Gritstone bio Reports First Quarter 2024 Financial Results and Provides Corporate Updates

May 9, 2024

-- Favorable progression-free survival (PFS) trend observed in preliminary data from the randomized Phase 2 study evaluating GRANITE (personalized neoantigen vaccine) in front-line metastatic, microsatellite-stable colorectal cancer (MSS-CRC); mature PFS data expected in the third quarter of 2024 --

-- Nature Medicine publication of Phase 1 study of SLATE (off-the-shelf neoantigen vaccine) and AACR-presented improvements to EDGE™ (tumor antigen identification platform that was recently enhanced using large language models) highlight Gritstone's leadership in neoantigen-directed cancer vaccine field --

-- Latest data from Phase 1 CORAL-CEPI study highlights the durability and potential broad utility of Gritstone's novel self-amplifying mRNA (samRNA) "Spike-plus" COVID-19 vaccine --

-- Recent financing resulted in $32.5 million in gross proceeds to Gritstone in April 2024 --

-- Gritstone to host conference call today at 4:30pm ET --

EMERYVILLE, Calif., May 09, 2024 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, today reported financial results for the first quarter ended March 31, 2024 and provided recent corporate and clinical updates.

"The preliminary Phase 2 data we recently shared are very promising as they suggest that GRANITE is potentially driving benefit in metastatic CRC patients and that our objective of unlocking immunologically 'cold' tumors to the benefits of immunotherapy may be within reach," said Andrew Allen, MD, PhD, Co-founder, President & CEO of Gritstone bio. "The emerging trend in progression-free survival, that we anticipate will strengthen as data mature, is particularly encouraging as it puts us in a strong position to potentially engage regulators later this year regarding a Phase 3 study for this common and difficult to treat disease. If successful, we see great potential for GRANITE to expand the scope of immunotherapy and bring meaningful clinical benefit to patients with metastatic CRC as well as other 'cold' tumors."

Dr. Allen added, "The progress in, and recognition of our other programs and capabilities is also encouraging. The recent paper in *Nature Medicine* highlights the scientific rigor with which we built our SLATE platform, describes the discovery of a previously unknown hierarchy of neoantigen immunodominance, and underscores the promise for the ongoing collaboration with Dr. Rosenberg of the NCI to evaluate our SLATE-KRAS vaccine in combination with an autologous T cell therapy. We also continue to push the boundaries of neoantigen identification with EDGE™, our powerful AI-driven platform, that can now predict presentation of HLA Class I neoantigens with what we believe to be field-leading accuracy."

Corporate Updates

- In April 2024, Gritstone completed an underwritten public offering resulting in gross proceeds of $32.5 million.
- In April 2024, Gritstone appointed Stephen Webster to its Board of Directors. A veteran finance executive with over 30 years in the biotechnology industry, Mr. Webster has held several key roles and been involved in multiple strategic transactions. Mr. Webster was the Chief Financial Officer of Spark Therapeutics from July 2014 until its acquisition by Roche for $4.3 billion in December 2019.

Clinical Program Updates
Tumor-Specific Neoantigen Oncology Programs (GRANITE and SLATE)
GRANITE – Personalized neoantigen vaccine program
SLATE – "Off-the-shelf" neoantigen vaccine program

- **Preliminary results (n = 67) from the randomized Phase 2 study evaluating GRANITE as a front-line maintenance therapy in metastatic microsatellite-stable colorectal cancer (MSS-CRC) demonstrated a favorable trend in progression-free survival (PFS). Long-term circulating tumor DNA (ctDNA) data align with PFS trend and favor GRANITE vs. control patients.**
  - Trend of extended PFS in GRANITE-treated vs. control patients, with greatest difference observed in high-risk group[1] where clinical data are more mature.
    - Hazard ratio of 0.82 (18% relative risk reduction of progression or death with GRANITE vs. control) in the overall population, where clinical data are less mature ([95% CI, 0.34-1.67]; 62% censored)
    - Hazard ratio of 0.52 (48% relative risk reduction of progression or death with GRANITE vs. control) in a high-risk group[1], where clinical data are more mature ([95% CI, 0.15-1.38]; 44% censored)

[1]High-risk subgroup defined as baseline ctDNA above the median value (2%) for the control group (ctDNA quantified as mean variant allele frequency [VAF] at time of study randomization).

