Galera Therapeutics Reports First Quarter 2020 Financial Results and Provides Business Updates

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ROMAN Phase 3 Trial Topline Data Readout Guidance Updated to 2H21 Due to Impact of COVID-19

Amendment to Royalty Agreement for Additional $37.5M Extends Cash Runway into 2H22

Locally Advanced Pancreatic Cancer Phase 1b/2a Trial Topline Data Readout and Initiation of NSCLC Anti-cancer Phase 1b/2a Trial Both Remain On Track for 2H20

MALVERN, Pa., May 12, 2020 (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, 2020, and provided business updates.

“Despite these unprecedented times, we have continued to progress patient enrollment in our three ongoing clinical trials of lead candidate avasopasem manganese (GC4419),” said Mel Sorensen, M.D., President and CEO of Galera. “The COVID-19 pandemic has delayed the initiation of our Phase 2a trial in Europe in patients with head and neck cancer indefinitely, which we planned to start in the first half of this year. As a result, we are increasing the size of the Phase 3 ROMAN trial for the treatment of severe oral mucositis (SOM) in patients with locally advanced head and neck cancer to ensure we are positioned to achieve our targeted number of patients for the NDA safety database, and are updating our guidance for completing enrollment to the first half of 2021 and for reporting topline data to the second half of 2021. Investigator enthusiasm remains high and we are confident in our ability to complete our ongoing trials and maintain our supply chain. In addition, we’re pleased to announce that we added $37.5 million in funding under our amended royalty agreement with Blackstone Life Sciences (formerly Clarus Ventures) which further strengthens our financial foundation and extends our cash runway into the second half of 2022.”

“In the near term, we are looking forward to avasopasem data being presented at ASCO, and are preparing to initiate an anti-cancer efficacy trial of our second product candidate, GC4711, in combination with stereotactic body radiation therapy (SBRT) in non-small cell lung cancer (NSCLC) in the second half of this year. We will continue to carefully monitor the COVID-19 situation and remain committed to thoughtfully executing our clinical programs to realize the potential of our pipeline in addressing radiation toxicities and improving the anti-cancer effect of radiation while prioritizing the health and safety of our partners and trial participants.”

Clinical Program Updates

Galera will continue to assess the rapidly evolving impacts of COVID-19 on clinical programs and operations.

Radiation-induced toxicity clinical trials:

- Updated guidance for topline data from the Phase 3 ROMAN clinical trial of avasopasem for the treatment of SOM in patients with locally advanced head and neck cancer receiving radiotherapy to the second half of 2021. COVID-19 has delayed the initiation of the Phase 2a multi-center trial in Europe in patients with head and neck cancer indefinitely. This trial was expected to enroll up to 70 patients and contribute to the safety database for avasopasem for SOM in head and neck cancer. As a result, in order to ensure we are positioned to maintain the size of the safety database, the ROMAN trial target enrollment has been increased to 450 patients.

- Continued enrollment in the Phase 2a clinical trial of avasopasem to evaluate its ability to reduce the incidence of radiation-induced esophagitis in patients with lung cancer.

Anti-cancer efficacy clinical trials:

- Reaffirmed guidance for topline data from the pilot Phase 1b/2a safety and anti-cancer efficacy clinical trial of avasopasem in combination with SBRT in patients with locally advanced pancreatic cancer in the second half of 2020.

- Reaffirmed guidance for initiation of a Phase 1b/2a trial of GC4711 with SBRT in non-small cell lung cancer in the second

half of 2020. GC4711 is Galera's second small molecule superoxide dismutase mimetic being developed to increase the anti-cancer efficacy of radiotherapy. This trial will evaluate GC4711 in combination with SBRT and with SBRT plus concurrent checkpoint inhibitor therapy in approximately 75 patients. A primary objective of the trial will be to assess the effects of GC4711 on measures of pneumonitis, or inflammation of the lungs. Other key objectives will include safety, local tumor control, distant metastasis rate, progression-free survival and overall survival.

Corporate Updates

- In May 2020, entered into an amendment to the 2018 royalty purchase agreement with Blackstone Life Sciences, which adds $37.5 million in additional funding to the existing $80 million royalty financing commitment that Blackstone Life Sciences (formerly Clarus Ventures) made in 2018. Under the updated agreement terms, we have agreed to pay Blackstone up to high single-digit percentage future commercial royalties from the sales of avasopasem and GC4711 until the total royalty amount achieves an unchanged fixed single-digit multiple of the aggregate financing sum received, upon which the royalty terminates. Additional information regarding this amendment is included in a Form 8-K filed by the Company with the U.S. Securities and Exchange Commission on May 12, 2020.

