Galera Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Accomplishments

March 11, 2021

Pivotal Phase 3 ROMAN Trial in Severe Oral Mucositis on Track for Completion of Enrollment in 1H21; Topline Data Readout in 2H21

Anticipate Final Data Readout from Locally Advanced Pancreatic Cancer (LAPC) Pilot Trial in 2H21

On Track for Initiation of Phase 2b GRECO-2 Trial of GC4711 in Combination with Stereotactic Body Radiation Therapy (SBRT) for LAPC in 1H21

MALVERN, Pa., March 11, 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 fourth quarter and year ended December 31, 2020, and highlighted recent corporate accomplishments.

“In 2020, Galera presented positive interim data demonstrating that our dismutase mimetics have the potential to benefit the anti-cancer side of the therapeutic index of radiotherapy,” said Mel Sorensen, M.D., President and CEO of Galera. “This encouraging interim data from our pilot placebo-controlled Phase 1/2 trial in patients with pancreatic cancer was presented at ASTRO in late 2020. We look forward to providing the final data readout from this trial in the second half of 2021 and advancing this regimen with the initiation of our Phase 2b GRECO-2 trial of GC4711 in combination with SBRT in patients with LAPC in the first half of 2021.”

Dr. Sorensen continued, “We are excited for the year ahead, which we believe will be transformative for our company, with the topline data readout of our Phase 3 ROMAN trial. In anticipation, we continue our preparations for the commercial launch of avasopasem manganese.”

Recent Corporate Highlights

Severe Oral Mucositis (SOM)

- Continued enrollment in the Phase 3 ROMAN trial of avasopasem for the treatment of SOM in patients with locally advanced head and neck cancer (HNC) undergoing standard-of-care radiotherapy. The Company remains on track to complete enrollment in the first half of 2021 and report topline data in the second half of 2021.
- Completed enrollment in the Phase 2a EUSOM multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy. The Company remains on track to report topline data in the second half of 2021.

Locally Advanced Pancreatic Cancer (LAPC)

- Presented positive interim data from the pilot placebo-controlled Phase 1/2 anti-cancer trial of avasopasem in combination with SBRT in patients with LAPC at the American Society for Radiation Oncology (ASTRO) virtual Annual Meeting in late 2020. Data on all patients through a minimum follow-up of three months demonstrated better tumor outcomes, including overall survival, with avasopasem compared to placebo. The Company plans to provide final data from this trial with at least one year of follow-up data on all patients in the second half of 2021.
- Remain on track to initiate the Phase 2b GRECO-2 trial of GC4711, Galera’s second superoxide dismutase mimetic candidate, in combination with SBRT in patients with LAPC in the first half of 2021. GRECO-2 is a randomized, double-blind, placebo-controlled trial to evaluate the effect of 100 mg of GC4711 versus placebo in combination with SBRT on overall survival in patients with LAPC. The trial is expected to enroll approximately 160 patients.

Non-Small Cell Lung Cancer (NSCLC)

- Continued enrollment in the Phase 1/2 GRECO-1 trial of GC4711 in combination with SBRT in patients with NSCLC. The

Phase 2 portion of GRECO-1 is randomized, double-blind, and placebo-controlled to evaluate the effect of 100 mg of GC4711 versus placebo. The Company continues to expect to report initial data in the first half of 2022.

Esophagitis

- Continued enrollment 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 remains on track to report topline data in the first half of 2022.

Fourth Quarter 2020 Financial Highlights

- Research and development expenses were $14.6 million in the fourth quarter of 2020, compared to $13.3 million for the same period in 2019. The increase was primarily attributable to avasopasem and GC4711 development costs, as well as higher employee-related costs due to increased headcount and share-based compensation expense. The increases were partially offset by decreased avasopasem and GC4711 preclinical spend.

- General and administrative expenses were $4.3 million in the fourth quarter of 2020, compared to $2.9 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 $(20.1) million, or $(0.80) per share, for the fourth quarter of 2020, compared to a net loss of $(16.7) million, or $(1.31) per share, for the same period in 2019.

- As of December 31, 2020, Galera had cash, cash equivalents and short-term investments of $72.8 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. We expect to achieve these clinical enrollment milestones in the first half of 2021.

Full Year 2020 Financial Highlights

- Research and development expenses were $54.8 million for the year ended December 31, 2020, compared to $42.3 million for the year ended December 31, 2019. The increase was primarily attributable to avasopasem development costs due to increased expenses in the Phase 3 ROMAN trial, additional clinical trials including the Phase 2a AESOP trial and the Phase 2a EUSOM trial, and manufacturing scale-up activities. In addition, employee-related costs also increased due to increased headcount and share-based compensation expense.

- General and administrative expenses were $15.7 million for the year ended December 31, 2020, compared to $8.4 million for the year ended December 31, 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 $(74.2) million, or $(2.98) per share, for the year ended December 31, 2020, compared to a net loss of $(51.9) million, or $(16.31) per share, for the year ended December 31, 2019.

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, also referred to as avasopasem), a highly selective small molecule superoxide dismutase (SOD) mimetic initially being developed for the reduction of radiation-induced severe oral mucositis (SOM). Avasopasem is being studied in the Phase 3 ROMAN trial to assess its ability to reduce the incidence and severity of SOM induced by radiotherapy in patients with locally advanced head and neck cancer (HNC), its lead indication. It is also being studied in the EUSOM Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, the AESOP Phase 2a trial to assess its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer, and a Phase 2 trial in hospitalized patients who are critically ill with COVID-19. A pilot Phase 1/2 trial of avasopasem in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer (LAPC) has completed enrollment and reported interim results, with follow-up ongoing. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. Galera's second dismutase mimetic product candidate, GC4711, is being developed specifically to augment the anti-cancer efficacy of SBRT, and is currently being studied in the GRECO-1 Phase 1/2 trial in combination with SBRT in patients with non-small cell lung 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 plans for the commercial launch of avasopasem; the potential, safety, 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; expected payments from Blackstone; 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 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 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
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 14,620	$ 13,276	$ 54,845	$ 42,333
General and administrative	4,323	2,892	15,708	8,358
Loss from operations	(18,943)	(16,168)	(70,553)	(50,691)
Other income (expense), net	(1,138)	(513)	(3,681)	(1,248)
Loss before income tax benefit	(20,081)	(16,681)	(74,234)	(51,939)
Income tax benefit	16	9	16	9
Net loss	(20,065)	(16,672)	(74,218)	(51,930)
Accretion of redeemable convertible preferred stock to redemption value	-	(998)	-	(7,176)
Net loss attributable to common stockholders	$ (20,065)	$ (17,670)	$ (74,218)	$ (59,106)
Net loss per share of common stock, basic and diluted	$ (0.80)	$ (1.31)	$ (2.98)	$ (16.31)
Weighed average common shares outstanding, basic and diluted	24,955,986	13,489,826	24,869,770	3,625,005

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

	December 31,	
	2020	2019
Cash, cash equivalents, and short-term investments	$ 72,776	$ 112,290
Total assets	84,098	123,376
Total current liabilities	13,968	9,694
Total liabilities	77,980	53,768
Total stockholders' equity	6,118	69,608

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