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ONCOLOGY

Gritstone Oncology Advances into Phase 2 Expansion Cohorts for its Personalized Neoantigen Immunotherapy GRANITE and its Off-the-Shelf Neoantigen Immunotherapy SLATE

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--The Phase 1 portions of the studies are closed for enrollment; patient treatment and follow-up for efficacy and safety continues--

EMERYVILLE, Calif., Nov. 02, 2020 (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 it has begun dosing patients in the Phase 2 expansion cohorts of the Phase 1/2 clinical studies for GRANITE and SLATE, its neoantigen-based immunotherapies.

"We are excited to advance the highest doses of GRANITE and SLATE tested in the Phase 1 studies into Phase 2 clinical cohorts and interrogate the ability of our immunotherapies at full dose to elicit robust immune responses against historically cold (or non-immunogenic) tumor types such as metastatic colorectal cancer," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "We have seen promising data in our Phase 1 study, which is still ongoing, including in gastro-esophageal and colorectal cancers, and we look forward to presenting the full dataset by mid-2021. Additionally, we continue to remain highly interested in the adjuvant setting where immunotherapy is likely to have the greatest impact and where diagnostic blood tests such as circulating tumor DNA (ctDNA) can be employed to run efficient trials in patients in need."

Daniel Catenacci, M.D., director of the Gastrointestinal Oncology Program at the University of Chicago Medicine and principal investigator on the studies, added, "The early Phase 1 data clearly show robust induction of neoantigen-specific CD8+ T cells, expansion of those cells in the tumor microenvironment, and early evidence of benefit to our patients. Delivering effective immunotherapy to patients with cold tumors would change the landscape of cancer treatment and expand the role of immunotherapy significantly."

The Phase 2 portion of the GRANITE Phase 1/2 study (GO-004) includes a cohort for patients with microsatellite stable colorectal cancer (MSS CRC) who have progressed on FOLFOX/FOLFIRI therapy and a second cohort for patients with gastro-esophageal cancer (GEA) who have progressed on chemotherapy. GRANITE was granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of MSS CRC.

In the Phase 2 part of the SLATE Phase 1/2 study (GO-005), the company has begun enrolling non-small cell lung cancer patients with relevant KRAS mutations who have progressed on prior immunotherapy, and patients with tumors where a relevant TP53 mutation exists.

Raphaël Rousseau, M.D., Ph.D., executive vice president and chief medical officer of Gritstone Oncology, added, "These expansion cohorts are designed to rapidly and unambiguously identify efficacy signals by studying patients in whom checkpoint inhibitor therapy is essentially inactive (MSS CRC) or has low activity (GEA). Furthermore, and related to the low activity of immunotherapy observed to date, patients with metastatic colorectal or gastro-esophageal cancers have poor prognoses, with estimated 12-month survival figures of only 56% and 30% respectively (SEER18 data). Registrational studies in these contexts can be consequently fast, particularly if observed treatment effects are strong."

About GRANITE and SLATE

Gritstone's neoantigen-based immunotherapies are engineered to elicit a significant T-cell response (particularly CD8+ cytotoxic T cells) against mutation-derived tumor-specific neoantigens, or TSNA, that are identified by the company using its proprietary Gritstone EDGE™ artificial intelligence platform and tumor HLA peptide sequencing. Data demonstrating the neoantigen identification capabilities of EDGE were published in *Nature Biotechnology*.

GRANITE is Gritstone's personalized immunotherapy that consists of two components: first, a priming adenoviral vector is used to deliver a cassette of 20 patient-specific TSNA derived from the patient's own tumor; and second, the same personalized TSNA cassette is delivered using a self-amplifying RNA vector in a repeated boost sequence. GRANITE is being evaluated in combination with immune checkpoint blockade in a Phase 1/2 clinical study, referred to as GO-004. GRANITE was granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of MSS CRC.

SLATE is Gritstone's "off-the-shelf" immunotherapy. It uses the priming adenoviral vector and self-amplifying RNA vector to deliver a cassette of 20 shared TSNA, representing mutated gene sequences that are shared across patients (such as TP53 and K-RAS mutations). SLATE is being evaluated in combination with immune checkpoint blockade in a Phase 1/2 clinical study called GO-005.

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—second, 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 individualized neoantigen-based immunotherapy, GRANITE, and its "off the shelf" shared neoantigen-based immunotherapy, SLATE, are being evaluated in clinical studies. 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 of Gritstone's therapeutic programs; the advancements in the Company's ongoing clinical trials; the timing of data announcements related to ongoing clinical trials and the initiation of future 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 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 August 5, 2020 and any current and periodic reports filed with the Securities and Exchange Commission.

Contacts

Media:

Dan Budwick

1AB

(973) 271-6085

dan@1abmedia.com

Investors:

Alexandra Santos

Wheelhouse Life Science Advisors

(510) 871-6161

asantos@wheelhousesa.com



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