Galera Reports First Quarter 2023 Financial Results and Recent Corporate Updates

May 11, 2023

Avasopasem NDA granted FDA priority review for radiotherapy-induced severe oral mucositis (SOM); PDUFA target date of August 9, 2023

Company raised $30 million in gross proceeds from registered direct offering

Company expanded commercial team and appointed leading biopharmaceutical executives with decades of experience successfully launching and commercializing new oncology products

MALVERN, Pa., May 11, 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 financial results for the first quarter ended March 31, 2023, and provided recent corporate updates.

"Galera has made tremendous progress since the start of the year, securing Priority Review designation for our avasopasem NDA, raising $30 million in a registered direct offering, and expanding our commercial leadership team," said Mel Sorensen, M.D., Galera's President and CEO. "In February, the FDA granted priority review and assigned a PDUFA date of August 9, 2023, to the NDA for avasopasem for the reduction of radiotherapy-induced severe oral mucositis in patients with head and neck cancer. In preparation for the potential U.S. commercial launch of avasopasem in 2023, we built out our commercial leadership team, appointing leading life sciences executives with demonstrated success launching and commercializing market-leading oncology therapies. We look forward to bringing avasopasem to market as potentially the first FDA approved drug for radiotherapy-induced SOM in patients with head and neck cancer."

Recent Corporate Updates

Radiotherapy-Induced Toxicity Programs:

Severe Oral Mucositis (SOM)

- In February 2023, the Company announced that the U.S. Food and Drug Administration (FDA) accepted for filing and granted priority review to the New Drug Application (NDA) for avasopasem manganese (avasopasem) for radiotherapy-induced SOM in patients with head and neck cancer (HNC) undergoing standard-of-care treatment. With Priority Review designation, the Prescription Drug User Fee Act (PDUFA) target date assigned by the FDA for the NDA is August 9, 2023. The FDA indicated in its acceptance of filing letter that it is not planning to hold an advisory committee meeting on the application.
- Dr. Carryn Anderson, M.D., Clinical Associate Professor of Radiation Oncology at the University of Iowa, presented a net treatment benefit analysis from the Phase 3 ROMAN trial at the European Congress on Head and Neck Oncology (ECHNO), which took place March 8-11, 2023, in Lisbon, Portugal. The analysis demonstrated the overall impact of avasopasem in reducing the burden of SOM.
- Elizabeth Cullen, MSN, ARNP, Nurse Practitioner at the University of Iowa Hospitals and Clinics, presented data from the Phase 3 ROMAN trial and additional information describing the general workflow management for the infusion of avasopasem prior to radiation therapy during the Phase 3 ROMAN study at the Oncology Nursing Society (ONS) Congress, which took place April 26-30, 2023, in San Antonio, TX.
- An abstract featuring avasopasem, "One-year reductions in cisplatin-related chronic kidney

disease (CKD) in patients with head and neck (HNC) cancer treated with avasopasem manganese: A prespecified analysis from the phase 3 ROMAN trial," has been selected for a poster presentation as part of the Head and Neck Cancer session at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting, taking place June 2-6, 2023, in Chicago, IL.

Esophagitis

- In May 2022, the Company announced topline results from the open-label, single-arm Phase 2a AESOP trial evaluating avasopasem for its potential to reduce the incidence of radiotherapy-induced esophagitis in patients with lung cancer. The results demonstrated that avasopasem was generally well tolerated and substantially reduced the incidence of severe esophagitis in patients with lung cancer receiving chemoradiotherapy compared to expectations based on review of historical data in the literature. Based on these data, Galera intends to pursue a strategy for avasopasem, if approved for the reduction of SOM, to support the use of avasopasem to reduce radiotherapy-induced esophagitis in patients with lung cancer as a medically accepted indication in published drug compendia.

Anti-Cancer Programs:

Locally Advanced Pancreatic Cancer (LAPC)

- Enrollment is ongoing in the randomized, placebo-controlled Phase 2b GRECO-2 trial of rucosopasem in combination with stereotactic body radiation therapy (SBRT) in patients with LAPC. The primary endpoint of the trial is overall survival. The trial is enrolling well. As a result, the Company plans to expand the target enrollment from 160 to 220 patients in order to accrue the necessary events (number of deaths) for data analysis sooner. Completion of enrollment is now anticipated in the first half of 2024, and topline data readout is expected by the end of 2024.

