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ONCOLOGY

Gritstone Oncology Announces First Patient Dosed in a Clinical Study Evaluating its Personalized Immunotherapy, GRANITE-001

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EMERYVILLE, Calif., March 21, 2019 (GLOBE NEWSWIRE) -- Gritstone Oncology, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing the next generation of cancer immunotherapies to fight multiple cancer types, today announced that the first patient has been dosed with its personalized immunotherapy candidate targeting the patient's tumor-specific neoantigens, called GRANITE-001. The Phase 1/2 clinical study, referred to as GO-004, is evaluating GRANITE-001 in combination with immune checkpoint blockade for the treatment of patients with advanced solid tumors, including microsatellite stable colorectal cancer (MSS CRC), gastroesophageal cancer, metastatic non-small cell lung cancer, and bladder cancer. GRANITE-001 was granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of MSS CRC.

"We have been building towards this moment since our company was founded in the autumn of 2015 with just a compelling idea," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "With GRANITE-001, we are analyzing the patient's own tumor cell data through our artificial intelligence platform EDGE™ and using the identified neoantigens as the basis of a potent, virus-driven, personalized immunotherapy candidate which we manufacture in-house in large part. Our team has impeccably executed the design, build-out, and implementation of this unique platform and our clinical trial collaborators have joined us in this exciting and innovative effort to apply novel scientific insights to the treatment of this grim disease. Having dosed the first patient on our previously projected timeline, we now look forward to sharing early clinical data from this study in the fourth quarter of this year."

Patients are currently being enrolled into the Phase 1 portion of the GO-004 study. The Phase 1 study includes two parts. In part A, patients receive a full, fixed dose of adenovirus-based prime vector (containing each patient's own EDGE-selected neoantigens) with escalating doses of self-amplifying RNA-based boost vector (containing the same neoantigens) in combination with intravenous anti-PD-1 therapy, nivolumab. In part B, patients receive the prime and boost vectors at the selected dose in combination with both nivolumab and subcutaneous anti-CTLA-4 antibody, ipilimumab. Gritstone has a clinical collaboration agreement with Bristol-Myers Squibb for the use of their immune checkpoint inhibitors in GO-004.

"We have learned that neoantigens are key targets for solid tumor immunotherapy, and Gritstone has overcome the two key challenges of accurate neoantigen identification from within a large sea of tumor mutations and delivery of those neoantigens to patients within a highly immunogenic vector system," said Daniel Catenacci, M.D., director of the Gastrointestinal Oncology Program at the University of Chicago Medicine. "We will soon learn if this approach generates in patients the desired large number of neoantigen-specific T cells, especially CD8+ cytolytic T cells, which we hope will kill tumor cells in a highly specific fashion."

About GRANITE-001

GRANITE-001 is Gritstone's personalized tumor-specific immunotherapy product candidate. It is engineered to elicit a significant T-cell response (particularly CD8+ cytotoxic T cells) against mutation-derived tumor-specific neoantigens, or TSNA, identified for each patient through the company's proprietary EDGE™ artificial intelligence platform. Data demonstrating the neoantigen identification capabilities of EDGE were published in [Nature Biotechnology](#). GRANITE-001 consists of two components, first a priming adenoviral vector followed by monthly boosting with an RNA vector, each containing the same 20 patient-specific TSNA.

About Gritstone Oncology

Gritstone Oncology (Nasdaq: GRTS), a clinical-stage biotechnology company, is developing the next generation of cancer immunotherapies to fight multiple cancer types. Gritstone develops its products by leveraging two key pillars—first, a proprietary machine learning-based platform, Gritstone EDGE™, which is designed to predict, from a routine tumor biopsy, the tumor-specific neoantigens (TSNA) that are presented on a patient's tumor cells; and second, the ability to develop and manufacture potent immunotherapies utilizing patients' TSNA to potentially drive the patient's immune system to specifically attack and destroy tumors. The company's lead product candidate, GRANITE-001, is a personalized neoantigen-based immunotherapy beginning Phase 1 clinical testing. Gritstone's second product candidate, SLATE-001, is a shared neoantigen ("off-the-shelf") immunotherapy which is advancing towards the clinic. Novel tumor-specific antigens can also provide targets for bispecific antibody (BiSAb) therapeutics for solid tumors, and Gritstone's BiSAb program is currently in lead optimization. For more information, please visit gritstoneoncology.com.

Gritstone Forward-Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Gritstone, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995, including, but not limited to, statements related to Gritstone's expectations regarding the predictive capabilities of its EDGE Platform, the timing of results from Gritstone's clinical trials, and the potential for Gritstone's investigational immunotherapy candidates in treating the disease and conditions for which they are being developed, its T cell and T cell receptor discovery program, and its investigational immunotherapies. 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' early 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 Quarterly Report on Form 10-Q filed on November 14, 2018 and any subsequent current and periodic reports filed with the Securities and Exchange Commission.

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