- Long-term ctDNA data align with PFS trend and favor GRANITE-treated vs. control patients
  - Analysis in the high-risk group[1] showed that between first blood draw (time of randomization) and last blood draw (most recent study visit), ctDNA shifted from high (>2% VAF) to low (≤2% VAF) in 56% (9/16) of GRANITE patients vs 22% (2/9) of control patients. Progressive disease was observed in 44% (7/16) vs 78% (7/9), respectively, within this group.
  - Analysis in low-risk group (ctDNA negative group) showed sustained ctDNA negativity was observed in 67% (6/9) GRANITE recipients vs 38% (3/8) control patients. PD observed in 11% (1/9) and 38% (3/8) of these patients, respectively.
- Gritstone expects to share mature PFS data and additional long-term ctDNA data in the third quarter of 2024.

- **In April 2024, Gritstone presented an update on its state-of-the-art neoantigen prediction platform, EDGE™, at the 2024 American Association for Cancer Research (AACR) Annual Meeting in San Diego, CA.** EDGE now predicts HLA Class I presentation, associated with CD8+ T cell induction, with >80% accuracy, a performance level that Gritstone believes to be leading the field. Gritstone is also advancing EDGE-II, a new model that has achieved superior predictive performance of HLA Class II presentation and CD4+ immunogenicity over publicly available models. The improvements leverage advances in protein large language models and in-house immunopeptidomics.

- **In March 2024, Nature Medicine published a paper detailing the development of our "off-the-shelf" neoantigen platform, SLATE.** The paper described a novel immunodominance hierarchy of tumor neoantigens (including KRAS) that Gritstone discovered in Phase 1 translational studies and leveraged to develop SLATE-KRAS, a "pure" KRAS-directed vaccine candidate that demonstrated superior immunogenicity to the initial version in a subsequent Phase 2 study.

- **The clinical trial collaboration with the National Cancer Institute (NCI) to evaluate an autologous mutant KRAS-directed TCR-T cell therapy in combination with SLATE-KRAS, Gritstone's KRAS-directed "off the shelf" vaccine candidate, is ongoing.** The study is led by Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI's Center for Cancer Research and builds into the growing interest in combining tumor-antigen specific cell therapy with matched vaccines. The IND was cleared by the U.S. Food and Drug Administration (FDA) in October 2023.

Infectious Disease Programs

CORAL – Next-generation SARS-CoV-2 vaccine program that serves as proof-of-concept for Gritstone's samRNA platform and novel approach in infectious diseases.

- **In February 2024, Gritstone announced that it plans to incorporate GMP-grade materials in the manufacture of its self-amplifying mRNA (samRNA) candidate, resulting in a delay of the CORAL Phase 2b study** (the anticipated 10,000 subject, comparative Phase 2b study contracted by the Biomedical Advanced Research and Development Authority [BARDA][2]). This decision is expected to increase the regulatory utility of the study. Gritstone is currently preparing to launch the study and will do so as soon as the company is able.

- **In April 2024, Gritstone presented a poster highlighting the durability and potential broad utility of its samRNA COVID-19 vaccine at ESCMID Global 2024.** The results, which were from the Phase 1 CORAL-CEPI study in South Africa, reinforced previous findings showing induction of broad and durable immune responses through 12 months.

