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

Nov 10, 2020

Presented Promising Interim Data from Placebo-controlled Pilot Dismutase Mimetic SBRT Combination Trial for Pancreatic Cancer

Announced Planned Phase 2b GC4711 SBRT Combination Trial for Pancreatic Cancer (GRECO-2)

Initiated Randomized Phase 1/2 GC4711 SBRT Combination Trial for NSCLC (GRECO-1)

Remain on Track with Ongoing Phase 3 ROMAN Trial and Other Radiation-Induced Toxicity Trials of Avasopasem

MALVERN, Pa., Nov. 10, 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 third quarter ended September 30, 2020, and provided business updates.

“We continue to make great strides advancing the clinical development of our small molecule superoxide dismutase mimetics’ ability to address radiation toxicities and augment the anti-cancer efficacy of radiation,” said Mel Sorensen, M.D., President and CEO of Galera. “We are delighted with the encouraging data from our placebo-controlled trial of GC4419 in combination with stereotactic body radiation therapy (SBRT) for patients with locally advanced pancreatic cancer (LAPC), which were presented during a late-breaker session at the American Society for Radiation Oncology (ASTRO) 2020 Annual Meeting. The findings are the first clinical evidence supporting our extensive preclinical science that showed synergy of our dismutase mimetics with SBRT. In this first trial with the addition of a dismutase mimetic to SBRT in patients, we observed better tumor responses, saw more patients succeed in going to surgical resection, and are particularly pleased by the initial signal in survival. With these promising early activity results in hand, coupled with the preliminary safety findings of the combination, we look forward to continuing to advance the potential of our dismutase mimetics to enhance the anti-cancer efficacy of SBRT and improve outcomes for cancer patients. We have initiated the GRECO-1 Phase 1/2 trial of GC4711 with SBRT in non-small cell lung cancer (NSCLC), and also anticipate initiating a Phase 2b trial of GC4711 with SBRT in pancreatic cancer (GRECO-2) in the first half of 2021. Our most advanced program, the ROMAN Phase 3 trial, continues to enroll well and we look forward to reporting topline results in the second half of 2021.”

Third Quarter 2020 and Recent Corporate Highlights

- In October, presented interim efficacy and safety data from the randomized, double-blind, multicenter, placebo-controlled pilot Phase 1/2 clinical trial of avasopasem manganese (GC4419) in combination with SBRT in patients with LAPC at ASTRO. In the analysis of the intent-to-treat population, multiple endpoints to date show a positive trend in favor of improved anti-cancer efficacy with avasopasem compared to placebo. While many of the patients are early in their follow-up post treatment, addition of the dismutase mimetic to SBRT appears to improve overall survival (OS) versus placebo (HR=0.4, 95% CI: 0.12-1.11; median OS not yet reached for avasopasem vs. 38.7 weeks for placebo; p=0.06). Best overall response within the SBRT field was partial response, according to modified RECIST criteria, or better in 33% of avasopasem patients versus 17% of placebo patients. Five patients in the avasopasem arm and two in the placebo arm were surgically resected. Among the resected avasopasem patients, all five achieved clear margins (R0), compared to only one of the two in the placebo arm. Progression-free survival hazard ratio as of the cut-off date also appears to favor the avasopasem arm (HR=0.6, 95% CI: 0.23-1.56; p=0.29). Toxicity was comparable across both treatment arms, with no significant differences in overall or Grade 3 GI toxicity post-SBRT. The data presented included all patients followed for a minimum of three months and 19 for more

than one year, with data through August 24, 2020. The Company plans to provide an update on this trial with at least one year of follow-up on all patients in the second half of 2021.

- In October, announced that the first patient had been dosed in the Phase 1/2 GRECO-1 trial of GC4711 in combination with SBRT in patients with central or large peripheral NSCLC tumors. GC4711 is Galera's second highly selective small molecule superoxide dismutase mimetic candidate and is being developed specifically for use in combination with SBRT. Following a safety run-in cohort, up to 66 NSCLC patients with locally advanced disease will receive GC4711 with SBRT or placebo with SBRT over five consecutive weekdays in a first stage of the randomized, double-blind, placebo-controlled Phase 2 portion of the GRECO-1 trial. A second stage is planned to add a checkpoint inhibitor to the SBRT combination. The GRECO-1 trial is supported in part by a recently awarded Small Business Innovation Research grant (4R44CA206795-02) from the National Cancer Institute of the National Institutes of Health. The Company anticipates reporting topline data from the first stage of this trial in the first half of 2022.

- In October, hosted a virtual Key Opinion Leader (KOL) event featuring Sarah Hoffe, M.D., Section Head of GI Radiation Oncology and Senior Member at Moffitt Cancer Center. Dr. Hoffe provided an overview of the management of patients with localized pancreatic cancer, including the current clinical treatment paradigm and the use of SBRT.

- In September, announced the first patient had been dosed in a pilot Phase 2 clinical trial of avasopasem to evaluate its ability to improve 28-day mortality in hospitalized patients who are critically ill with COVID-19. The Company anticipates reporting topline data from this trial in the first half of 2021.

- Continued enrollment in multiple clinical trials of avasopasem for radiation-induced toxicities, including the Phase 3 ROMAN trial to assess its ability to reduce the incidence and severity of severe oral mucositis induced by radiotherapy in patients with locally advanced head and neck cancer (HNC), the Phase 2a EUSOM multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, as well as the AESOP Phase 2a trial to assess its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer. The Company remains on track to announce topline data from the ROMAN trial in the second half of 2021.

Third Quarter 2020 Financial Highlights

- Research and development expenses were $12.1 million in the third quarter of 2020, compared to $11.0 million for the same period in 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 trial for the treatment of esophagitis in patients with lung cancer and the Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC. In addition, employee-related costs also increased due to increased headcount and share-based compensation expense. The increases were partially offset by decreased avasopasem preclinical spend and decreased GC4711 development expenses.

- General and administrative expenses were $3.9 million in the third quarter of 2020, compared to $1.8 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 $(17.1) million, or $(0.69) per share, for the third quarter of 2020, compared to a net loss of $(13.4) million, or $(51.43) per share, for the same period in 2019.

- As of September 30, 2020, Galera had cash, cash equivalents and short-term investments of $89.2 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 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 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 clinical 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, 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 12,133	$ 11,040	$ 40,225	$ 29,057
General and administrative	3,945	1,816	11,384	5,466
Loss from operations	(16,078)	(12,856)	(51,609)	(34,523)

Other income (expense), net	(1,000)	(495)	(2,543)	(735)
Net Loss	(17,078)	(13,351)	(54,152)	(35,258)
Accretion of redeemable convertible preferred stock to redemption value	-	(2,108)	-	(6,178)
Net loss attributable to common stockholders	$ (17,078)	$ (15,459)	$ (54,152)	$ (41,436)
Net loss per share of common stock, basic and diluted	$ (0.69)	$ (51.43)	$ (2.18)	$ (137.85)
Weighed average common shares outstanding, basic and diluted	24,874,805	300,597	24,840,822	300,597

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

	September 30, 2020	December 31, 2019
Cash, cash equivalents, and short-term investments	$ 89,151	$ 112,290
Total assets	98,075	123,376
Total current liabilities	10,503	9,694
Total liabilities	73,380	53,768
Total stockholders' equity	24,695	69,608

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