



The Omicron Variant of SARS-CoV-2 has Minimal Impact on the T Cell Epitopes (Targets) Contained within Gritstone's Self-Amplifying mRNA COVID-19 Vaccines

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Omicron mutations, while impacting Spike substantially, have minimal impact (~2%) on the T Cell Epitope (TCE) sequences included within Gritstone's COVID-19 vaccines (CORAL program)

T cell immunity against conserved non-Spike epitopes may offer clinical benefit

Gritstone-sponsored, CEPI-funded Phase 1 study of Spike (Beta variant) plus novel TCE constructs expected to initiate in South Africa by year end

Initial Phase 1 data from Gritstone-sponsored UK study expected early in the first quarter of 2022

EMERYVILLE, Calif., Nov. 29, 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 SARS-CoV-2 T cell epitopes (TCEs) administered within its self-amplifying mRNA (SAM) COVID-19 vaccines are minimally impacted by mutations found within the Omicron (B.1.1.529) variant, reinforcing the platform's potential to address emerging variants of concern.

The recently described Omicron variant, first identified in South Africa on November 9, 2021, was designated a Variant of Concern (VOC) by the World Health Organization (WHO) on November 26, 2021. Early evidence suggests that Omicron carries an increased risk of re-infection, and sequence analysis has revealed many mutations in Spike, including both the N terminal domain (NTD) and receptor binding domain (RBD), which may reduce clinical effectiveness of existing vaccines and/or therapeutic antibodies.

Gritstone's CORAL program is a second-generation SARS-CoV-2 vaccine platform delivering a stabilized Spike protein and highly conserved TCEs derived from other SARS-CoV-2 viral genes, offering the potential for more durable protection and broader immunity against SARS-CoV-2 variants. Delivery vectors can comprise self-amplifying mRNA (SAM), a chimpanzee adenovirus (ChAd), or both (mix-and-match).

Sequence analysis suggests that Gritstone's TCEs are minimally impacted by Omicron. Specifically, of the 146 non-Spike TCE delivered within Gritstone's vaccine currently in clinical trials in the UK and US, only 3 (~2%) are impacted by Omicron. Similar minimal impact of Omicron is observed in two new vaccine TCE constructs expected to enter clinical trials in South Africa before year end.

"Our value proposition in immunotherapy has always centered around two core pillars – cutting-edge TCE identification and delivering potent vaccines that can elicit strong, broad, and durable immune responses," said Andrew Allen, MD, PhD, Gritstone's Chief Executive Officer. "Strong neutralizing antibody responses to Spike-based vaccines have been shown to be highly protective against COVID-19. However, the possibility of substantial viral resistance arising from Spike mutations has always been present, and Omicron may represent the embodiment of this threat. While engineering an Omicron form of Spike is achievable, it is clearly ideal to both address novel Spike variants and also reduce the likelihood of further variants arising, by delivering a coordinated immune attack against both Spike and other more conserved SARS-CoV-2 genes. This is the path Gritstone has followed to date. With our trial in South Africa scheduled to begin imminently and initial clinical data from our UK trial expected in early 2022, we look forward to unlocking the immense potential of this platform."

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. Delivery vectors can comprise a chimpanzee adenovirus, self-amplifying mRNA or both. The program is supported by several key relationships: Bill & Melinda Gates Foundation, National Institute of Allergy and Infectious Disease (NIAID), and the Coalition for Epidemic Preparedness Innovations (CEPI). An ongoing Gritstone-sponsored Phase 1 trial is evaluating SAM as a boost and immunogenicity enhancer of AstraZeneca's first-generation COVID-19 vaccine AZD1222 (Vaxzevria) in healthy adults ≥ 60 years in the UK. Preliminary data from this trial are expected in early 2022. A two-dose SAM regimen is also being evaluated in an ongoing clinical trial sponsored by the National Institute of Health (NIH) Division of Microbiology and Infectious Disease (DMID) (NCT04776317, GO-009, GO-012), and in the Coalition for Epidemic Preparedness Innovations (CEPI)-funded, Gritstone-sponsored clinical trial in South Africa expected to begin by year end 2021.

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 (LJI). 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.

Gritstone Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to Gritstone bio, Inc.'s ("Gritstone", "we" or

"our") preclinical and clinical product candidates, including GRANITE, SLATE, CORAL, and HIV programs; the advancements in our 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. Forward-looking statements generally contain words such as "believes," "expects," "may," "will," "should," "seeks," "approximately," "intends," "plans," "estimates," "anticipates," and other expressions that are predictions of or indicate future events and trends and that do not relate to historical matters. 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 November 3, 2021 and any current and periodic reports filed with the Securities and Exchange Commission.

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