Gritstone Announces First Person Dosed with its Second-Generation COVID-19 Vaccine in Phase 1 Study Conducted and Supported by NIAID/IDCRC

March 29, 2021

– Preliminary Data from Phase 1 Study of CORAL Expected Mid-year –

– Study will Assess Antibody and CD8+ T Cell Responses to Spike and Additional Non-Spike Antigens from SARS-CoV-2 with Aim of Augmenting Clinical Protection Against Spike Variants of Concern –

– Phase 2 Study Evaluating CORAL as a Boost Vaccine Following Vaccination with Authorized First-Generation COVID-19 Vaccines Planned –

EMERYVILLE, Calif., March 29, 2021 (GLOBE NEWSWIRE) -- Gritstone Oncology, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing the next generation of cancer and infectious disease immunotherapies, today announced that the first person has been dosed under Gritstone's "CORAL" program with its candidate COVID-19 vaccine in a Phase 1 study. The study is evaluating the immunogenicity and safety of using its self-amplifying mRNA (SAM) and/or adenoviral vectors to deliver SARS-CoV-2 viral antigens, including both Spike and other viral antigens outside of Spike that are not included in currently authorized vaccines. The Phase 1 study (clinicaltrials.gov identifier: NCT04776317) is supported by the National Institute of Allergy and Infectious Diseases (NIAID) and is being conducted through their Infectious Diseases Clinical Research Consortium (IDCRC).

"This study has been met with great enthusiasm as Gritstone's vaccine is differentiated in its potential to broaden the immune response to SARS-CoV-2, potentially preserving clinical protection even if Spike variants arise," said Daniel Hoft, M.D., Ph.D., director of Saint Louis University's Center for Vaccine Development and Division of Infectious Diseases, Allergy and Immunology; National Vaccine Advisory Committee member; and protocol chair and lead principal investigator of Gritstone's COVID-19 vaccine study. "Based on pre-clinical work and data from Gritstone's cancer patients, we hope and expect to see strong neutralizing antibodies to Spike, as well as CD8+ T cell responses to both Spike and additional viral antigens, which may provide clinical protection against emerging Spike variants. We are also exploring the potential to use a lower dose of the self-amplifying mRNA vaccine, which could enable more patients to be treated with a given amount of manufactured vaccine."

The Phase 1 clinical trial is a multicenter, open-label, dose- and age-escalation study to examine the immunogenicity and safety of Gritstone's CORAL COVID-19 vaccine in healthy adult volunteers. Both heterologous and homologous prime-boost vaccinations of the adenoviral vector and/or SAM vector expressing either SARS-CoV-2 Spike alone or Spike plus additional SARS-CoV-2 T cell epitopes are being studied in a parallel design.

"We are excited to be advancing CORAL, our second-generation COVID-19 vaccine candidate, under our clinical collaboration with NIAID," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone. "As we look to the future, we believe CORAL has the potential to address coronavirus immunity challenges that are likely to emerge, particularly around novel Spike variants of concern. Building on this NIAID/IDCRC first-in-human study, we are planning to examine the expected broad immunity elicited by our vaccine by delivering it as a boost for people who have received first-generation vaccines in a Phase 2 study starting later this year. We hope that strong CD8+ T cell immunity generated against key non-Spike gene fragments will provide protection against future Spike variants."

Dr. Allen continued, "Additionally, the repeated emergence of new coronavirus epidemics/pandemics over the last 20 years supports the desire for a pan-coronavirus vaccine to prevent or mitigate future pandemics. Certain non-Spike genes, some of which are included in our vaccine, tend to be conserved in coronaviruses over time and across variants. This observation may catalyze the development of a pan-coronavirus vaccine."

About Gritstone Oncology

Gritstone Oncology, 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^{TM}, 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. The company also has a bispecific antibody (BiSAb) program for solid tumors in lead optimization. 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, as well as 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 gritstoneoncology.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 Annual Report on Form 10-K filed on March 11, 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

Investors:
Alexandra Santos
Wheelhouse Life Science Advisors
(510) 871-6161
asantos@wheelhouselsa.com

Source: Gritstone Oncology, Inc