Gritstone Announces Updated Overall Survival Results in Advanced Colorectal Cancer Patients from Phase 1/2 Study of GRANITE and Trial in Progress Poster at ASCO

May 31, 2022

-- Overall survival (OS) for patients with metastatic, microsatellite stable colorectal cancer (MSS-CRC) who had two prior lines of therapy and had molecular response as presented at ESMO 2021 will now exceed 18 months – median not yet reached --

-- Trial in Progress poster at ASCO outlines the ongoing, randomized Phase 2/3 trial of GRANITE for first-line maintenance treatment of metastatic, MSS-CRC --

EMERYVILLE, Calif., May 31, 2022 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company that aims to develop the world's most potent vaccines, today announced updated overall survival (OS) results from its Phase 1/2 study evaluating GRANITE, an individualized vaccine-based immunotherapy, to treat advanced solid tumors. Additionally, the company announced it is presenting a "Trial in Progress" poster summarizing the Phase 2/3 GRANITE-CRC-1L- study (randomized study for first-line maintenance treatment of metastatic, microsatellite stable colorectal cancer) at the 2022 American Society for Clinical Oncology (ASCO) Annual Meeting.

"The updated OS data from our Phase 1/2 study continue to demonstrate a correlation between molecular response and overall survival, and points to the potentially significant impact GRANITE is having on lives of patients with advanced stage cancer," said Andrew Allen, M.D., Ph.D., Co-founder, President and Chief Executive Officer of Gritstone. "The median overall survival observed in multiple trials of various therapies in the third-line MSS-CRC setting has been around 6-7 months, which is consistent with what we observed in our study in patients who did not have molecular response (median overall survival of 7.8 months). The very different outcome observed in the molecular responder subset, with median overall survival of over 18 months, is all the more striking given how rarely long-term survival is observed in MSS-CRC patients who have been treated with and progressed on two prior therapies. These maturing data, demonstrating long-term clinical benefit, further support moving GRANITE upstream in the treatment of patients with this grim cancer in the ongoing randomized Phase 2/3 study, which has registrational intent."

The Phase 1/2 study is evaluating the safety, immunogenicity, and clinical activity of GRANITE in combination with PD-1 checkpoint inhibitor, Opdivo® (nivolumab) and subcutaneous anti-CTLA-4 antibody, Yervoy® (ipilimumab) in advanced solid tumors. This study enrolled and treated 26 patients as of ESMO 2021 presentation with previously treated, metastatic solid tumors including patients with colorectal cancer, gastroesophageal adenocarcinoma, and non-small cell lung cancer. As presented at ESMO 2021, of 9 patients with MSS-CRC who were treated and evaluable for molecular response, 4 experienced a molecular response (as evidenced by a reduction in circulating tumor DNA [ctDNA]) and continue to have an OS advantage compared to those patients who did not have a molecular response.

Opdivo® and Yervoy® are trademarks of Bristol-Myers Squibb Company.

Updated overall survival data from GRANITE Phase 1/2:

- 4 of 9 treated patients with MSS-CRC had a molecular response (as reported during the ESMO 2021 data presentation) and the observed median overall survival in this group will now exceed 18 months (median OS not yet reached versus 7.8 months in those who did not have a molecular response).
- All patients with MSS-CRC assessed for molecular response and alive at the time of the ESMO 2021 data presentation remain alive after an additional 35 weeks of follow-up.

ASCO presentation details are as follows:

Abstract TPS3635: Phase 2/3, randomized, open-label study of an individualized neoantigen vaccine (self-amplifying mRNA and adenoviral vectors) plus immune checkpoint blockade as maintenance for patients with newly diagnosed metastatic colorectal cancer (GRANITE)
Date/Time: Saturday 04 June 2022, 8:00am CST
Session: Gastrointestinal Cancer – Colorectal and Anal
Location: Poster 425b

About Gritstone bio
Gritstone bio, Inc. (Nasdaq: GRTS) is a clinical-stage biotechnology company that aims to create 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

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 vaccine-based 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.

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 Gritstone'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 Gritstone in general, see Gritstone's most recent Quarterly Report on Form 10-Q filed on May 5, 2022 and Gritstone's future reports to be filed with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Gritstone as of the date hereof. Gritstone disclaims any obligation to update any forward-looking statements, except as required by law.

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