Galera Reports Third Quarter 2022 Financial Results and Recent Corporate Updates

November 9, 2022

Company on track to submit NDA to U.S. FDA for avasopasem by end of 2022

One-year ROMAN follow-up data presented at 2022 American Society for Radiation Oncology (ASTRO) Annual Meeting showed tumor outcomes and overall survival maintained compared to placebo

One-year ROMAN follow-up data also showed cisplatin-related chronic kidney disease reduced by 50% in avasopasem patients compared to placebo

Meta-analysis of both randomized placebo-controlled trials of avasopasem (ROMAN and GT-201) further underscores efficacy across all key SOM endpoints

MALVERN, Pa., Nov. 09, 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 third quarter ended September 30, 2022 and provided recent corporate updates.

“During the quarter, we added to the package of data supporting our planned avasopasem New Drug Application in radiotherapy-induced severe oral mucositis, which we are on track to submit by the end of the year,” said Mel Sorensen, M.D., Galera’s President and CEO. “We presented long-term follow-up data from ROMAN at ASTRO, the major annual radiation oncology conference, affirming what we saw in GT-201, specifically that avasopasem reduced severe oral mucositis while maintaining the clinical benefit of radiation therapy. Moreover, patients were also evaluated for renal function during the one-year follow-up period, and the data showed a 50% reduction in chronic kidney disease, a known cisplatin-related superoxide toxicity.”

Dr. Sorensen continued: “Our market research continues to indicate that radiation and medical oncologists treating head and neck cancer view the avasopasem profile favorably and that the majority would prescribe avasopasem if approved by the FDA. The research also indicates that physicians view SOM — the most burdensome side effect of radiation therapy for head and neck cancer — as something best characterized by several key measures. These include not only whether a patient develops SOM, but also how long they suffer from it, when it first develops and whether it worsens into the most severe grade, Grade 4 OM. The meta-analysis of the already positive results from both the ROMAN and GT-201 trials underscores that avasopasem improves SOM across these measures.”

Recent Corporate Updates

Radiotherapy-Induced Toxicity Programs:

Severe Oral Mucositis (SOM)

- The Company remains on track to submit a New Drug Application (NDA) for avasopasem manganese 90 mg for radiotherapy-induced SOM to the U.S. Food and Drug Administration (FDA) by the end of 2022.

- Long-term follow-up data from the ROMAN trial was presented in an oral presentation at the 2022 American Society for Radiation Oncology (ASTRO) Annual Meeting. After one-year follow-up on ROMAN, patients receiving avasopasem in combination with the standard-of-care regimen demonstrated comparable tumor outcomes and overall survival to patients in the placebo arm, showing that avasopasem protected patients with head and neck cancer from SOM without affecting the treatment benefit of standard-of-care chemoradiotherapy.

- In a prospectively defined component of the ROMAN long-term follow-up data, also presented at ASTRO, patients treated with avasopasem in combination with radiotherapy and cisplatin had a 10% incidence of chronic kidney disease (CKD) after one year of post treatment follow-up, half the 20% rate in the placebo arm (p=0.0043). This exploratory endpoint was based on mechanism-driven non-clinical studies and a retrospective analysis of GT-201 and suggests avasopasem may offer a further benefit for these patients.

- Additionally, a meta-analysis of Galera's two randomized placebo-controlled trials (ROMAN and GT-201; n=551) was included in the ASTRO presentation, and showed clinically meaningful reductions in the incidence, duration, onset and severity of SOM compared to placebo across both trials.

- A poster presentation during ASTRO highlighted the completed Phase 2 EUSOM trial of avasopasem for radiotherapy-induced SOM in Europe.

Esophagitis

- Final data from the open-label, single-arm Phase 2 AESOP trial of avasopasem for severe acute radiotherapy-induced esophagitis in patients with lung cancer receiving concurrent chemoradiotherapy were presented at ASTRO. The Company previously reported positive topline data from the trial demonstrating that avasopasem was well tolerated and the incidence of Grade 3 esophagitis was substantially reduced in comparison to expectations based on review of historical data in the literature. No patients experienced Grade 4 or 5 esophagitis at any point during the AESOP trial.

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. Completion of enrollment is expected in the second half of 2023.

Non-Small Cell Lung Cancer (NSCLC)

- A poster presentation at ASTRO highlighted the ongoing randomized, placebo-controlled Phase 2 stage of the GRECO-1 trial of rucosopasem in combination with SBRT in patients with NSCLC. Completion of enrollment in the Phase 2 stage of this trial is expected in the second half of 2023.

General Corporate Updates:

- The Company appointed Eugene P. Kennedy, M.D., F.A.C.S., as Chief Medical Officer. Dr. Kennedy is a renowned Johns Hopkins-trained surgical oncologist and former Chief of Pancreatic and Hepatobiliary Surgery at Thomas Jefferson University with over 15 years' experience in clinical development and biopharma leadership. He will succeed Jon T. Holmlund, M.D., who plans to retire at the end of this year following the planned submission of the Company's NDA for avasopasem to the FDA.

Third Quarter 2022 Financial Highlights

- Research and development expenses were $8.1 million in the third quarter of 2022, compared to $14.8 million for the same period in 2021. 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 $4.9 million in the third quarter of 2022, compared to $5.5 million for the same period in 2021. The decrease was primarily attributable to the timing of spend for avasopasem commercial preparations.

- Galera reported a net loss of ($16.0) million, or $(0.60) per share, for the third quarter of 2022, compared to a net loss of $(22.6) million, or $(0.86) per share, for the same period in 2021.

- As of September 30, 2022, Galera had cash, cash equivalents and short-term investments of $42.8 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 second half 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 evaluated for radiotherapy-induced toxicities. 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. 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; the timing of the submission of an NDA for avasopasem for radiotherapy-induced SOM in patients with locally advanced head and neck cancer with the FDA; the ability of avasopasem to reduce SOM while maintaining the clinical benefit of radiation therapy; the ability of avasopasem to reduce the incidence of CKD; the expectations surrounding the progress of the Phase 2b trial of rucosopasem in patients with LAPC and the timing of completion of enrollment of the trial; the expectations surrounding the progress of the Phase 1/2 trial of rucosopasem in patients with NSCLC and the timing of completion of enrollment of the trial; 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 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; substantial doubt regarding our 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; the possibility of Galera's common stock being delisted from The Nasdaq Global Market; 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 and Quarterly Report on Form 10-Q for the quarter ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 8,106	$ 14,813	$ 22,875	$ 43,203
General and administrative	4,853	5,487	15,193	15,667
Loss from operations	(12,959)	(20,300)	(38,068)	(58,870)
Other income (expense), net	(3,074)	(2,326)	(7,966)	(4,857)
Net loss	$ (16,033)	$ (22,626)	$ (46,034)	$ (63,727)
Net loss per share of common stock, basic and diluted	$ (0.60)	$ (0.86)	$ (1.72)	$ (2.49)
Weighted average common shares outstanding, basic and diluted	26,823,546	26,304,920	26,798,348	25,569,545

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

	September 30, 2022	December 31, 2021
Cash, cash equivalents, and short-term investments	$ 42,769	$ 71,217
Total assets	50,713	83,311
Total current liabilities	11,632	12,935
Total liabilities	148,215	141,315
Total stockholders' deficit	(97,502)	(58,004)

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