

Gritstone wins 'Project NextGen' funding to run headto-head COVID vaccine study

The planned trial would enroll 10,000 people and compare Gritstone's experimental mRNA vaccine against an approved coronavirus shot.

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An electron micrograph image of a cell infected with SARS-CoV-2 virus particles. National Institute of Allergy and Infectious Diseases. (2020). "Novel Coronavirus SARS-CoV-2" [Micrograph]. Retrieved from Flickr.

Gritstone Bio, a cancer and infectious disease drug developer, has won a contract from the U.S. government to test its experimental COVID vaccine against an approved coronavirus shot in a head-tohead study.

The contract, announced Wednesday, is part of the "Project NextGen," an initiative launched by the U.S. Department of Health and Human Services to bring new COVID drugs and vaccines to market.

Gritstone will conduct a double-blind, Phase 2b study of its "self-amplifying" messenger RNA vaccine in a study of 10,000 people. The agreement, which is managed by the Biomedical Advanced Research and Development Authority, or BARDA, is worth up to \$433 million.

Initially, BARDA will fund up to \$10 million over a "base period" that runs through the first quarter of 2024. Should Gritstone

successfully complete the base period's objectives, it could unlock as much as \$423 million in further funding to run the clinical trial itself and completing additional analyses.

Gritstone has been working on a next-generation COVID vaccine since 2021, when it partnered with the National Institutes of Health. The company aims to build a shot capable of generating both B cell and T cell immunity, potentially translating to broader protection. The vaccine is designed to be self-amplifying, meaning it spurs cells to create multiple copies of the encoded antigen RNA.

Prior to its COVID research, Gritstone was working on developing cancer immunotherapies — testing it has continued to progress with a mid-stage study of a personalized cancer vaccine.

According to Evercore ISI analyst Jonathan Miller, that research is the primary focus of investors, who don't put much value in the company's COVID program. But the BARDA contract with Gritstone makes the program "basically free for investors," he wrote in a note to clients, adding that it will also extend the company's cash runway by about one quarter.

"The contract does give some validation for Gritstone's approach, and is certainly a nice signal of continued government support for COVID research," Miller continued.

According to the company's second quarter financial results,
Gritstone had cash and cash equivalents of \$122 million as of June
30. Shares in the company rose by one-fourth in Thursday
morning trading.