Non-Small Cell Lung Cancer (NSCLC)

- Enrollment is ongoing in the randomized, placebo-controlled Phase 2 stage of the GRECO-1 trial of rucosopasem in combination with SBRT in patients with NSCLC. Completion of enrollment continues to be anticipated in the second half of 2023, and topline data readout is expected in the second half of 2024.

General Corporate Updates

- On February 17, 2023, the Company completed a registered direct offering, which resulted in the issuance and sale of 14,320,000 shares of common stock and warrants to purchase up to 14,320,000 shares of common stock at a combined offering price of $2.095 per share and accompanying warrant, generating gross proceeds of $30 million. The Company received net proceeds of $27.6 million, after deducting placement agent fees and offering expenses.
- On May 1, 2023, the Company expanded its commercial leadership team with the appointment of accomplished pharmaceutical sales, market access, and commercial operations executives, including Patrick Campbell as Vice President of Sales & Account Management, Elizabeth Turner as Vice President of Market Access, and Henning Thorsen as Vice President of Commercial Operations. The new executives joined Lorraine Walker, Pharm.D., the Company’s Vice President of Marketing. Under the direction of the Company’s Chief Commercial Officer, Mark Bachleda, Pharm.D., MBA, the team is responsible for building out commercial operations, strategy development, and execution in preparation for the potential U.S. commercial launch of avasopasem in 2023.

First Quarter 2023 Financial Highlights

- Research and development expenses were $7.3 million in the first quarter of 2023, compared to $8.1 million for the same period in 2022. 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 $6.6 million in the first quarter of 2023, compared to $5.0 million for the same period in 2022. The increase was primarily attributable to avasopasem commercial preparations.
- Galera reported a net loss of $(17.7) million, or $(0.50) per share, for the first quarter of 2023, compared to a net loss of $(15.4) million, or $(0.58) per share, for the same period in 2022.
- As of March 31, 2023, Galera had cash, cash equivalents and short-term investments of $47.8 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 fourth quarter of 2023.

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) target 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. 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 potential for avasopasem to be the first FDA-approved drug to reduce SOM in head and neck cancer patients undergoing standard-of-care treatment; the ability of the Company to successfully launch and commercialize avasopasem, if approved, and the timing thereof; the Company's intention to pursue a strategy for avasopasem, if approved for the reduction of SOM, to support the use of avasopasem to reduce radiotherapy-induced esophagitis in patients with lung cancer as a medically accepted indication in published drug compendia; the ability of avasopasem to reduce radiotherapy-induced esophagitis; 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 LAPC, including the Company's plans to expand target enrollment, and the timing of completion of enrollment of the trial and topline data readout therefrom; the expectations surrounding the randomized, placebo-controlled Phase 2 stage of the GRECO-1 trial of rucosopasem in combination with SBRT in patients with NSCLC and the timing of completion of enrollment of the trial and topline data readout therefrom; the Company's ability to fund its operating expenses and capital expenditures into the fourth quarter of 2023; 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 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 March 31,

	2023	2022
Operating expenses:		
Research and development	$ 7,272	$ 8,107
General and administrative	6,609	5,047
Loss from operations	(13,881)	(13,154)
Other income (expense), net	(3,829)	(2,289)
Net loss	$ (17,710)	$ (15,443)
Net loss per share of common stock, basic and diluted	$ (0.50)	$ (0.58)
Weighed average common shares outstanding, basic and diluted	35,196,134	26,749,379

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

	March 31, 2023	December 31, 2022
Cash, cash equivalents, and short-term investments	$ 47,751	$ 31,597
Total assets	59,714	44,036
Total current liabilities	13,266	13,379
Total liabilities	157,327	153,217
Total stockholders' deficit	(97,613)	(109,181)

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

William Windham
Solebury Strategic Communications
646-378-2946
wwindham@soleburystrat.com

Media Contact:
Zara Lockshin
Solebury Strategic Communications
330-417-6250
zlockshin@soleburystrat.com