Gritstone bio Announces Update to Comparative Phase 2b COVID-19 Clinical Trial

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EMERYVILLE, Calif., Feb. 12, 2024 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, today announced that it is now preparing to launch the Phase 2b head-to-head trial of its next-generation COVID-19 vaccine in the Fall of 2024 rather than 1Q24. This is to allow use of fully GMP-grade raw materials in the vaccine, which is expected to increase the regulatory utility of the trial.

"After recent communication with the FDA and input from our colleagues at BARDA, we are now making the necessary preparations to begin the Phase 2b study later this year using fully GMP-grade materials in the manufacture of our self-amplifying mRNA (samRNA) vaccine," said Andrew Allen, MD, PhD, Co-founder President & CEO of Gritstone bio. "The change likely increases the regulatory value of this large study, is expected to improve study interpretability, and may enable us to contemporaneously address the latest seasonal variant. We would like to thank the FDA for their collaboration and BARDA for their teamwork in support of this study, which aims to help deliver to the world a broader and more durable vaccine against COVID-19."

This project has been supported in whole or in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50123C00062.

About the CORAL-BARDA study
The CORAL-BARDA study is an intended 10,000 participant, randomized Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of Gritstone bio's next-generation COVID-19 vaccine candidate with an approved COVID-19 vaccine. The goal of this study is to determine whether Gritstone bio's next-generation vaccine candidate, a self-amplifying mRNA (samRNA) vaccine, can provide better and longer protection against COVID-19 than the currently FDA-approved vaccines.

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

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 next-generation COVID-19 vaccine, the timing of commencement of our CORAL-BARDA study and our belief regarding the use of GMP-grade raw materials in the vaccine manufacturing process and its impact on the regulatory utility of our CORAL-BARDA trial; our expectations regarding the data to be derived in our ongoing and planned clinical trials; our ability to discover, develop, manufacture and advance product candidates into, and successfully complete, clinical trials, including, in particular, our next-generation COVID-19 vaccine. 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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