



## **Gritstone Announces First Patient Enrolled for Phase 2/3 Trial Evaluating Individualized Neoantigen Vaccine GRANITE for First Line (1L) Maintenance Treatment of Metastatic, Microsatellite-Stable Colorectal Cancer (MSS-CRC)**

January 13, 2022

*-- Phase 2/3 GRANITE-CRC-1L trial has registrational intent --*

*-- Updated data from Phase 1/2 trial in end-stage metastatic MSS-CRC further support the association of circulating tumor DNA (ctDNA) reduction with extended overall survival --*

*-- GRANITE has received Fast Track designation by the U.S. Food and Drug Administration for the treatment of MSS-CRC --*

EMERYVILLE, Calif., Jan. 13, 2022 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing the next generation of cancer and infectious disease immunotherapies, today announced that the first patient has been enrolled for inclusion in the Phase 2/3 GRANITE-CRC-1L trial. The trial evaluates the individualized neoantigen vaccine GRANITE in combination with immune checkpoint blockade for the first line (1L) maintenance treatment of newly diagnosed patients with metastatic, microsatellite-stable colorectal cancer (MSS-CRC). This trial has registrational intent and has been discussed previously with the FDA.

"Building on the success of our GRANITE program, which continues to demonstrate extended survival in multiple end-stage colorectal cancer patients, we are excited to launch this randomized, open-label Phase 2/3 trial to evaluate earlier use of GRANITE as a maintenance treatment in newly diagnosed patients with metastatic, microsatellite-stable colorectal cancer," said Andrew Allen, M.D., Ph.D., Co-founder, President and Chief Executive Officer of Gritstone. "We are pleased with the degree of clinical benefit seen with GRANITE to date in hard-to-treat, late-line CRC patients, and are optimistic we will see greater benefit from neoantigen immunotherapy in earlier lines of treatment where immune responses are likely stronger and tumor genomic complexity is lower. We expect to report initial Phase 2 data from the GRANITE-CRC-1L trial in mid-2023."

Additionally, the company reported updated overall survival (OS) data from its Phase 1/2 GRANITE trial evaluating individualized immunotherapy in combination with nivolumab (OPDIVO®) and ipilimumab (YERVOY®) in patients with advanced solid tumors, specifically end-stage metastatic MSS-CRC. Patients with MSS-CRC who experienced a molecular response (as evidenced by a decrease in circulating tumor DNA [ctDNA]) continue to have an OS advantage compared to those patients who did not have a molecular response. All patients alive at the time of the ESMO 2021 data presentation remain alive after an additional ~22 weeks of follow-up (January 5, 2022 data cut-off).

Dr. Allen continued, "These results reinforce our original observation that molecular response is associated with extended overall survival, the gold standard clinical outcome, in patients with advanced MSS-CRC. The fact that no new patient has succumbed to their disease after an additional ~22 weeks of observation and treatment is encouraging and would not typically be expected in third line CRC patients, for whom median overall survival is typically only around 26-30 weeks from initiation of therapy in multiple Phase 3 trials."

Gritstone will address these developments and present the updated OS data (from the Phase ½ trial in patients with advanced solid tumors) in a presentation at the 40<sup>th</sup> Annual JP Morgan Healthcare Conference occurring at 8:15am ET today. To access this presentation, visit: <http://ir.gritstonebio.com/investors/events>.

### **About GRANITE-CRC-1L Phase 2/3 Trial**

The [GRANITE-CRC-1L trial \(NCT05141721\)](#) is a Phase 2/3, randomized, open-label study evaluating the GRANITE individualized immunotherapy regimen as a first line (1L) maintenance treatment in combination with atezolizumab (TECENTRIQ®) and ipilimumab (YERVOY®) in newly diagnosed patients with metastatic, microsatellite-stable colorectal cancer (MSS-CRC) who received fluoropyrimidine, oxaliplatin and bevacizumab (FOLFOX-bevacizumab) induction therapy. The Phase 2 portion of the study will measure changes in ctDNA over time to characterize the clinical activity of maintenance therapy with GRANITE (GRT-C901/GRT-R902). The Phase 3 portion will further measure the clinical efficacy of the regimen as assessed by progression-free survival using iRECIST criteria.

### **About Phase 1/2 Trial Evaluating GRANITE Against Advanced Solid Tumors**

The purpose of this study was to evaluate the safety, dose, immunogenicity and early clinical activity of the GRANITE individualized neoantigen cancer vaccine, in combination with OPDIVO® (nivolumab) and YERVOY® (ipilimumab), in patients with end-stage metastatic MSS-CRC, NSCLC, gastroesophageal adenocarcinoma, and urothelial cancer ([NCT03639714](#)).

### **About GRANITE**

Gritstone's neoantigen-based immunotherapies are engineered to elicit a significant T-cell response (particularly CD8+ cytotoxic T cells) against mutation-derived tumor-specific neoantigens that are identified by the company using its proprietary Gritstone EDGE™ artificial intelligence platform. GRANITE is an individualized neoantigen-based immunotherapy and uses a priming adenoviral vector (GRT-C901) and self-amplifying mRNA (samRNA) vector (GRT-R902) to deliver individualized immunotherapy containing the relevant neoantigens. GRANITE was granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of MSS-CRC.

### **About Gritstone**

Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company, is developing the next generation of immunotherapies against multiple cancer types and infectious diseases. Gritstone develops its products by leveraging two key pillars—first, a proprietary machine learning-based platform, Gritstone EDGE™, which is designed to predict antigens that are presented on the surface of cells, such as tumor or virally-infected cells, that can be seen by the immune system; and, second, the ability to develop and manufacture potent immunotherapies utilizing these antigens to

potentially drive the patient's immune system to specifically attack and destroy disease-causing cells. The company's lead oncology programs include an individualized neoantigen-based immunotherapy, GRANITE, and an "off-the-shelf" shared neoantigen-based immunotherapy, SLATE, which are being evaluated in clinical studies. Within its infectious disease pipeline, Gritstone is advancing CORAL, a COVID-19 program to develop a second-generation vaccine, with support from departments within the National Institutes of Health (NIH), the Bill & Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI) and through a license agreement with La Jolla Institute for Immunology. Additionally, the company has a global collaboration for the development of a therapeutic HIV vaccine with Gilead Sciences. For more information, please visit [www.gritstonebio.com](http://www.gritstonebio.com).

#### **Gritstone Forward-Looking Statements**

This press release contains forward-looking statements, including, but not limited to, statements related to the potential of Gritstone's therapeutic programs; the advancements in the company's ongoing clinical trials; the timing of data announcements related to ongoing clinical trials and the initiation of future clinical trials. 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' early 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 Quarterly Report on Form 10-Q filed on November 3, 2021 and any current and periodic reports filed with the Securities and Exchange Commission.

#### **Gritstone Contacts**

Media:

Dan Budwick

1AB

(973) 271-6085

[dan@1abmedia.com](mailto:dan@1abmedia.com)

Investors:

George E. MacDougall

Director, Investor Relations & Corp Comms

Gritstone bio, Inc.

[IR@gritstone.com](mailto:IR@gritstone.com)

