Gritstone Oncology Announces FDA Fast Track Designation for GRANITE-001 for the Treatment of Colorectal Cancer

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EMERYVILLE, Calif., Dec. 20, 2018 (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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation to GRANITE-001 for the treatment of colorectal cancer. GRANITE-001 is a personalized immunotherapy containing patient-specific neoantigens identified by Gritstone's proprietary EDGE ^{TM} artificial intelligence platform as the most relevant neoantigens to drive a tumor-specific T-cell attack.

"Colorectal cancer remains a major contributor to cancer deaths and has not yet proved very amenable to first generation immunotherapy," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "We believe GRANITE-001 has the potential to be a valuable therapeutic option for these patients through its highly personalized design. The ability to leverage tumor markers, or neoantigens, specific to a patient's own tumor cells in the development of a personalized immunotherapy is regarded as the next frontier of cancer therapy. We look forward to continuing our productive dialogue with the FDA under their Fast Track program as we seek to advance GRANITE-001 expeditiously for the potential benefit of patients."

The FDA grants Fast Track designation to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need. A therapeutic that receives Fast Track designation can benefit from early and frequent communication with the agency, in addition to a rolling submission of the marketing application, with the objective of getting important new therapies to patients more quickly.

Ongoing Phase 1/2 Clinical Study
GRANITE-001 in combination with immune checkpoint blockade is being evaluated in a Phase 1/2 clinical study called GO-004 for the treatment of patients with common solid tumors, including metastatic non-small cell lung cancer, microsatellite stable colorectal cancer, gastroesophageal cancer, and bladder cancer. The Phase 1 study includes two parts: in part A patients receive an adenovirus-based prime with escalating doses of an RNA-based boost vaccinations in combination with anti-PD-1 therapy; and in part B patients receive the prime and the boost vaccinations at the selected dose in combination with both anti-PD-1 and anti-CTLA-4 immuno-modulatory antibodies.

About GRANITE-001
GRANITE-001 is Gritstone Oncology's lead, 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. 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
This press release contains forward-looking statements, including, but not limited to, statements related to the potential benefits of the FDA's Fast Track designation for its GRANITE-001 investigational immunotherapy. 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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