Gritstone Announces Updated Overall Survival Results from GRANITE Phase 1/2 Study and Poster at SITC 2022

November 10, 2022

-- Median overall survival (OS) for patients with metastatic, microsatellite stable colorectal cancer (MSS-CRC) who had two prior lines of therapy and had molecular response will now exceed 22 months – median not yet reached --

-- Patients who achieve a molecular response include those with liver metastasis and are not enriched for baseline PD-L1 expression, high tumor mutation burden or IFNg-related genes --

EMERYVILLE, Calif., Nov. 10, 2022 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working 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, for the treatment of advanced solid tumors. These results, along with results from a clinicopathologic analysis of metastatic MSS-CRC patients with and without a molecular response, will be presented via a poster at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting.

"The follow-up data from our Phase 1/2 study in patients with MSS-CRC who have received at least two prior lines of therapy continue to demonstrate an association between molecular response and overall survival," said Andrew Allen, M.D., Ph.D., Co-founder, President and Chief Executive Officer of Gritstone. "The median overall survival (MOS) in patients with MSS-CRC that had a molecular response has still not been reached and will now exceed 22 months; an additional four months since our last update in May 2022. This is a notable difference compared to the 6–7-month MOS typically observed in third-line MSS-CRC and the 7.8 month MOS in patients without a molecular response within our study. The clinicopathologic analysis shows MSS-CRC patients who achieve a molecular response do not have high tumor mutation burden, PD-L1 expression or high expression of IFNg-related genes. We are also observing molecular responses in patients with liver metastases, a subset that typically receives little benefit from immunotherapy. The recent publication of GRANITE Phase 1/2 results in Nature Medicine detail the program's novel approach, and the data to date demonstrate its promise in hard-to-treat, late-line settings. The randomized Phase 2/3 GRANITE study in first-line CRC, where patients generally have more time to mount an immune response, is ongoing and preliminary data are expected in 4Q2023."

The Phase 1/2 study is evaluating the safety, immunogenicity, and clinical activity of GRANITE in combination with PD-1 checkpoint inhibitor, nivolumab and subcutaneous anti-CTLA-4 antibody ipilimumab in advanced solid tumors. This study enrolled and treated 29 patients with previously treated, metastatic solid tumors including patients with colorectal cancer, gastroesophageal adenocarcinoma, and non-small cell lung cancer. Of 13 patients with MSS-CRC, 6 experienced a molecular response defined as ≥30% reduction in circulating tumor DNA (ctDNA) and continue to have an overall survival advantage compared to those patients without a molecular response.

Updated OS data from GRANITE Phase 1/2:

- 6 of 13 treated patients with MSS-CRC had a molecular response and the observed median overall survival in this group will now exceed 22 months (median OS not yet reached versus 7.8 months in those without a molecular response). This compares to a median overall survival not yet reached and exceeding 18 months as reported in May 2022.

Clinicopathologic characteristics from GRANITE Phase 1/2:

- 4 of 6 patients with molecular response had liver metastasis.
- All patients had PD-L1 expression <1% and low levels of IFNg-related gene expression.
- Median tumor mutational burden was 2.9 and 3.6 mutations/MB in those with and without molecular response, respectively.

SITC presentation details are as follows:
Abstract 660: Clinicopathologic Characteristics of Patients with Metastatic Colorectal Cancer with Molecular Responses Following Treatment with an Individualized Neoantigen Vaccine Regimen
Date/Time: Friday, Nov. 11, 2022: 9:00am – 8:30pm EST
Session: Clinical Trials In Progress
Location: Boston Convention & Exhibition Center: Hall C

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 (TSNA). Gritstone identifies these TSNA using its proprietary artificial intelligence platform, EDGE™. GRANITE is an individualized neoantigen-based immunotherapy program that uses adenoviral ("prime") and self-amplifying mRNA ("boost") vectors to deliver personalized 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 bio
Gritstone is working 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 and have programs in viral diseases and solid tumors. Independently and with our partners, we are advancing a portfolio of product candidates with the aim 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 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' 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 10, 2022, as well as Gritstone's Quarterly Reports on Form 10-Q filed on May 5, 2022 and August 4, 2022 and any current and periodic reports filed with the Securities and Exchange Commission.

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