Gritstone Presentations at AACR Further Support Expertise in Neoantigen Vaccine Design and Delivery

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-- Translational immunology data and cassette design capabilities enabled development of an optimized, KRAS-specific version of “off-the-shelf” vaccine candidate now in Phase 2 (SLATE-KRAS) --

-- GRANITE data (individualized neoantigen-based therapeutic vaccine program) support circulating tumor DNA (ctDNA) response as a predictor of overall survival in metastatic colorectal cancer --

-- Detailed analysis from oncology programs supports potency and dose sparing potential of self-amplifying mRNA (samRNA) --

EMERYVILLE, Calif., April 12, 2022 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing next generation cancer and infectious disease immunotherapies, delivered three presentations (one oral and two posters) further supporting the potential of its novel vaccine development capabilities and delivery platforms to develop transformational therapeutic cancer vaccines at the 2022 American Association for Cancer Research (AACR) Annual Meeting.

“The collective data we presented at AACR reinforce our expertise in designing and delivering potent vaccines, and support the optimization of antigen cassette design, dose and vaccine regimen as key tools to induce differentiated immune response,” said Andrew Allen, M.D., Ph.D., Co-founder, President and Chief Executive Officer of Gritstone. “Vaccines targeting neoantigens identified from common tumor driver mutations are of increasing interest, and the presentation on our ‘off-the-shelf’ candidate for KRAS-specific mutations, SLATE-KRAS, demonstrates our ability to both accurately define those targets and engineer the cassette and vaccine to optimize immune response based on those specific mutations. Early signals from our ongoing Phase 2 study presented at AACR support the potential of SLATE-KRAS to drive stronger CD8+ T cell responses to mutant KRAS than our original candidate, SLATE v1. We look forward to further demonstrating the value of SLATE as evidence of clinical benefit builds.”

Oral Presentation: Optimization of shared neoantigen vaccine design to increase vaccine potency: From bench to bedside and back
Presenter: Christine D Palmer, PhD
Key Highlights:

- SLATE v1* was well-tolerated and demonstrated a favorable safety profile in all subjects dosed (n=26). Greatest activity was seen in six (6) NSCLC patients with $KRAS^{mut}$ G12C mutations.
- Gritstone subsequently developed a second, optimized product candidate (SLATE-KRAS) that exclusively includes epitopes from mutated KRAS.
- SLATE-KRAS is being evaluated in the Phase 2 portion of a Phase 1/2 trial (NCT03953235), with initial data expected in the second half of 2022.

**SLATE v1 was administered in combination with Opdivo® (nivolumab) and subcutaneous anti-CTLA-4 antibody Yervoy® (ipilimumab). Opdivo® and Yervoy® are trademarks of Bristol-Myers Squibb Company.*

Additional presentations at AACR further elucidated the correlation between patient survival and circulating tumor DNA (ctDNA) in solid tumors (relevant to the company’s individualized vaccine program, GRANITE) and detailed a dose-response analysis, the results of which further support the dose-sparing potential of the company’s novel vector which is it utilizing in both oncology and infectious disease, self-amplifying mRNA (samRNA).

Karin Jooss, Ph.D., Executive Vice President, and Head of R&D added, “Clinical data from SLATE and GRANITE characterizing the optimal dosing regimen for our novel samRNA vector demonstrate more robust immune responses at lower doses, further supporting the overall potency and dose sparing potential of samRNA. The collective data we presented at AACR has readthrough across our pipeline programs in both oncology and infectious disease, and further demonstrates Gritstone’s leadership in the field of neoantigen vaccines.”

Poster Presentation: Comprehensive ctDNA monitoring provides early signal of clinical benefit with a novel personalized neoantigen directed immunotherapy for late-stage cancer patients
Presenter: Matthew Davis, PhD
Key Highlights:

- Majority of neoantigens are retained in tumor even after patient receives treatment
- ctDNA longitudinal monitoring enables real-time assessment of response/resistance
- Molecular response elicited in four (4) of nine (9) treated subjects that correlated with prolonged progression-free survival and overall survival support clinical benefit of GRANITE in patients with advanced MSS-CRC

Poster Presentation: Lower doses of self-amplifying mRNA drive superior neoantigen-specific CD8+ T cell responses in cancer patients versus high doses
Presenter: Amy Rappaport, PhD
Key Highlights:

- samRNA demonstrated a favorable safety profile at all 3 dose levels, with no evidence of increasing reactogenicity with sequential doses
- Lower dose samRNA (30 µg) increased T cell and humoral responses following a ChAd prime, while higher doses of samRNA (300 µg) only maintained initial response to ChAd
- Dose dependent induction of IFNα in cancer patients and nonhuman primates suggest inhibitory impact of early innate immune activation

To view Gritstone's AACR presentations, visit ir.gritstonebio.com/investors/events.

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. SLATE, Gritstone's "off-the-shelf" immunotherapy program, uses a priming adenoviral vector and self-amplifying mRNA vector 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). Along with the candidates developed to date, SLATE represents the potential to develop a suite of "off-the-shelf" product candidates that target tumor-specific mutations across a number of patient populations and cancer types.

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 artificial intelligence-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 program delivering T cell enhanced self-amplifying mRNA (samRNA) vaccines for COVID-19 that is supported by 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.

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 Annual Report on Form 10-K filed on March 10, 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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