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Gritstone Oncology Reports Third Quarter Financial Results and Recent Highlights

November 5, 2020

EMERYVILLE, Calif., Nov. 05, 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 reported financial results for the third quarter ended September 30, 2020 and reviewed business highlights.

"This year we have made important clinical and scientific progress in advancing our two immunotherapies, GRANITE and SLATE," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "Recently, we began enrolling cancer patients in Phase 2 expansion cohorts for both programs. These cohorts are designed to build upon the evidence of clinical benefit seen in our Phase 1 studies, and we are expanding at dose level four, the highest dose level studied in Phase 1, which continues to be well-tolerated by patients. Our clinical work has confirmed the differentiated ability of our vaccine vectors to consistently drive robust CD8 T cell responses specific to administered antigens. Our clinical work with SLATE has demonstrated that certain antigens are immunodominant and can drive focused immune responses. With our strategy to develop two versions of an off-the-shelf cassette, we can be more specific to a patient's mutations and address this phenomenon prospectively, ensuring that dominant neoantigens are not permitted to impair immune responses to other neoantigens."

Select Accomplishments

- Presented preliminary efficacy, immunogenicity, and safety data up to dose level 3 from the ongoing Phase 1 study evaluating GRANITE in combination with immune checkpoint blockade for the treatment of patients with advanced solid tumors, including microsatellite stable colorectal cancer (MSS-CRC), gastroesophageal (GEA) cancer, metastatic non-small cell lung cancer (NSCLC), and bladder cancer
- Demonstrated consistent, strong neoantigen-specific CD8+ T cells generated in all patients tested and evidence of clinical benefit, as well as a favorable safety profile
- Presented the same data types from the Phase 1 study evaluating SLATE in combination with immune checkpoint blockade for the treatment of patients with metastatic NSCLC, pancreatic ductal adenocarcinoma and MSS-CRC, as well as in patients with other solid tumor types who have relevant mutation/human leukocyte antigen (HLA) combinations
 - Induced CD8+ T cells against multiple KRAS driver mutations, with the most pronounced response against immunodominant neoantigens such as TP53mut, and demonstrated a favorable safety profile
- Initiated single-arm Phase 2 expansion cohorts with GRANITE for patients with MSS CRC who have progressed on FOLFOX/FOLFIRI therapy and a second cohort for patients with GEA who have progressed on chemotherapy
- Initiated single-arm Phase 2 expansion cohorts with SLATE v1 in NSCLC patients with relevant KRAS mutations who have progressed on prior immunotherapy, and patients with tumors where a relevant TP53 mutation exists

Anticipated Upcoming Milestones

- Nominate a lead bispecific antibody development candidate directed towards a novel solid tumor-specific HLA-peptide complex by the end of 2020
- Present additional efficacy and safety data from the Phase 1 GRANITE study, including at the higher GRANITE dose level, in the first half of 2021
- Present data from Phase 2 SLATE cohorts (v1 cassette) in the first half of 2021
- Launch a SLATE v2 cassette into clinical trials in NSCLC patients in the first half of 2021, optimized for KRAS neoantigens (leveraging insights into immunodominance derived from v1 cassette)
- Present data from Phase 2 GRANITE cohorts in the second half of 2021
- Report data from SLATE v2 cassette in the second half of 2021

Third Quarter 2020 Financial Results

For the three months ended September 30, 2020, Gritstone reported a net loss of \$26.1 million, compared to a net loss of \$27.5 million for the three months ended September 30, 2019.

Collaboration revenue was \$0.8 million for the three months ended September 30, 2020, compared to \$1.0 million for the three months ended September 30, 2019. Collaboration revenue was due to the Research Collaboration and License Agreement with bluebird bio Inc and another small collaboration agreement.

Total research and development expenses were \$22.1 million for the three months ended September 30, 2020, compared to \$24.9 million for the three months ended September 30, 2019. The decrease was primarily attributable to a decrease in milestone and license payments and outside services and consultants, offset by increases in manufacturing-related expenses, lab supplies and research and development personnel.

General and administrative expenses were \$5.0 million for the three months ended September 30, 2020, compared to \$4.6 million for the three months ended September 30, 2019. The increase was primarily attributable to an increase in personnel-related expenses.

Cash, cash equivalents, marketable securities and restricted cash were \$72.1 million as of September 30, 2020, compared to \$128.8 million as of December 31, 2019.

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, including the timing thereof. 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 5, 2020 and any current and periodic reports filed with the Securities and Exchange Commission.

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Gritstone Oncology, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Collaboration	\$ 795	\$ 984	\$ 2,544	\$ 3,481
Contribution	144	-	144	-
Total revenue	939	984	2,688	3,481
Operating expenses:				
Research and development	22,050	24,886	65,807	59,314
General and administrative	5,031	4,582	15,751	13,794
Total operating expenses	27,081	29,468	81,558	73,108
Loss from operations	(26,142)	(28,484)	(78,870)	(69,627)

Interest and other income, net	69	936	723	2,898
Net loss	\$ (26,073)	\$ (27,548)	\$ (78,147)	\$ (66,729)
Net loss per common share, basic and diluted	\$ (0.69)	\$ (0.77)	\$ (2.10)	\$ (2.04)
Shares used to compute for net loss per common share, basic and diluted	37,750,145	35,690,600	37,268,318	32,762,176

Gritstone Oncology, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 57,648	\$ 57,408
Marketable securities	12,897	70,368
Prepaid expenses and other current assets	3,202	3,497
Total current assets	73,747	131,273
Property and equipment, net	23,306	26,911
Operating lease right-of-use assets	22,706	23,427
Deposits and other long-term assets	2,749	2,778
Long-term marketable securities	-	-
Total assets	\$ 122,508	\$ 184,389
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,284	\$ 4,621
Accrued compensation	4,910	4,598
Accrued liabilities	665	1,041
Accrued research and development	2,557	1,779
Lease liabilities, current portion	5,069	2,505
Deferred revenue, current portion	5,528	4,956
Total current liabilities	22,013	19,500
Other non-current liabilities	634	-
Lease liabilities, net of current portion	20,791	20,985
Deferred revenue, net of current portion	7,086	9,560
Total liabilities	50,524	50,045
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	-	-
Common stock	17	17
Additional paid-in capital	371,097	355,291
Accumulated other comprehensive loss	5	24
Accumulated deficit	(299,135)	(220,988)
Total stockholders' equity	71,984	134,344
Total liabilities and stockholders' equity	\$ 122,508	\$ 184,389



Source: Gritstone Oncology, Inc