Gritstone bio Highlights the Durability and Potential Broad Utility of its Self-amplifying mRNA (samRNA) COVID-19 Vaccine at ESCMID Global 2024

April 30, 2024

-- IgG levels and neutralizing antibodies against variants of concern persisted for at least 12 months, consistent with previous findings --

-- Antigen-specific T cell responses increased in the majority of participants studied, including those living with HIV, after administration of any of the samRNA constructs --

-- Comprehensive data set demonstrates a consistent and strong immunogenicity profile across multiple patient populations in South Africa, including people living with HIV --

EMERYVILLE, Calif., April 30, 2024 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, today presented updated Phase 1 data from its CORAL-CEPI study, a Coalition for Epidemic Preparedness Innovations (CEPI)-funded study that is evaluating Gritstone's self-amplifying mRNA (samRNA) vaccine against COVID-19 in HIV-negative and people living with HIV (PLWH) participants. The presentation, at ESCMID Global 2024, reviewed the latest findings demonstrating the durability and potential broad utility of Gritstone's samRNA vaccine against COVID-19. The new findings came from Group D, which evaluated immunogenicity of Gritstone's samRNA vaccine candidate delivering the Spike BA.1 variant as compared to the Spike Beta variant evaluated in Groups A-C.

"The data presented at ESCMID Global, our most comprehensive Phase 1 dataset to date, highlights the potential of our samRNA vaccine to generate robust and durable immune responses across a diverse set of populations; naïve, convalescent and previously vaccinated," said Andrew Allen, M.D., Ph.D., Co-founder, President, and Chief Executive Officer of Gritstone bio. "Previously, we had shown our samRNA vaccine capable of driving potentially broad and durable protection through 12 months across three Phase 1 studies spanning multiple other populations and settings. The new findings announced today demonstrate the vaccine is capable of driving broad and durable B and T cell responses in previously unvaccinated or vaccinated individuals in South Africa, including in people living with HIV. These results add to the growing body of evidence suggesting this differentiated immune response extends beyond healthy individuals and potentially to the most vulnerable of patients."

Karin Jooss, Ph.D., Executive Vice President and Head of R&D of Gritstone bio added, "As our Phase 1 data set grows, the potential advantages of the immune response induced by our samRNA vaccine candidates compared to currently approved COVID-19 vaccines is becoming increasingly clear. The ability of our candidates to generate T cell responses to Spike and non-Spike epitopes in people living with HIV, who are believed to have reduced T cell activity, highlights the potential power of our samRNA platform. The fact that we continue to observe a consistently strong immunogenicity profile as we evaluate more new patient populations and constructs speaks to the potential global utility of self-amplifying mRNA."

Highlights from CORAL-CEPI Poster at ESCMID Global 2024 Poster (Abstract 02893, Poster Presentation)
Title: Durable Immune Response Induced by Self-amplifying mRNA (samRNA) SARS-CoV-2 Vaccine Candidates in HIV Negative and People Living with HIV (PLWH) Populations in South Africa

CORAL-CEPI (NCT05435027) is a Phase 1 study evaluating three samRNA-based SARS-CoV-2 vaccine candidates containing Spike plus other viral targets in HIV-negative (both SARS-CoV-2-naïve and convalescent) and people living with HIV (PLWH) in South Africa (N = 342). Results demonstrated:

- Favorable tolerability profile was consistent with previous findings, including in PLWH
  - All doses of the three samRNA vaccine candidates were well tolerated in both HIV-negative participants and PLWH participants irrespective of age, SARS-CoV-2 serostatus, or prior SARS-CoV-2 vaccination status at baseline
- Across all vaccine candidates, IgG levels and nAb titers were high and sustained to multiple variants
  - All three samRNA vaccine candidates increased and maintained IgG levels and nAb titers against vaccines of concern for at least 12 months irrespective of prior SARS-CoV-2 vaccination status or serostatus
- After vaccination, T cell responses were induced and/or sustained in the vast majority of subjects, including PLWH
  - Antigen-specific T cell responses were increased in the majority of participants tested to date after administration of any of the 3 samRNA vaccine candidates
- Gritstone's samRNA platform is well tolerated with consistent ability to drive robust and durable binding (IgG) and neutralizing antibodies (nAb) across SARS-CoV-2 variants in addition to broad T cell responses to both Spike and non-Spike epitopes

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 12 months as well as broad T cell responses. The CORAL program has been 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

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