HIV – Collaboration with Gilead under Gilead's HIV Cure Program to research and develop vaccine-based HIV immunotherapy treatment

- **The collaboration to research and develop a vaccine-based HIV immunotherapy treatment continues under Gilead's direction.**

First Quarter 2024 Financial Results

- **Cash, cash equivalents, marketable securities and restricted cash** were $52.8 million as of March 31, 2024, compared to $86.9 million as of December 31, 2023.

- **Research and development expenses** were $33.0 million for the three months ended March 31, 2024 compared to $30.5 million for the three months ended March 31, 2023. The increase of $2.5 million was primarily attributable to a one-time severance charge and increases in facilities-related costs, offset by decreases in laboratory supplies, personnel-related costs and outside services.

- **General and administrative expenses** were $8.5 million for the three months ended March 31, 2024 compared to $6.7 million for the three months ended March 31, 2023. The increase of $1.8 million was primarily attributable to increases in personnel-related expenses, facilities-related costs, outside services and a one-time severance charge.

- **Collaboration, license, and grant revenues** were $1.7 million for the three months ended March 31, 2024. During the three months ended March 31, 2024, we recorded $0.4 million in grant revenue from the BARDA Contract, $1.0 million in grant revenue from CEPI, and $0.3 million in grant revenue from the Gates Foundation.

Conference Call & Webcast Details
A conference call and webcast will be held at 4:30pm ET today (May 9):

Conference call: 1-877-407-4018
Conference ID: 13746126
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1667088&tp_key=d0e680f7aa

An archived replay will be accessible at https://ir.gritstonebio.com/investors/events for 30 days following the event.

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[2] This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50123C00062.

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 5, 2024, our Form 10-Q filed on May 9, 2024, and any subsequent current reports filed with the Securities and Exchange Commission.

This press release concerns drugs that are under clinical investigation, and which have not yet been approved for marketing by the U.S. Food and Drug Administration. They are currently limited by Federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

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Gritstone bio, Inc.
Condensed Consolidated Balance Sheets (unaudited)
(In thousands)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 42,395	$ 62,986
Marketable securities	3,908	16,288
Restricted cash	1,247	2,299
Prepaid expenses and other current assets	4,303	5,862
Total current assets	51,853	87,435
Long-term restricted cash	5,290	5,290
Property and equipment, net	14,088	17,281

Lease right-of-use assets	65,057	66,839
Deposits and other long-term assets	924	924
Total assets	$ 137,212	$ 177,769
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,248	$ 3,819
Accrued compensation	4,340	9,357
Accrued liabilities	2,141	1,213
Accrued research and development expenses	4,045	3,696
Lease liabilities, current portion	6,811	6,904
Deferred revenue, current portion	1,285	2,350
Total current liabilities	25,870	27,339
Other liabilities, noncurrent	907	709
Lease liabilities, net of current portion	56,141	57,727
Debt, noncurrent	40,330	40,144
Total liabilities	123,248	125,919
Stockholders' equity:		
Preferred stock	—	—
Common stock	22	22
Additional paid-in capital	713,889	711,386
Accumulated other comprehensive (loss) gain	(1)	3
Accumulated deficit	(699,946)	(659,561)
Total stockholders' equity	13,964	51,850
Total liabilities and stockholders' equity	$ 137,212	$ 177,769

Gritstone bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	**2023**
Revenues:		
Collaboration and license revenues	$ 49	$ 542
Grant revenues	1,693	1,901
Total revenues	1,742	2,443
Operating expenses:		
Research and development	33,041	30,514
General and administrative	8,502	6,745
Total operating expenses	41,543	37,259
Loss from operations	(39,801)	(34,816)
Interest income	712	1,678
Interest expense	(1,296)	(844)
Net loss	(40,385)	(33,982)
Other comprehensive loss:		
Unrealized (loss) gain on marketable securities	(4)	28
Comprehensive loss	$ (40,389)	$ (33,954)
Net loss per share, basic and diluted	$ (0.34)	$ (0.30)
Weighted-average number of shares used in computing net loss per share, basic and diluted	118,391,224	114,423,000