence of SOM and the secondary endpoint of number of days of SOM, more than halving the median number of days a patient suffered SOM. Avasopasem also appeared to be well tolerated compared to placebo.
- Data from the Phase 3 ROMAN trial of avasopasem for SOM was presented at the Multinational Association of Supportive Care in Cancer (MASCC)/International Society for Oral Oncology (ISOO) Annual Meeting in June 2022.

Esophagitis

- The Company reported positive topline data from the open-label, single-arm Phase 2a AESOP trial of avasopasem for the treatment of severe acute radiation-induced esophagitis in patients with lung cancer receiving concurrent chemoradiotherapy. Overall, avasopasem was well tolerated and the incidence of Grade 3 esophagitis was substantially reduced in comparison to expectations based on review of historical data in the literature. No patients experienced Grade 4 or 5 esophagitis at any point during the trial.

Anti-Cancer Programs:

Locally Advanced Pancreatic Cancer (LAPC)

- A Trials in Progress poster on the Phase 2b GRECO-2 trial was presented at the 2022 ASCO Annual Meeting.

- Enrollment is ongoing in the Phase 2b GRECO-2 trial of rucosopasem in combination with SBRT in patients with LAPC. The primary endpoint of the trial is overall survival. Completion of enrollment is expected in the second half of 2023.

Non-Small Cell Lung Cancer (NSCLC)

- The Company recently reported results from the open-label, seven-patient Phase 1 stage of the GRECO-1 trial of rucosopasem in combination with SBRT in patients with NSCLC. Through six months follow-up, in-field partial responses were observed in three patients and stable disease was observed in three others based on RECIST criteria. These include target tumor reductions in five patients of 61%, 58%, 33%, 29% and 27% and one patient with an 8% increase. Preservation of pulmonary lung function was also observed in comparison to expectations based on review of historical data in the literature. Completion of enrollment in the randomized, placebo-controlled Phase 2 stage of this trial is expected in the second half of 2023.

Second Quarter 2022 Financial Highlights

- Research and development expenses were $6.7 million in the second quarter of 2022, compared to $16.0 million for the same period in 2021. The decrease was primarily attributable to a decrease in avasopasem development costs, partially offset by an increase in rucosopasem development costs.

- General and administrative expenses were $5.3 million in the second quarter of 2022, broadly consistent with the second quarter of 2021.

- Galera reported a net loss of $(14.6) million, or $(0.54) per share, for the second quarter of 2022, compared to a net loss of $(22.4) million, or $(0.88) per share, for the same period in 2021.

- As of June 30, 2022, Galera had cash, cash equivalents and short-term investments of $52.0 million. Galera expects that its existing cash, cash equivalents and short-term investments will enable Galera to fund its operating expenses and capital expenditure requirements for at least the next twelve months.

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 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 the submission of an NDA for avasopasem for the treatment of radiotherapy-induced SOM in patients with locally advanced head and neck cancer with the FDA; the expectations surrounding the progress of the Phase 2b trial of rucosopasem in patients with LAPC and the timing of completion of enrollment of the trial; the expectations surrounding the progress of the Phase 1/2 trial of rucosopasem in patients with NSCLC and the timing of completion of enrollment of the trial; the Company's ability to achieve its goal of transforming radiotherapy in cancer treatment with its selective dismutase mimetics; the potential of GC4711 to augment the anti-cancer efficacy of SBRT in patients with NSCLC and LAPC; and the Company's ability to fund its operating expenses and capital expenditure requirements for at least the next twelve months. 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; 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, 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.

Galera Therapeutics, Inc.
Consolidated Statements of Operations
(unaudited, in thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 6,662	$ 15,966	$ 14,769	$ 28,389
General and administrative	5,293	5,122	10,340	10,180
Loss from operations	(11,955)	(21,088)	(25,109)	(38,569)
Other income (expense), net	(2,603)	(1,298)	(4,892)	(2,532)
Net loss	$ (14,558)	$ (22,386)	$ (30,001)	$ (41,101)
Net loss per share of common stock, basic and diluted	$ (0.54)	$ (0.88)	$ (1.12)	$ (1.63)
Weighted average common shares outstanding, basic and diluted	26,821,303	25,401,046	26,785,540	25,195,763

Galera Therapeutics, Inc.
Selected Consolidated Balance Sheet Data
(unaudited, in thousands)

	June 30, 2022	December 31, 2021
Cash, cash equivalents, and short-term investments	$ 52,007	$ 71,217
Total assets	61,078	83,311
Total current liabilities	10,986	12,935
Total liabilities	144,324	141,315
Total stockholders' deficit	(83,246)	(58,004)

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