



## Gritstone Announces Dosing of First Solid Tumor Patient with Optimized SLATE “Off-the-Shelf” Mutant KRAS-directed Neoantigen Immunotherapy in Phase 2 Clinical Trial

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- SLATE version (v) 1, Gritstone’s “off the-shelf” neoantigen immunotherapy (including KRAS, TP53 mutations), elicited multiple molecular responses and an unconfirmed RECIST radiologic response in patients with NSCLC who had progressed on prior immunotherapy
- SLATE v2 (a mutant KRAS-focused version), which is optimized for increased immune response, has been administered to the first patient in Phase 2 testing

EMERYVILLE, Calif., Sept. 17, 2021 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing next generation cancer and infectious disease immunotherapies, today announced results with its SLATE v1 product (“off-the-shelf” shared neoantigen immunotherapy in combination with intravenous nivolumab and subcutaneous ipilimumab) and dosing of the first patient in a Phase 2 clinical trial of the optimized SLATE v2 product. SLATE v2 has been engineered, based on human translational immunology data from v1 patients, to drive a more potent immune response to mutant KRAS neoantigens than were observed with SLATE v1. The data from SLATE v1 will be reviewed during the company’s previously announced investor event taking place today at 1:30pm ET.

The v1 format of the SLATE immunotherapy was studied in a Phase 1/2 study, in collaboration with Bristol-Myers Squibb, in 26 patients with metastatic solid tumors, largely focused on non-small cell lung cancer (NSCLC), microsatellite-stable colorectal cancer (MSS-CRC) and pancreatic ductal adenocarcinoma (PDAC). There were no safety signals of note with the most common adverse events being low grade, self-limiting fever and injection site reactions. SLATE v1 exhibited evidence of efficacy in patients with NSCLC who had all progressed on prior anti-PD-(L)1 therapy (often in combination with chemotherapy) – with molecular responses (>50% decrease in ctDNA levels in the blood from baseline) observed in 3/5 NSCLC patients who were eligible for analysis.

SLATE v1 demonstrated the greatest activity in 6 NSCLC patients with the KRAS<sup>mut</sup> G12C presented by the HLA protein A\*02:01. Among these patients, ctDNA responses were observed in 66% of these patients (2/3 eligible for analysis), correlating with clinical benefit, and a RECIST radiologic response (unconfirmed) was observed in one 2nd line patient who had progressed after 3 months of 1st line chemo-immunotherapy. One patient who had progressed on prior chemo-immunotherapy after 8 months of treatment is nearing completion of 2 years of therapy with persistent ~20% tumor lesion shrinkage. The patient’s ctDNA was undetectable throughout the study.

A next generation, optimized SLATE cassette (v2), which exclusively includes epitopes from mutated KRAS and exhibited immunogenic superiority over v1 in human HLA-transgenic mice, is now in Phase 2 testing in patients with advanced NSCLC and CRC.

“We are excited to dose the first patient with the KRAS-specific version (v2) of our SLATE immunotherapy,” said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone. “We are very encouraged by the clinical data generated with v1, and product redesign using translational immunology data has enabled this optimized v2, which we are initially evaluating in more non-small cell lung cancer patients following progression on immunotherapy, as well as patients with microsatellite-stable colorectal cancer. We expect that these treatment settings will enable us to demonstrate the differentiated therapeutic potential of SLATE v2, and we anticipate having initial data by mid-2022. We look forward to presenting the data from SLATE v1 and from our individualized GRANITE program during our investor event in conjunction with ESMO 2021 later this week.”

The SLATE v2 Phase 2 portion of the study is expected to enroll up to 60 patients with KRAS mutant-driven tumors in total across three cohorts: NSCLC post chemo-immunotherapy, first line MSS-CRC and third-line MSS-CRC. All patients will receive SLATE v2, consisting of a dose of intramuscular adenovirus-based prime with intramuscular self-amplifying mRNA-based boost vaccinations, in combination with PD-1 checkpoint inhibitor Opdivo® (nivolumab) and subcutaneous anti-CTLA-4 antibody Yervoy® (ipilimumab). Opdivo® and Yervoy® are trademarks of Bristol-Myers Squibb Company.

### About SLATE

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, or TSNA, that are identified by the company using its proprietary Gritstone EDGE™ artificial intelligence platform and tumor HLA peptide sequencing. Gritstone’s SLATE “off-the-shelf” immunotherapy uses a priming adenoviral vector (GRT-C903) and self-amplifying mRNA vector (GRT-R904) to deliver a cassette of shared TSNA, representing mutated gene sequences that are found in multiple patients (such as KRAS mutations). SLATE is being evaluated in combination with immune checkpoint blockade in the Phase 2 portion of its clinical study ([NCT03953235](https://clinicaltrials.gov/ct2/show/study/NCT03953235)).

### 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 AI-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, manufacture, and deliver selected antigens to the patient’s immune system to drive the destruction of tumors or virally-infected 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 [gritstone.com](http://gritstone.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, including that interim results obtained may differ from those at completion of the studies and clinical trials. 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 August 5, 2021 and any current and periodic reports filed with the Securities and Exchange Commission.

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