- In April 2020, announced three abstracts regarding avasopasem were accepted for presentation at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program, taking place May 29-31, 2020. The titles of the abstracts are currently available in the ASCO digital program, with the full abstracts scheduled to be published on May 13, 2020. As previously announced, this includes the presentation titled "Effects of GC4419 (avasopasem manganese) on chronic kidney disease in head and neck cancer patients treated with radiation and cisplatin."

- In April 2020, announced the appointment of Linda B. West to our board of directors. Ms. West brings nearly 40 years of business experience to Galera's board of directors, having served in multiple leadership roles of increasing responsibility for E. I. du Pont de Nemours and Company (DuPont) until her retirement in 2019.

- In March 2020, implemented a work-from-home policy for office-based employees for the safety of employees and their families and to reduce the spread of COVID-19, while ensuring essential staffing levels in our operations remain in place, including maintaining key personnel in our laboratory.

First Quarter 2020 Financial Highlights

- Research and development expenses were $14.3 million in the first quarter of 2020, compared to $8.5 million for the same period in 2019. The increase was primarily attributable to avasopasem development costs due to greater patient enrollment and additional clinical site initiations in the Phase 3 ROMAN trial, additional clinical trials including the Phase 2a trial for the treatment of esophagitis in patients with lung cancer, initiation of additional toxicology studies and costs associated with manufacturing scale-up activities. Employee-related costs also increased due to increased headcount and share-based compensation expense.

- General and administrative expenses were $3.6 million in the first quarter of 2020, compared to $1.9 million for the same period in 2019. The increase was primarily the result of employee-related costs from increased headcount and share-based compensation expense, and increased insurance, professional fees and other operating costs as a result of becoming a public company.

- Galera reported a net loss of $(18.4) million, or $(0.74) per share, for the first quarter of 2020, compared to a net loss of $(10.3) million, or $(41.12) per share, for the same period in 2019.

- As of March 31, 2020, Galera had cash, cash equivalents and short-term investments of $120.5 million. Galera expects that its existing cash, cash equivalents and short-term investments, together with the expected payments from Blackstone in the amount of $57.5 million upon the achievement of certain clinical enrollment milestones in the ROMAN trial and the anti-cancer program in combination with SBRT under the amended royalty agreement, will enable Galera to fund its operating expenses and capital expenditure requirements into the second half of 2022.

About Galera Therapeutics

Galera Therapeutics, Inc. is 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. Galera's lead product candidate is avasopasem manganese (GC4419), a highly selective small molecule superoxide dismutase (SOD) mimetic initially being developed for the reduction of radiation-induced severe oral mucositis (SOM). Avasopasem manganese is being studied in the Phase 3 ROMAN trial for its ability to reduce the incidence and severity of SOM induced by radiotherapy in patients with locally advanced head and neck cancer, its lead indication, and in the Phase 2a trial for its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem manganese for the reduction of SOM induced by radiotherapy. Galera is developing a second product candidate, GC4711, which successfully completed Phase 1 trials in healthy volunteers. 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, the potential, efficacy, and regulatory and clinical development of Galera's product candidates, plans and timing for the commencement of and the release of data from Galera's clinical trials, the anticipated direct and indirect impact of COVID-19 on Galera's business and operations, anticipated funding and payments under Galera's amended agreement with Blackstone, and the sufficiency of Galera's cash, cash equivalents and short-term investments, or cash runway. 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020 filed with the U.S. Securities and Exchange Commission (SEC), Annual Report on Form 10-K for the year ended December 31, 2019 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,	
	2020	**2019**
Operating expenses:		
Research and development	$ 14,252	$ 8,502
General and administrative	3,566	1,894
Loss from operations	(17,818)	(10,396)
Other income (expense)	(599)	47
Net loss	(18,417)	(10,349)
Accretion of redeemable convertible preferred stock to redemption value	-	(2,011)
Net loss attributable to common stockholders	$ (18,417)	$ (12,360)
Net loss per share of common stock, basic and diluted	$ (0.74)	$ (41.12)
Weighed average common shares outstanding, basic and diluted	24,815,024	300,597

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

	March 31, 2020	**December 31, 2019**
Cash, cash equivalents, and short-term investments	$ 120,517	$ 112,290
Total assets	130,813	123,376
Total current liabilities	12,648	9,694
Total liabilities	77,755	53,768
Total stockholders' equity	53,058	69,608

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