



Gritstone bio and the National Cancer Institute (NCI) Establish a Clinical Trial Agreement to Evaluate a Neoantigen Cell Therapy-Vaccine Combination

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-- NCI will lead the Phase 1 study using Gritstone's proprietary "off the shelf" vaccine technology for mutant KRAS solid tumors --

EMERYVILLE, Calif., Feb. 14, 2023 (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 has entered into a clinical trial agreement with the National Cancer Institute (NCI), an institute of the National Institutes of Health, to evaluate an autologous T cell therapy expressing a T cell receptor targeting mutated KRAS in combination with Gritstone's KRAS-directed vaccine candidate, SLATE-KRAS, in a Phase 1 study. The study will be led by Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI's Center for Cancer Research.

"We are privileged to establish this collaboration with NCI and Dr. Rosenberg, a pioneer of cancer immunotherapy and an expert in cell therapy," said Andrew Allen, M.D., Ph.D, Co-founder, President & Chief Executive Officer of Gritstone bio. "To date, cell therapy's success in treating blood cancers has not translated to the more common solid tumors. There is a mechanistic synergy in having cell therapy and cancer vaccines in combination. We are thrilled to test this hypothesis in patients in collaboration with a leader in the cell therapy field. We look forward to collaborating with Dr. Rosenberg and his team to generate proof-of-concept data from this promising study."

Under the terms of the agreement, NCI will identify patients with metastatic cancer that are eligible for adoptive cell transfer based on the presence of a G12V or G12D KRAS mutation (KRAS^{mut}). Gritstone will provide the SLATE-KRAS vaccine as requested by NCI for the trial.

"The use of neoantigen vaccines to enhance the potency of neoantigen-directed T cell therapy is an attractive concept with supportive pre-clinical data," said Karin Jooss, Executive Vice President & Head of R&D at Gritstone bio. "Our KRAS-directed vaccine has demonstrated the ability to induce and expand KRAS^{mut}-specific T cells and drive them into solid tumors in multiple clinical studies. Combining this modality with autologous KRAS^{mut}-specific TCR transduced T cells (TCR-T), as delivered by Dr Rosenberg in his clinical program at the NCI, is a rational approach to augmenting therapeutic efficacy. As a leader in the development of cancer neoantigen vaccines, we believe this approach to potentially deepening and extending the therapeutic effect of TCR-T could provide improved outcomes to solid tumor patients."

An "off the shelf" neoantigen vaccine candidate, SLATE-KRAS demonstrated early evidence of efficacy as defined by molecular response in immune checkpoint blockade (ICB)-resistant/refractory subjects in the Phase 2 portion of an ongoing Phase 1/2 study (NCT03953235). Based on the results to date from the Phase 1/2 study, Gritstone has elected to initiate a separate, randomized Phase 2 study evaluating SLATE against a KRAS^{mut}-driven tumor type. Gritstone expects to initiate this separate, randomized study in the second half of 2023.

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 10, 2022, as well as Gritstone's Quarterly Reports on Form 10-Q filed on May 5, 2022 and August 4, 2022 and any current and periodic reports filed with the Securities and Exchange Commission.

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