Galera Reports Second Quarter 2021 Financial Results and Recent Accomplishments

Aug 10, 2021

Completed enrollment in pivotal Phase 3 ROMAN trial for severe oral mucositis (SOM) in patients with head and neck cancer; topline data expected in Q4 2021

Announced near doubling in median overall survival observed in interim analysis of 42-patient placebo-controlled pancreatic cancer trial; final results expected in Q3 2021

Initiated 160-patient placebo-controlled GRECO-2 pancreatic cancer trial

Clinical programs triggered two milestone payments from Blackstone Life Sciences

MALVERN, Pa., Aug. 10, 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 financial results for the second quarter ended June 30, 2021, and highlighted recent corporate accomplishments.

“We had a highly productive quarter in the clinic, including completion of enrollment in our 455-patient pivotal Phase 3 ROMAN trial of our lead product candidate, avasopasem, for SOM in patients with head and neck cancer, promising tumor outcome and survival data in an interim analysis of our 42-patient pancreatic cancer trial, and initiation of our 160-patient double-blinded placebo-controlled GRECO-2 pancreatic cancer trial,” said Mel Sorensen, M.D., President and CEO. “We look forward to reporting clinical trial results from our key programs later this year. In parallel, Galera continues to strengthen our cash position and build our commercial capabilities as we work toward potential FDA approval of avasopasem in radiotherapy-induced SOM.”

Recent Corporate Highlights

Severe Oral Mucositis (SOM)

- Completed enrollment in the pivotal Phase 3 ROMAN trial of avasopasem for SOM in patients with locally advanced head and neck cancer (HNC) undergoing standard-of-care radiotherapy, which triggered a $37.5 million milestone payment from funds managed by Blackstone Life Sciences (Blackstone) received in July 2021. The Company expects to report topline data in the fourth quarter of 2021.

- The Company expects to report topline data from the Phase 2a EUSOM multi-center trial of avasopasem in Europe in patients with HNC undergoing standard-of-care radiotherapy in the fourth quarter of 2021.

Locally Advanced Pancreatic Cancer (LAPC)

- Reported updated data from the placebo-controlled 42-patient trial of Galera’s dismutase mimetic in patients with LAPC who are undergoing stereotactic body radiation therapy (SBRT). The updated results include a minimum follow-up of six months on all 42 patients. As of the interim data analysis, median overall survival in the treatment arm (20.1 months) was nearly twice as long as observed in the placebo arm (10.9 months); and positive results were also observed in local tumor control, time to metastases and progression-free survival. The Company expects to report final results from the trial, with at least one year of follow-up on all

patients, in the third quarter of 2021.

- Initiated the 160-patient randomized, multicenter, placebo-controlled GRECO-2 trial of GC4711, Galera's second dismutase mimetic product candidate, in combination with SBRT in patients with LAPC in May 2021, which triggered a $20 million milestone payment from Blackstone received in June 2021.

Non-Small Cell Lung Cancer (NSCLC)

- Enrollment is ongoing in the Phase 1/2 GRECO-1 trial of GC4711 in combination with SBRT in patients with NSCLC. The Company expects to report initial data from this trial in the first half of 2022.

Esophagitis

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

Second Quarter 2021 Financial Highlights

- Research and development expenses were $16.0 million in the second quarter of 2021, compared to $13.8 million for the same period in 2020. The increase was primarily attributable to avasopasem development costs due to increased clinical expenses, primarily related to the ROMAN trial, and an increase in manufacturing and regulatory activities.

- General and administrative expenses were $5.1 million in the second quarter of 2021, compared to $3.9 million for the same period in 2020. The increase was primarily attributable to employee-related costs from increased headcount and share-based compensation expense, increased expenses related to pre-commercial activities for avasopasem, and increased insurance expense and professional fees.

- Galera reported a net loss of $(22.4) million, or $(0.88) per share, for the second quarter of 2021, compared to a net loss of $(18.7) million, or $(0.75) per share, for the same period in 2020.

- As of June 30, 2021, Galera had cash, cash equivalents and short-term investments of $66.5 million. Galera expects that its existing cash, cash equivalents and short-term investments, together with the payment from Blackstone in the amount of $37.5 million received in July 2021, 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 lead product candidate is avasopasem manganese (avasopasem, or GC4419), a selective small molecule dismutase mimetic in late-stage development to reduce the incidence and severity of radiotherapy-induced severe oral mucositis (SOM) in patients with head and neck cancer. Avasopasem is also in development for radiotherapy-induced esophagitis in patients with lung cancer. Avasopasem has been granted FDA Fast Track and Breakthrough Therapy designations for the reduction of SOM induced by radiotherapy, with or without systemic therapy. Galera's second dismutase mimetic product candidate, 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. 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 the potential,

safety, efficacy, clinical development and regulatory approval of Galera's product candidates, including with respect to the updated results from the LAPC pilot trial; plans and timing for the commencement of and the release of data from Galera's clinical trials, including with respect to the Phase 3 ROMAN trial, the Phase 2a EUSOM trial, and the LAPC pilot trial, among others; plans for the commercial launch of avasopasem; and the sufficiency of Galera's cash, cash equivalents and short-term investments. 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 or otherwise completing clinical trials; the FDA's acceptance of data from clinical trials conducted 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, 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.

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 15,966	$ 13,839	$ 28,389	$ 28,092
General and administrative	5,122	3,874	10,180	7,439
Loss from operations	(21,088)	(17,713)	(38,569)	(35,531)
Other income (expense), net	(1,298)	(944)	(2,532)	(1,543)
Net loss	$ (22,386)	$ (18,657)	$ (41,101)	$ (37,074)
Net loss per share of common stock, basic and diluted	$ (0.88)	$ (0.75)	$ (1.63)	$ (1.49)
Weighted average common shares outstanding, basic and diluted	25,401,046	24,832,264	25,195,763	24,823,644

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

	June 30, 2021	December 31, 2020
Cash, cash equivalents, and short-term investments	$ 66,527	$ 72,776
Total assets	115,269	84,098
Total current liabilities	16,843	13,968
Total liabilities	140,786	77,980
Total stockholders' equity (deficit)	(25,517)	6,118

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