# Gritstone Oncology Announces Clinical Acceleration of “Off-The-Shelf” Personalized Neoantigen Immunotherapy Program (SLATE) Following FDA Feedback

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EMERYVILLE, Calif., April 22, 2019 (GLOBE NEWSWIRE) -- Gritstone Oncology, Inc. (Nasdaq: GRTS), an immuno-oncology company developing tumor-specific cancer immunotherapies to fight multiple cancer types, today announced that following feedback from the U.S. Food and Drug Administration (FDA) the SLATE Phase 1 clinical study may be accelerated by up to six months from the company’s prior expectations by leveraging pre-clinical data generated for the original GRANITE Investigational New Drug (IND) application.

“Both SLATE and GRANITE use the same immunogenic viral vector system to deliver tumor-specific neoantigens (TSNA) to patients with the objective of driving a powerful and sustained T-cell response against their own tumors,” said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. “SLATE is designed for the subset of patients whose tumors carry specific oncogenic driver mutations resulting in neoantigens that are common across certain tumor types and patients. SLATE unites the expected potency of a TSNA-directed immunotherapy with the convenience of an ‘off-the-shelf’ product. Following our recent FDA interactions, we are expecting to open the SLATE Phase 1 study to patient enrollment as early as mid-2019, which is substantially faster than we had forecasted.”

Based on the similarities in the two investigational therapies, the common patient populations, and the consistency in manufacturing that has led to comparable drug products, the FDA has in principle agreed to accept previously conducted GRANITE IND-enabling toxicology studies in support of the SLATE IND, which brings the anticipated IND filing date closer. The Phase 1 study will evaluate SLATE in combination with immune checkpoint blockade for the treatment of patients with advanced solid tumors, including metastatic lung cancer, pancreatic cancer and colorectal cancer. There will also be a cohort of patients with other solid tumor types who possess appropriate mutation/HLA combinations. Clinical acceleration is also enabled by early identification of eligible patients using a screening protocol which is currently running at multiple trial sites. The company expects to present preliminary data from the first part of both the SLATE and GRANITE Phase 1 trials in the fourth quarter of 2019 at a scientific meeting.

**About SLATE-001**
SLATE-001, or SLATE, is Gritstone’s shared neoantigen (“off-the-shelf”) immunotherapy. It is engineered to elicit a significant T-cell response (particularly CD8+ cytotoxic T-cells) against encoded TSNA. SLATE consists of two components, first a priming adenoviral vector followed by monthly boosting with an RNA vector, each containing the same 20 TSNA. These TSNA were identified by Gritstone using the EDGE artificial intelligence platform and tumor HLA peptide sequencing, and represent mutated gene sequences that are shared across patients (such as K-RAS mutations). Suitable patients must possess both the appropriate DNA mutation and, importantly, a relevant HLA type that can present the mutant sequence to the patient’s T cells. For the first SLATE product candidate, it is estimated that approximately 12-13% of patients with colorectal and non-small cell lung cancer, and nearly 30% of pancreatic cancer patients may be eligible for treatment. Gritstone is continuing its research efforts to identify new TSNA which can enable the development of additional SLATE product candidates targeting different mutations and/or tumor types.

**About Gritstone EDGE™ (Epitope Discovery in cancer GEnomes) Platform**
The EDGE platform is designed to be a best-in-class machine-learning tool for the identification of tumor neoantigens presented on the surface of tumor cells. EDGE’s prediction model was initially trained using a large dataset of human tumor and normal tissue samples with paired class I HLA-presented peptide sequences, HLA types and transcriptome RNA sequencing. The training dataset for EDGE includes hundreds of tumor and normal tissue samples, yielding over one million peptides, from patients of various ancestries with diverse HLA types. EDGE leverages a novel integrated neural network model architecture to model key features that are essential for accurate prediction of true tumor-specific neoantigens. Data demonstrating the neoantigen identification capabilities of EDGE were published in *Nature Biotechnology* in December 2018. EDGE is also increasingly capable of predicting class II HLA-presented peptides, as presented at an oral session at AACR in April 2019. Gritstone has issued patent coverage on EDGE. Neoantigens identified by EDGE are being utilized in our lead immunotherapy programs, GRANITE and SLATE, to educate the immune system to attack these key tumor targets.

**About Gritstone Oncology**
Gritstone Oncology (Nasdaq: GRTS) is an immuno-oncology company developing tumor-specific cancer immunotherapies to fight multiple cancer types. The company has built its tumor-specific immunotherapy approach on key pillars—first, a proprietary machine learning-based platform, Gritstone EDGE™, which provides a powerful ability 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 drive the patient’s immune system to attack and destroy tumors.

**Gritstone Forward-Looking Statements**
This press release contains forward-looking statements, including, but not limited to, statements related to its SLATE clinical development 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 risk that the SLATE program is not initiated in 2019 or that the

IND is placed on clinical hold, and 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 Annual Report on Form 10-K filed on March 28, 2019 and any current and periodic reports filed with the Securities and Exchange Commission.

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