



Gritstone Announces Dosing of First Volunteer in Trial Evaluating Self-Amplifying mRNA as a COVID-19 Vaccine Booster and Immunogenicity Enhancer

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GRT-R910, a self-amplifying mRNA (SAM) SARS-CoV-2 vaccine, delivers antigens from both the spike protein and highly conserved non-spike proteins for broad protection across variants

Induction of CD8+ T cells in addition to neutralizing antibody responses offers potential for robust and persistent immunity, especially in at-risk populations (eg older individuals and those who are immunocompromised)

Initial Phase 1 data from this study are expected in the first Quarter 2022

EMERYVILLE, Calif., Sept. 20, 2021 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing next generation cancer and infectious disease immunotherapies, today announced that the first volunteer has been dosed in a Phase 1 trial evaluating the ability of GRT-R910, a self-amplifying mRNA (SAM) second generation SARS-CoV-2 vaccine to boost and expand the immunogenicity of first-generation COVID-19 vaccines in subjects 60 years of age or older. This single-center study is being conducted in collaboration with The University of Manchester and Manchester University NHS Foundation Trust in the United Kingdom.

GRT-R910 is part of Gritstone's CORAL program, a second-generation COVID-19 vaccine platform that uses a SAM vector formulated with lipid nanoparticles to deliver a broad set of antigens against SARS-CoV-2 that includes both stabilized spike protein and highly conserved viral protein regions containing T cell epitopes. By virtue of self-amplification, extended duration and magnitude of antigen production with SAM vaccines may offer the opportunity of lowering vaccine doses or eliminate the need for repeat administrations, and has potential to safely elicit strong, durable and broad immune responses across SARS-CoV-2 variants.

"Our SAM COVID vaccine is designed to drive robust CD8+ T cell responses, in addition to strong neutralizing antibody responses, offering the promise of longer lasting immunity, especially in more vulnerable populations," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone. "Additionally, since viral surface proteins like the spike protein are evolving and sometimes partially evading vaccine-induced immunity, we designed GRT-R910 to have broad therapeutic potential against a wide array of SARS-CoV-2 variants by also delivering highly conserved viral proteins that may be less prone to antigenic drift."

Professor Andrew Ustianowski, who is Clinical Lead for the NIHR COVID Vaccine Research Programme, Consultant in Infectious Diseases and Tropical Medicine at North Manchester General Hospital (part of MFT) and Honorary Clinical Chair at The University of Manchester, will be the local lead investigator for this study. Professor Ustianowski is Chief Investigator for the study and MFT is the chief site.

He added, "The observed waning of vaccine-elicited immune responses, particularly in older individuals, coupled with the prevalence of emerging variants, highlights the need for continued vigilance to keep COVID-19 at bay. Using GRT-R910 as a boost vaccination is expected to elicit strong, durable, and broad immune responses, which are likely critical to maintaining protection in this vulnerable elderly population with increased mortality risk. We look forward to working with Gritstone in the clinical development of this promising next generation COVID vaccine."

Professor Ian Bruce, from The University of Manchester, is Chair of the Manchester COVID-19 Research Rapid Response Group (RRRG), Consultant Rheumatologist at Manchester Royal Infirmary's Kellgren Centre, and Director of the NIHR Manchester Biomedical Research Centre. He commented: "We're tremendously excited that this promising vaccine is to be trialed here in Manchester. As the only European site for this study, it is testament to the way our academic and clinical researchers have come together as part of the 'One Manchester R&I' approach to answer the questions the world needs answers to. Though the vaccine is being evaluated in the over 60s, future studies will also examine its efficacy in other-vulnerable populations. If successful, we feel it has the potential to play a significant role in the battle against COVID-19, which has so devastated vulnerable populations across the globe. We look forward to working with Gritstone in the clinical development of this promising next generation COVID-19 vaccine."

The Gritstone sponsored Phase 1 trial, which is initially expected to enroll 20 volunteers, will explore the ability of GRT-R910 to boost and expand the immunogenicity of AstraZeneca's first-generation COVID-19 vaccine AZD1222 (Vaxzevria) in healthy adults ≥ 60 years. This open-label dose-escalation design study will examine dose, safety, tolerability, and immunogenicity of GRT-R910 at two dose levels at least 4 months after the second administration of their initial vaccine. GRT-R910 is also being investigated as part of a National Institutes of Health sponsored Phase 1 study in the United States. Additional trials of the CORAL platform, including an additional Phase 1 trial in collaboration with the Coalition for Epidemic Preparedness Innovations (CEPI) are planned. Data from these studies will inform the future development of CORAL, Gritstone's SARS-COV-2 second generation vaccine program.

About the CORAL Program

Gritstone's CORAL program is a second-generation SARS-CoV-2 vaccine platform delivering spike and additional SARS-CoV-2 T cell epitopes, offering the potential for more durable protection and broader immunity against SARS-CoV-2 variants. Gritstone's delivery platform employs a heterologous prime-boost approach where delivery vectors can comprise a chimpanzee adenovirus, self-amplifying mRNA or both. The program is supported by several key relationships: La Jolla Institute for Immunology, Bill & Melinda Gates Foundation, National Institute of Allergy and Infectious Disease (NIAID), and the Coalition for Epidemic Preparedness Innovations (CEPI). A phase 1 clinical trial is currently being sponsored by NIAID examining the reactogenicity and immunogenicity of CORAL in healthy volunteers, both young and elderly. Gritstone is sponsoring and conducting its own Phase 1 studies in select populations. Together with CEPI's planned study, this set of clinical trials will test four different vaccine candidates and establish optimal dosing and antigenic content for the CORAL program in young subjects, the elderly, the previously vaccinated, and the immunocompromised (who typically respond poorly to current EUA vaccines).

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 machine learning-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 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.

About the University of Manchester

The University of Manchester, a member of the prestigious Russell Group, is one of the UK's largest single-site university with more than 40,000 students – including more than 10,000 from overseas. It is consistently ranked among the world's elite for graduate employability. The University is also one of the country's major research institutions, rated fifth in the UK in terms of 'research power' (REF 2014). World-class research is carried out across a diverse range of fields including cancer, advanced materials, global inequalities, energy and industrial biotechnology.

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 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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