Gritstone bio Announces Presentations from Phase 1 Studies Evaluating Next-Generation Vaccine Candidate for COVID-19 at IDWeek 2023

October 4, 2023

EMERYVILLE, Calif., Oct. 04, 2023 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, today announced results from all three (3) Phase 1 studies evaluating its self-amplifying mRNA (samRNA) vaccine candidates against COVID-19 (part of the company's CORAL program) are to be presented at IDWeek 2023, occurring October 11-15, 2023, in Boston, MA. Last week, Gritstone bio announced a contract with the Biomedical Advanced Research and Development Authority (BARDA) to advance the program into a 10,000 patient, randomized Phase 2b comparative study against COVID-19. The agreement 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.

Gritstone last presented data from the CORAL-BOOST and CORAL-CEPI studies in April 2023 (press release). At IDWeek, Gritstone will present further follow up from both of those studies. Additionally, representatives from the Infectious Diseases Clinical Research Consortium (IDCRC), a clinical trials network established by the National Institute of Allergy and Infectious Disease (NIAID), will present the first results from the CORAL-NIH study, a Phase 1 study conducted by IDCRC and supported by NIAID (and the third and final Phase 1 study from the CORAL program).

CORAL-CEPI and CORAL-BOOST presentations (presented by Gritstone):

- **Abstract 1538194 (Poster Presentation): Preliminary evidence of durable immune responses induced by self-amplifying mRNA (samRNA) vaccine candidates against SARS-CoV-2 in vaccine-naive South African population** (CORAL-CEPI study)
  Date/Time: Saturday, Oct 14, 2023, 12:15 - 1:30 PM
  Poster #: 2372
  Presenter: Atul Nagare, MD
  Location: BCEC Poster Hall

- **Abstract 1530224 (Poster Presentation): Preliminary results of durable immune response induced by a self-amplifying mRNA (samRNA) SARS-CoV-2 vaccine candidate, GRT-R910, in adults previously vaccinated with mRNA or AZD1222 primary series** (CORAL-BOOST study)
  Date/Time: Saturday, Oct 14, 2023, 12:15 - 1:30 PM
  Poster #: 2346
  Presenter: Meghan G. Hart
  Location: BCEC Poster Hall

CORAL-NIH presentation (presented by IDCRC):

- **Abstract 1530224 (Poster Presentation): An Interim Report of the Safety, Reactogenicity, and Immunogenicity of a Self-amplifying mRNA (samRNA) COVID-19 Vaccine GRT-R910 as a Booster in Healthy Adults**
  Date/Time: Saturday, Oct 14, 2023, 12:15 - 1:30 PM
  Poster #: 2395
  Presenter: Jennifer Whitaker
  Location: BCEC Poster Hall

Copies of the presentations will be posted on the Events page of the Gritstone bio website after their conclusion.

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.

Gritstone Contacts

Investors:
George E. MacDougall
Gritstone bio, Inc.
ir@gritstone.com

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