# Gritstone bio and CEPI Expand Vaccine Agreement to Tackle Omicron Variant

December 6, 2021

EMERYVILLE, Calif. and OSLO, Norway, Dec. 06, 2021 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing next generation cancer and infectious disease immunotherapies, and CEPI, the Coalition for Epidemic Preparedness Innovations, today announced the expansion of their agreement in order to support the development of a self-amplifying mRNA (SAM) vaccine designed to tackle the Omicron COVID-19 variant. CEPI will provide up to $5 million in additional funding to conduct a Phase 1 clinical trial of Gritstone's Omicron vaccine candidate in South Africa, where a CEPI-funded clinical trial of Gritstone's Beta variant COVID-19 vaccine is due to begin shortly. The SARS-CoV-2 T cell epitopes (TCEs) administered within Gritstone's SAM COVID-19 vaccines are minimally impacted by mutations found within the Omicron variant, reinforcing the platform's potential to address both Omicron and future variants of concern.

CEPI is already funding up to $20.6 million to support preclinical studies, manufacturing process optimization, and a Phase 1 trial of Gritstone's Beta variant vaccine candidate (containing beta-Spike plus additional TCEs), which will be initiated by South Africa's University of the Witwatersrand in the coming weeks. The funding announced today will expand the Phase 1 trial to include additional arms to evaluate an Omicron-specific version of the vaccine (which contains omicron-Spike plus TCEs). Gritstone has commenced manufacturing its SAM vaccine to specifically target the Omicron variant, and the Omicron arms of the Phase 1 trial are expected to begin in Q2 2022, subject to regulatory approval.

The recently described Omicron variant, first identified in South Africa on November 9, 2021, was designated a variant of concern 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, which may reduce clinical effectiveness of existing vaccines and/or therapeutic antibodies.

**Enabling equitable access**
CEPI is committed to global equitable access to COVID-19 vaccines so, through this agreement, CEPI and Gritstone have agreed that this Omicron vaccine candidate will be made available to the COVAX Facility for procurement and allocation, if it is proven to be safe and effective. The COVAX Facility aims to deliver equitable access to COVID-19 vaccines for all countries, at all levels of development, that wish to participate.

Dr Richard Hatchett, CEO of CEPI, said: "While key questions are yet to be answered about Omicron, its transmissibility, and its potential ability to evade our current vaccines, the stakes are too high to delay developing Omicron-specific vaccine candidates. Given the uncertainties, we must accelerate crucial R&D so vaccines are available to tackle Omicron as soon as possible – just in case we need them. There is no time to lose, so I'm pleased that within 10 days of Omicron being declared a Variant of Concern by the WHO, CEPI is expanding its partnership with Gritstone to support a new Omicron vaccine candidate which can be made globally accessibly through COVAX."

"Our vaccine platforms are built on the premise that a best-in-class vaccine against a virus will drive strong neutralizing antibodies directed to surface antigens such as Spike, and strong cytotoxic T cell responses against other conserved viral antigens to eliminate virally infected cells. This broad immune response would, in principle, provide superior protection against a virus that is mutating its surface protein. Omicron is an example of a novel SARS-CoV-2 variant that may escape clinical protection conferred by vaccines that only afford narrow, Spike-specific immunity," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone. "Our SAM technology provides an innovative platform likely capable of delivering on the attractive concept of broad, durable immunity. We are thrilled to be quickly expanding our relationship with CEPI in our shared goal of finding new vaccine solutions to battle this deadly virus on a global scale and help prevent current and perhaps future COVID outbreaks."

**Self-amplifying mRNA vaccines**
As with the mRNA-based COVID-19 vaccines that are now in global use, self-amplifying mRNA vaccines use the body's own machinery to make antigenic protein itself rather than injecting the antigen directly into the body.

However, in self-amplifying mRNA vaccines, viral RNA is adapted in a way that allows only the genetic sequence for a specific antigen to be expressed, while keeping the part of the RNA that allows it to produce multiple copies of itself—the self-amplification machinery.

The benefit of this approach is that the dose of RNA can be reduced while maintaining the potency of the vaccine. Gritstone's vaccine candidate may also elicit T-cell immune responses against non-Spike gene fragments, which are slower to mutate than the genes associated with the SARS-CoV-2 Spike protein and could potentially provide broad protection against other SARS-CoV-2 strains.

**About CEPI**
CEPI is an innovative partnership between public, private, philanthropic, and civil organisations, launched at Davos in 2017, to develop vaccines against future epidemics. Prior to COVID-19 CEPI's work focused on developing vaccines against Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever virus and Chikungunya virus – it has over 20 vaccine candidates against these pathogens in development. CEPI has also invested in new platform technologies for rapid vaccine development against unknown pathogens (Disease X).

During the current pandemic, CEPI initiated multiple programmes to develop vaccines against SARS-CoV-2 and its variants with a focus on speed, scale and access. These programmes leverage the rapid response platforms developed by CEPI's partners prior to the emergence of COVID-19 as well as new collaborations. The aim is to advance clinical development of a diverse portfolio of safe and effective COVID-19 candidates and to enable fair allocation to these vaccines worldwide through COVAX.

CEPI's 5-year plan lays out a $3.5 billion roadmap to compress vaccine development timelines to 100 days, develop a universal vaccine against COVID-19 and other Betacoronaviruses, and create a "library" of vaccine candidates for use against known and unknown pathogens. The plan is available at http://www.endpandemics.cepi.net.

Follow our news page for the latest updates. Follow us ia @CEPIvaccines, @DrRHatchett, and LinkedIn.

**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 (mix and match). 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. 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 EDGETM, 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.

**About COVAX**
COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, is co-convened by CEPI, Gavi, the Vaccine Alliance Gavi) and the World Health Organization (WHO) – working in partnership with UNICEF as key implementing partner, developed and developing country vaccine manufacturers, the World Bank, and others. It is the only global initiative that is working with governments and manufacturers to ensure COVID-19 vaccines are available worldwide to both higher-income and lower-income countries.

**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.

**Gritstone Contacts**
Media:
Dan Budwick
1AB
(973) 271-6085
dan@1abmedia.com

Investors:
Tim McCarthy, CFA
LifeSci Advisors, LLC
tim@lifesciadvisors.com

gritstone bio