Presentations at IDWeek 2023 Highlight Potentially Differentiated Immunogenicity of Gritstone bio's Next Generation COVID-19 Vaccine

October 11, 2023

-- High neutralizing antibody (nAb) responses sustained through at least 12 months, highlighting potential for durable clinical protection --

-- T cell responses to Spike plus other viral targets observed in all Phase 1 studies, demonstrating broad and potentially variant-proof immune response --

-- Over 300 subjects dosed to date across Phase 1 studies; vaccine tolerability appears comparable to approved COVID-19 vaccines --

-- Head-to-head Phase 2b study evaluating Gritstone's self-amplifying mRNA with approved vaccine for COVID-19 expected to initiate in 1Q 2024 --

EMERYVILLE, Calif., Oct. 11, 2023 (GLOBE NEWSWIRE) -- October 11, 2023 (GLOBE NEWSWIRE) – Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, today announced the presentation of results from three ongoing Phase 1 studies evaluating its self-amplifying mRNA (samRNA) vaccine candidates against COVID-19 (part of the company's CORAL program) at IDWeek 2023, occurring October 11-15, 2023, in Boston, MA.

Gritstone will present further follow up data from the CORAL-CEPI and CORAL-BOOST studies (most recent prior presentation in April 2023, press release). 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). Results across these studies generally reaffirm and extend previous CORAL findings that Gritstone's next-generation samRNA-based approach, which incorporates both Spike and other viral targets ("Spike plus"), can induce potent and durable immune responses with potential to drive broad and long-lasting clinical protection.

"The findings presented at IDWeek highlight the potential of our self-amplifying mRNA vaccine to address the limitations of today's approved vaccines against COVID-19 and provide additional clinical rationale for our novel 'spike-plus' approach as we advance into a large head-to-head study," said Andrew Allen, M.D., Ph.D., Co-founder, President, and Chief Executive Officer of Gritstone bio. "These data reaffirm previous findings that our samRNA vaccines have the potential to drive highly durable antibody responses, to enhance immunity through broader T cell responses, and to accomplish this at RNA doses as low as 3 micrograms, one tenth the dose of currently approved mRNA vaccines for COVID-19. The collective data showing that elicited neutralizing antibody titers persist at high levels for at least 12 months – data shared for the first time during IDWeek 2023 – are particularly exciting and further validate the rapid ongoing advancement of the CORAL program. Preparations for the BARDA-funded, 10,000 subject Phase 2b, head-to-head study are underway, having entered the base period, and we look forward to initiating the study in the first quarter of 2024."

Key Highlights from IDWeek Poster Presentations:
CORAL-CEPI and CORAL-BOOST presentations (presented by Gritstone)

CORAL-CEPI Presentation (Abstract 1538194, Poster Presentation): Durable Immune Response Induced by Self-amplifying mRNA (samRNA) SARS-CoV-2 Vaccine Candidates in Vaccine-naïve HIV Negative and People Living with HIV (PLWH) Populations
Date/Time: Saturday, Oct 14, 2023, 12:15 - 1:30 PM
Poster #: 2372
Presenter: Atul Nagare, MD
Location: BCEC Poster Hall

CORAL-CEPI (NCT05435027) is a Phase 1 study evaluating samRNA-based COVID-19 vaccine candidates containing Spike plus other viral targets in HIV negative (virus-naïve and convalescent) and people living with HIV (PLWH) populations in South Africa (N = 342). Results presented from Group A, B and C (n = 242) demonstrated:

- All doses (3ug, 10ug, and 30ug) were well tolerated in both HIV-negative participants and PLWH irrespective of SARS-CoV-2 serostatus at baseline (Figure 3).
- High IgG and neutralizing antibody responses were induced and sustained for at least 12 months (Figure 4).
- Spike and non-Spike T cell responses were increased and/or maintained in the majority of individuals across all dose levels (Figure 6). T cell data from PLWH are still being evaluated.

CORAL-BOOST Presentation (Abstract 1530224, Poster Presentation): Durable Immune Response Induced by a Self-amplifying mRNA (samRNA) SARS-CoV-2 Vaccine Candidate in Adults Previously Vaccinated with mRNA or Adenovirus Primary Series
Date/Time: Saturday, Oct 14, 2023, 12:15 - 1:30 PM
Poster #: 2346
Presenter: Meghan G. Hart
Location: BCEC Poster Hall

CORAL-BOOST (NCT05148962) is a Phase 1 study evaluating a samRNA-based COVID-19 vaccine candidate containing spike plus other viral targets in older adults ≥60 years of age (N = 40). Results presented from cohorts 1 - 4 (n = 37) demonstrated:

- Vaccine candidate was well tolerated as a booster regardless of primary vaccination series (samRNA administration post-Vaxzevria or samRNA administration post-mRNA, Figure 3).
- Robust, durable binding and high neutralizing antibodies were induced and sustained for up to at least 12 months against SpikeD614G and variants of concern (Figure 4).
- Broad T cell responses induced against Spike and non-Spike T cell epitopes included in the vaccine. Use of T cell receptor sequencing assays to assess T cell response breadth.

CORAL-NIH presentation (presented by IDCRC):
CORAL-NIH Presentation (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

CORAL-NIH (NCT04776317) is a Phase 1 study of a samRNA-based vaccine candidate containing spike plus other viral targets as a booster in healthy adults in the United States and sponsored and executed by the National Institute of Allergy and Infectious Diseases (NIAID) (N = 150). Results presented from adults across all age groups and dose levels (n = 48) demonstrated:

- Vaccine candidate was well-tolerated with no safety signals identified (Figure 2).
- Durable boosting of humoral immune responses to Spike and variants of concern, and high neutralizing antibody responses to at least 6 months were observed for all vaccine groups.
- Results are consistent across Phase 1 trials of GRT-R910 and similar vaccines (GRT-R912 and GRT-R914).

To view Gritstone's IDWeek 2023 poster presentations, visit ir.gritstonebio.com/investors/events.
Abstract details associated with these presentations are available on the conference website.

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 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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