



Gritstone bio Presents 6-month Neutralizing Antibody (nAb) Data at ECCMID 2023 from Two Phase 1 Studies Evaluating Self-amplifying mRNA (samRNA) Against SARS-CoV-2 (CORAL)

April 17, 2023

-- CORAL-CEPI: Primary series samRNA vaccination elicits strong neutralizing antibody (nAb) responses that persist for at least 6 months, including variant cross-reactive nAb, in previously unvaccinated ("vaccine-naïve") South African subjects --

-- Updated CORAL-BOOST: Boost samRNA vaccine elicits robust nAbs that persist for at least 6 months regardless of primary series (adenovirus or mRNA) --

-- Data further support the favorable tolerability and distinctive immunogenicity profile of self-amplifying mRNA (samRNA) --

EMERYVILLE, Calif., April 17, 2023 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, today presented 6-month follow up data from its ongoing Phase 1 CORAL-CEPI and CORAL-BOOST studies, which are evaluating the company's self-amplifying mRNA (samRNA) vaccine candidates against SARS-CoV-2, at the 33rd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) in Copenhagen, Denmark.

"Today, we presented new data from CORAL-BOOST and CORAL-CEPI showing that the robust neutralizing antibody responses boosted and/or induced by our self-amplifying mRNA (samRNA) candidates persist for at least 6 months across multiple settings and subject populations," said Andrew Allen, M.D., Ph.D., Co-founder, President, and Chief Executive Officer of Gritstone bio. "Previously, we reported initial 6-month data from CORAL-BOOST showing sustained high neutralizing antibody levels in the boost setting following Vaxzevria (AstraZeneca) primary series. We now report similar neutralizing antibody levels and persistence at 6 months in the larger CORAL-CEPI study, where our samRNA candidates are being administered as a primary series in vaccine-naïve subjects as well as in subjects that received mRNA primary series (cohort 4 of CORAL-BOOST)."

"The results shared today demonstrate that regardless of whether and/or how the immune system was previously exposed to SARS-CoV-2, our samRNA vaccine candidates are driving robust antibody titers that are sustained for at least 6 months in healthy adults," said Karin Jooss, EVP and Head of R&D at Gritstone bio. "Current vaccines against COVID-19 have demonstrated susceptibility to loss of immunity over time, posing a greater burden on individuals and our health systems. Developing a next-generation vaccine that drives more durable and broad neutralizing antibodies against variants of concern not included in the vaccine – both of which are demonstrated in these results - could serve as a key factor in delivering long-term, variant-proof immune protection. The results shared today further support our hypothesis that samRNA, unique from mRNA due to several distinct characteristics, could serve as a widely applicable next-generation vaccine platform technology against SARS-CoV-2 and beyond."

CORAL-CEPI Presentation (Poster Presentation): Study of Self-Amplifying mRNA (samRNA) Vaccine Candidates Against COVID-19 in Healthy Adults and People Living with Human Immunodeficiency Virus (HIV) in South Africa

New Data Presented (last data update October 25, 2022): Interim results from part A (n = 120, 20 patients/cohort). SARS-CoV-2 vaccine-naïve, virus-naïve participants receiving GRT-R914 as homologous prime-boost (cohorts A1, A2 and A3) and vaccine-naïve, virus-convalescent participants receiving GRT-R914 as a single boost (cohorts A4, A5 and A6). Designation as virus-naïve/convalescent was driven by baseline anti-Nucleocapsid (N) IgG serology status (negative/positive respectively).

Key Highlights:

- CORAL-CEPI (NCT05435027) is the first study assessing a samRNA-based vaccine in vaccine-naïve populations in South Africa
- All doses of GRT-R914 (3µg, 10µg and 30µg) were well tolerated in all study populations evaluated to date [HIV negative, virus-naïve and -convalescent participants]
- IgG and nAb levels to SpikeWT and variants of concern Beta and Delta are induced or boosted by GRT-R914 administration (10µg dose) and maintained for 6 months (cohorts A1, A2, A4 and A5)
- Majority of post-vaccine T cell responses observed to TCE epitopes focused on NSP and Nucleocapsid, irrespective of prior SARS-CoV-2 exposure (cohorts A1, A2, A4, A5)
- Previous SARS-CoV-2 exposure does not affect T cell responses post vaccination in both naïve and convalescent populations

CORAL-BOOST Presentation (Poster Presentation): First study of a Self-amplifying mRNA (samRNA) Vaccine, GRT-R910, as a COVID-19 Boost in Healthy Volunteers ≥60 years of age – Preliminary evidence of sustained immunogenicity

New Data Presented (last data update October 25, 2022): Additional data from cohorts 1-3 (samRNA administration post-Vaxzevria) and 6-month data from cohort 4 (samRNA administration post-mRNA).

Key Highlights:

- CORAL-BOOST is the first study assessing a samRNA-based SARS-CoV-2 vaccine as a booster following adenoviral- or mRNA-based primary vaccination series in a more vulnerable older population (≥60 years of age)
- GRT-R910 was as well tolerated at all dose levels
- GRT-R910 (samRNA) increased SpikeWT-specific IgG levels regardless primary series of immunization [adenoviral (cohort 3) or mRNA (cohort 4)]
- Consistent longevity of neutralizing antibody response for at least 6 months against different variants of concern not included in the vaccine construct
- GRT-R910 increased breadth of T cell responses against Spike and non-Spike T cell epitopes included in the vaccine

To view Gritstone's ECCMID presentations, visit ir.gritstonebio.com/investors/events.

About the CORAL Program

Gritstone's CORAL program is applying Gritstone's infectious disease approach, which aims to drive both B cell and T cell immunity using self-amplifying mRNA (samRNA) against SARS-CoV-2. CORAL currently includes three ongoing Phase 1 trials: CORAL-BOOST, which is evaluating one construct in a boost setting (following primary series of currently-approved COVID-19 vaccines); CORAL-CEPI, which is evaluating multiple constructs in virus-naïve, convalescent, and HIV+ subjects in South Africa; and CORAL-NIH, which is being run by the National Institute of Allergy and Infectious Disease (NIAID) and is evaluating multiple constructs in previously vaccinated healthy volunteers. The program serves as proof-of-concept for the application of Gritstone's platform against coronaviruses and other infectious diseases and is supported by the Bill & Melinda Gates Foundation, NIAID and the Coalition for Epidemic Preparedness Innovations (CEPI).

About Gritstone bio

Gritstone is working to create 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 and have programs in viral diseases and solid tumors. Independently and with our partners, we are advancing a portfolio of product candidates with the aim 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 the potential of Gritstone's therapeutic programs; the advancements in Gritstone's ongoing clinical trials; the timing of data announcements related to ongoing clinical trials and the initiation of future clinical trials. 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 current and periodic reports filed with the Securities and Exchange Commission.

Gritstone Contacts

Investors:

George E. MacDougall
 Director, Investor Relations & Corporate Communications
 Gritstone bio, Inc.
ir@gritstone.com

Media:

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

