Gritstone Oncology Announces Publication in Nature Biotechnology of Neoantigen Identification Capabilities of its Artificial Intelligence Platform, EDGE™

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EMERYVILLE, Calif., Dec. 17, 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 data demonstrating the predictive performance of its EDGE™ (**E**pitope **D**iscovery in cancer **GE**nomes) platform in the identification of tumor-specific neoantigens (TSNA) and neoantigen-reactive T-cells was published in _Nature Biotechnology_.

Three distinct datasets were used in the manuscript to validate the EDGE platform as a robust machine-learning tool for neoantigen identification. First, the authors showed that EDGE increases the accuracy of predicting human leukocyte antigen (HLA)-presented peptides on tumor cells by up to nine-fold over industry-standard methods using relevant metrics. Second, independently validated neoantigens from published third-party studies (mostly from the U.S. National Cancer Institute) were used to compare the performance of EDGE versus public prediction tools. Using only patient tumor mutation data from these studies to predict neoantigens, EDGE correctly identified validated TSNA for 11 of 12 patients, versus only 4 of 12 patients identified with the standard approach. Finally, using routine blood samples obtained from nine non-small cell lung cancer patients receiving PD-(L)1 checkpoint inhibitors, EDGE enabled identification of circulating T-cells specific for true neoantigens in the majority of (5 of 9) patients.

"Neoantigens are critical targets of immunotherapy and can drive an effective anti-tumor T-cell response; yet, existing tools have had low success rates in identifying true neoantigens," said Roman Yelensky, Ph.D., executive vice president and chief technology officer. "We built our EDGE platform to be a best-in-class machine-learning model using the largest dataset of HLA-presented peptides from human tumor samples. The data published in _Nature Biotechnology_ support EDGE as a transformative tool for the development of the next generation of neoantigen-targeted cancer immunotherapies."

"EDGE represents the cutting edge in personalized immunotherapy," said Timothy Chan, M.D., Ph.D., co-founder and scientific advisory board member of Gritstone. "I am very excited to see this state-of-the-art technology used to improve neoantigen vaccine development."

EDGE's prediction model was 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. A variety of tumor types, such as breast, lung, melanoma, colon and ovarian cancers were collected for sequencing, and combined with publicly available data. The training dataset for EDGE has since grown to now include more than 300 tumor and normal tissue samples, yielding over one million peptides, from patients of various ancestries with diverse HLA types. In addition to the training dataset, a key differentiator that contributed to improved performance was a novel integrated neural network model architecture. This neural network enabled EDGE to jointly model multiple key features, such as variable peptide length and the dependence of peptide presentation on gene expression level using RNA, essential for accurate prediction of true TSNA. The United States Patent Office issued Gritstone its first patent covering EDGE, on August 21, 2018 (Yelensky, et al., Neoantigen identification, manufacture and use, US 10,055,540.).

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 in 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 predictive capabilities of the EDGE platform in human clinical trials. 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 performance of EDGE and Gritstone's other products in 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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