Gritstone bio Announces Strengthening of Maturing Phase 2 PFS Data for GRANITE Study and Provides Business Update

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-- 27% relative risk reduction of progression or death with GRANITE vs. control in all treated population (HR=0.73 [90% CI, 0.44, 1.21]) --

-- 50% relative risk reduction of progression or death with GRANITE vs. control in low ctDNA subgroup (HR=0.50 [90% CI, 0.20-1.28]) --

-- Progressing through court-administered financial restructuring process with continued interest from multiple parties

EMERYVILLE, Calif., Nov. 11, 2024 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (OTC: GRTSQ), a clinical-stage biotechnology company working to develop the world's most potent vaccines, today announced encouraging updated interim Phase 2 data from the ongoing Phase 2 study evaluating GRANITE, its individualized neoantigen targeting immunotherapy, in first-line microsatellite stable colorectal cancer (MSS-CRC). The ongoing randomized, controlled study is evaluating the clinical benefit of maintenance therapy with GRANITE (GRT-C901/GRT-R902) in combination with immune checkpoint inhibitors (ICI) in addition to fluoropyrimidine/bevacizumab versus fluoropyrimidine/bevacizumab alone.

"Our encouraging Phase 2 data for GRANITE in MSS-CRC continue to mature and demonstrate durable benefit over time. With two additional months of follow-up, relative progression-free survival has further improved in the analysis of all patients treated with GRANITE, and most notably, in those with a lower tumor burden at study baseline," said Andrew Allen, MD, PhD, Co-founder, President & CEO of Gritstone bio. "The powerful anti-tumor immunity induced by GRANITE in an immunologically cold tumor setting like MSS-CRC underscores a differentiated approach with a multitude of expansion opportunities across solid tumor indications. Moreover, these data also further de-risk SLATE, our off-the-shelf cancer immunotherapy program, and more importantly, reinforce the transformative potential of Gritstone's overall immunotherapy platform."

Dr. Allen continued, "We are focused on our mission to deliver potentially life-saving treatments like GRANITE to millions of patients worldwide and continue to explore several strategic and funding alternatives during the financial restructuring process. The compelling progression-free survival data in a challenging disease context, coupled with a well-tolerated safety profile, supports further continuation of the GRANITE program by a party who shares our vision to deliver novel treatments leveraging the immune response to fight tough to treat cancers."

Key Findings from an Updated Interim Phase 2 Analysis in Front-Line Metastatic MSS-CRC
Data cut as of October 17, 2024 vs. August 19, 2024

An updated October analysis of progression-free survival (PFS) per RECIST v1.1 included an additional two months of follow-up.

- 28% (11/39) GRANITE and 13% (4/30) of control patients remain on study and free of progression vs. 33% (13/39) GRANITE and 23% (7/30) of control patients from August analysis; the majority of GRANITE patients still on study have undetectable ctDNA using Gritstone's high-sensitivity, tumor-informed assay
- Clinical benefit improved compared to previous analysis in patients with low and high disease burden (based on ctDNA levels)
- Clinical benefit was most notable in patients with low disease burden at study entry
    - Low baseline ctDNA levels (eg at study entry) is a likely prognostic and predictive factor
- Overall survival data remain immature, with mature data expected in 2H 2025
- GRANITE continues to demonstrate a favorable safety and tolerability profile

Summary of Progression-Free Survival Results

	Relative Risk Reduction; PFS Hazard Ratio*	
	October Analysis 2024	**August Analysis 2024**
All patients *n = 69*	**27%;** 0.73, [90% CI, 0.44-1.21]	**21%;** 0.79, [90% CI, 0.47-1.35]
ctDNA-lo^ *n = 31*	**50%;** 0.5, [90% CI, 0.20-1.28]	**43%;** 0.57, [90% CI, 0.20-1.58]
ctDNA-hi^ *n = 30*	**22%;** 0.78, [90% CI, 0.39-1.58]	**13%;** 0.87, [90% CI, 0.41- 1.86]

**The protocol-defined PFS analysis (per RECIST v1.1) is reported herein for all groups. An exploratory analysis using both radiographic and clinical progression data was reported for the ctDNA subgroups on September 30, 2024.*
^Not all patients had baseline samples for analysis

Restructuring Process
On October 10, 2024, Gritstone filed a voluntary petition under chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware (the "Court".) During its financial restructuring process, Gritstone intends to operate in the ordinary course and remains committed to advancing its clinical programs, including its ongoing neoantigen immunotherapy and infectious disease programs, and driving

innovation in immunotherapy and vaccine development.

Gritstone is continuing its sale process and actively pursuing bidders for all or any portion of the Company's assets to continue research and development of its next-generation vaccines and immunotherapies for oncology and infectious diseases. The bid deadline for the sale process is December 4, 2024. For more information, please reach out to projectchronos@raymondjames.com.

About the GO-010 Study
GO-010 (NCT05141721) is a Phase 2, randomized, open-label study designed to evaluate the clinical benefit of maintenance therapy with GRANITE (GRT-C901/GRT-R902), a neoantigen targeting immunotherapy, in combination with immune checkpoint inhibitors (ICI) in addition to fluoropyrimidine/bevacizumab versus fluoropyrimidine/bevacizumab alone in patients with first-line microsatellite stable colorectal cancer (MSS-CRC). 104 patients were randomized 1:1 in the study: 69 patients (39 GRANITE arm, 30 control arm) are included in the treated analysis above. Demographics and clinical characteristics were balanced between arms (e.g., stage, sidedness, presence of liver metastases), with the vast majority (80%) of patients having liver metastases in the treated analysis. Thirty-five patients did not advance to study treatment after oxaliplatin most commonly due to withdrawing consent (n=15), disease progression (n=7), and other reasons (n=13) (12 in GRANITE arm; 23 in control arm).

About Gritstone bio
Gritstone bio, Inc. (OTC: GRTSQ) is a clinical-stage biotechnology company that aims to develop the world's most potent vaccines. We leverage our innovative vectors and payloads to train multiple arms of the immune system to attack critical disease targets. Independently and with our collaborators, we are advancing a portfolio of product candidates to treat and prevent viral diseases and solid tumors in pursuit of improving patient outcomes and eliminating disease. www.gritstonebio.com

Gritstone Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to our clinical and regulatory development plans for our product candidates; our expectations regarding the data to be derived in our ongoing and planned clinical trials; statements regarding the process and potential outcomes of our chapter 11 case; our ability to continue to operate as usual during our chapter 11 case; the timing of commencement of our future nonclinical studies, clinical trials and research and development programs; our ability to discover, develop and advance product candidates into, and successfully complete, clinical trials; and our plans and strategy regarding maintaining existing and entering into new collaborations and/or partnerships. Such forward-looking statements involve substantial risks and uncertainties that could cause Gritstone's research and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including Gritstone's programs' clinical stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, Gritstone's ability to successfully establish, protect and defend its intellectual property and other matters that could affect the sufficiency of existing cash to fund operations. Gritstone undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see Gritstone's most recent Annual Report on Form 10-K filed on March 5, 2024 and any subsequent current and periodic reports filed with the Securities and Exchange Commission.

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