



Gritstone bio Awarded BARDA Contract to Conduct Comparative Phase 2b Study Evaluating Next-Generation Vaccine Candidate for COVID-19 Valued at up to \$433 Million

September 27, 2023

-- 10,000 participant randomized Phase 2b study will evaluate Gritstone's self-amplifying mRNA (samRNA) vaccine candidate containing Spike plus other viral targets with an approved vaccine against COVID-19 --

-- Contract is part of 'Project NextGen,' an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19 --

EMERYVILLE, Calif., Sept. 27, 2023 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, announced today that it was awarded a contract by the Biomedical Advanced Research and Development Authority (BARDA) to conduct a Phase 2b comparative study evaluating Gritstone's self-amplifying mRNA (samRNA) vaccine candidate containing Spike plus other viral targets to protect against COVID-19. The agreement, which is valued at up to \$433 million, was awarded as part of '[Project NextGen](#),' an initiative by the U.S. Department of Health and Human Services (HHS) to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19.

Under the contract, Gritstone bio will conduct a 10,000 participant, randomized Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of the Gritstone next-generation COVID-19 vaccine candidate with an approved COVID-19 vaccine. Preparations for the study are underway, and execution of the study will be fully funded by BARDA. Gritstone will run the study in the United States in collaboration with the COVID-19 Prevention Network (CoVPN), a NIAID-supported network of clinical trial sites based at Fred Hutchinson Cancer Center with experience conducting large COVID-19 vaccine trials.

"We are honored to receive this award from BARDA to advance our next-generation samRNA vaccine against COVID-19 (the CORAL program), which provides strong validation of our innovative vaccine platform in infectious diseases. Not only does this contract supply the necessary resources to advance the development of CORAL, but it also signifies the trust and confidence the U.S. government has placed in our novel vaccine approach," said Andrew Allen, M.D., Ph.D., Co-founder, President, and Chief Executive Officer of Gritstone bio. "First-generation COVID-19 vaccines provided great utility during the height of the pandemic but are limited in breadth and durability of clinical protection. CORAL was designed to address these limitations by inducing durable neutralizing antibody and T cell-based immunity against current and future SARS-CoV-2 variants. Across multiple Phase 1 studies, our samRNA vaccine, which incorporates both Spike and other viral targets (Spike plus), has demonstrated induction of potent immune responses with potential to drive broad and durable clinical protection – this potential will now be tested in a randomized setting. We are excited about this opportunity to work alongside BARDA and look forward to initiating the Phase 2b study (CORAL-BARDA) in the first quarter of 2024. With CORAL moving into a randomized Phase 2 study alongside our personalized cancer vaccine program (GRANITE), Gritstone now sits at the precipice of unlocking the full potential of our novel vaccine platforms in both oncology and infectious diseases."

This project has been funded with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50123C00062.

About the CORAL Program

Gritstone's CORAL program is applying Gritstone's infectious disease approach for the prevention of COVID-19. The program aims to drive both B cell and T cell immunity using self-amplifying mRNA (samRNA) and novel immunogens containing Spike plus additional viral targets. To date, the CORAL program has comprised three Phase 1 trials evaluating multiple samRNA vaccine candidates across various patient populations and settings: CORAL-BOOST (healthy volunteers following primary series of currently approved COVID-19 vaccines); CORAL-CEPI (vaccine-naïve healthy and HIV+ subjects in South Africa); and CORAL-NIH (run by the National Institute of Allergy and Infectious Disease [NIAID] in previously vaccinated healthy volunteers). Results to date have demonstrated induction and persistence of high neutralizing antibody levels through at least 6 months as well as broad T cell responses. The CORAL program is supported by Biomedical Advanced Research and Development Authority (BARDA), NIAID, the Coalition for Epidemic Preparedness Innovations (CEPI) and the Bill & Melinda Gates Foundation.

About Self-amplifying mRNA (samRNA)

Self-amplifying mRNA (samRNA) is rapidly emerging as a well-tolerated, scalable and widely-applicable platform technology which can be used to develop multiple vaccines simply by changing the sequence of the antigen (the target of the immune system) that is encoded in the vector RNA and delivered in a lipid nanoparticle. Like traditional mRNA vaccines, samRNA vaccines use the host cell's translation system to convert mRNA to protein target antigens in order to stimulate immunity. Unlike traditional mRNA, samRNA creates multiple copies of the antigen RNA once in the cell, potentially leading to extended duration and magnitude of antigen expression. Gritstone designs novel immunogens, the vaccine regions encoding virus antigens, and includes both Spike antigen (similar to first-generation COVID-19 vaccines) and evolutionarily conserved, non-Spike antigens likely to drive T cell responses in its next-generation COVID-19 vaccines. Potential benefits of this samRNA "Spike plus" approach include (1) strong and durable induction of neutralizing antibodies to Spike, (2) broad and durable T cell immunity (CD4+ and CD8+) to multiple viral proteins, (3) potency at lower doses (dose sparing), and (4) refrigerator stability.

About Gritstone bio

Gritstone bio, Inc. (Nasdaq: GRTS) is a clinical-stage biotechnology company that aims to develop the world's most potent vaccines. We leverage our innovative vectors and payloads to train multiple arms of the immune system to attack critical disease targets. Independently and with our collaborators, we are advancing a portfolio of product candidates to treat and prevent viral diseases and solid tumors in pursuit of improving patient outcomes and eliminating disease. www.gritstonebio.com.

Gritstone Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to our clinical and regulatory development plans for our product candidates; our expectations regarding the data to be derived in our ongoing and planned clinical trials; the timing of commencement of our future nonclinical studies, clinical trials and research and development programs; our ability to discover, develop and advance product candidates into, and successfully complete, clinical trials; and our plans and strategy regarding maintaining existing and entering into new collaborations and/or partnerships. 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' clinical 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 9, 2023 and any subsequent current and periodic reports filed with the Securities and Exchange Commission.

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