Galera Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Corporate Updates

March 10, 2022

Positive Phase 3 ROMAN trial of avasopasem for severe oral mucositis met primary and secondary endpoint; Company intends to meet with FDA in 2022 about NDA submission

Data readouts from AESOP in esophagitis and GRECO-1 in lung cancer expected in 1H 2022

Strong cash position of $71M with expected cash runway into 2H 2023

MALVERN, Pa., March 10, 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 fourth quarter and year ended December 31, 2021 and provided recent corporate updates.

“In 2021, we were pleased to report positive data from our lead program evaluating avasopasem for the treatment of severe oral mucositis, a radiotherapy-induced toxicity, in patients with head and neck cancer,” said Mel Sorensen, M.D., Galera’s President and CEO. “The Phase 3 ROMAN trial demonstrated a statistically significant reduction in the incidence of SOM, the primary endpoint, and in the number of days patients experienced SOM. This data is in line with the topline results observed in the Phase 2a EUSOM trial and our previously completed randomized Phase 2b trial, reinforcing avasopasem’s potentially transformative clinical benefit for patients undergoing radiotherapy for head and neck cancer. With this robust package of data in hand, we are preparing to meet with the FDA to discuss the potential NDA submission. Concurrently, we remain on track to report data from our Phase 2a AESOP trial evaluating avasopasem in esophagitis in the first half of this year.”

Dr. Sorensen continued: “We also continue to progress our Phase 1/2 GRECO-1 and Phase 2b GRECO-2 clinical trials evaluating our second product candidate, rucosopasem, in increasing the anti-cancer efficacy of higher daily doses of radiotherapy in patients with non-small cell lung cancer and locally advanced pancreatic cancer, respectively. We look forward to reporting initial data from our GRECO-1 trial in the first half of this year.”

Recent Corporate Updates

Radiotherapy-Induced Toxicity Programs:

Severe Oral Mucositis (SOM)

- On December 14, 2021, the Company announced corrected topline efficacy results from the Phase 3 ROMAN trial of avasopasem for the reduction of SOM in patients with locally advanced head and neck cancer (HNC). The Company had previously announced topline results from the ROMAN trial on October 19, 2021. Upon further analysis following the October announcement, an error by the contract research organization was identified in the statistical program. Correction of this error resulted in improved p-values for the primary and secondary endpoints. The corrected results demonstrated efficacy across multiple SOM endpoints with a statistically significant reduction 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 experienced SOM. Avasopasem appeared to be generally well tolerated compared to placebo. The Company announced that it plans to meet with the U.S. Food and Drug Administration (FDA) in 2022 to discuss a potential New Drug Application (NDA) submission.
- On December 14, 2021, the Company also reported topline data from the Phase 2a EUSOM multicenter trial of avasopasem in Europe in patients with HNC undergoing standard-of-care radiotherapy. Avasopasem appeared to be generally well tolerated and the incidence and number of days of SOM was in line with the avasopasem data reported in the Phase 3 ROMAN trial.

Esophagitis

- The Company expects to report topline data from the Phase 2a AESOP trial of avasopasem evaluating its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer in the first half of 2022.

Anti-Cancer Programs:

Locally Advanced Pancreatic Cancer (LAPC)

- Enrollment is ongoing in the Phase 2b, 160-patient randomized, multicenter, placebo-controlled GRECO-2 trial of rucosopasem, Galera's second dismutase mimetic product candidate, in combination with stereotactic body radiation therapy (SBRT) in patients with LAPC. The primary endpoint of the trial is overall survival.

Non-Small Cell Lung Cancer (NSCLC)

- Enrollment is ongoing in the Phase 1/2 GRECO-1 trial of rucosopasem in combination with SBRT in patients with NSCLC. The Company expects to report initial data from this trial in the first half of 2022.

Fourth Quarter 2021 Financial Highlights

- Research and development expenses were $9.2 million in the fourth quarter of 2021, compared to $14.6 million for the same period in 2020. 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 fourth quarter of 2021, compared to $4.3 million for the same period in 2020. The increase was primarily attributable to employee-related costs from increased headcount and share-based compensation expense, and increased insurance expense and professional fees.
- Galera reported a net loss of $(16.8) million, or $(0.64) per share, for the fourth quarter of 2021, compared to a net loss of $(20.1) million, or $(0.80) per share, for the same period in 2020.
- As of December 31, 2021, Galera had cash, cash equivalents and short-term investments of $71.2 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 into the second half of 2023.

Full Year 2021 Financial Highlights

- Research and development expenses were $52.4 million for the year ended December 31, 2021, compared to $54.8 million for the year ended December 31, 2020. 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 $21.0 million for the year ended December 31, 2021, compared to $15.7 million for the year ended December 31, 2020. The increase was primarily attributable to employee-related costs from increased headcount and share-based compensation expense, increased expenses related to preparation for potential commercialization of avasopasem, and increased insurance expense and professional fees.
- Galera reported a net loss of $(80.5) million, or $(3.12) per share, for the year ended December 31, 2021, compared to a net loss of $(74.2) million, or $(2.98) per share, for the year ended December 31, 2020.

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, including the interpretation of the safety and efficacy results from the Phase 3 ROMAN trial of avasopasem for the reduction of SOM in patients with locally advanced HNC and the Phase 2a EUSOM multi-center trial of avasopasem in Europe in patients with HNC undergoing standard-of-care radiotherapy; the timing of the meeting with the FDA to discuss the potential submission of an NDA for avasopasem; the expectations surrounding the progress of the Phase 2a AESOP trial of avasopasem evaluating its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer and the timing of the release of topline data therefrom; the expectations surrounding the progress of the Phase 2b trial of rucosopasem in patients with LAPC; the expectations surrounding the progress of the Phase 1/2 trial of rucosopasem in patients with NSCLC and the timing of the release of initial data therefrom; 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 into the second half of 2023. 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 9,215	$ 14,620	$ 52,417	$ 54,845
General and administrative	5,284	4,323	20,951	15,708
Loss from operations	(14,499)	(18,943)	(73,368)	(70,553)
Other income (expense), net	(2,307)	(1,138)	(7,166)	(3,681)
Loss before income tax benefit	(16,806)	(20,081)	(80,534)	(74,234)
Income tax benefit	-	16	-	16
Net Loss	$ (16,806)	$ (20,065)	$ (80,534)	$ (74,218)
Net loss per share of common stock, basic and diluted	$ (0.64)	$ (0.80)	$ (3.12)	$ (2.98)
Weighted average common shares outstanding, basic and diluted	26,442,028	24,955,986	25,789,458	24,869,770

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

	December 31, 2021	December 31, 2020
Cash, cash equivalents, and short-term investments	$ 71,217	$ 72,776
Total assets	83,311	84,098
Total current liabilities	12,935	13,968
Total liabilities	141,315	77,980
Total stockholders' equity (deficit)	(58,004)	6,118

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