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ONCOLOGY

Gritstone Oncology Reports Second Quarter Financial Results and Recent Highlights

August 5, 2020

EMERYVILLE, Calif., Aug. 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 second quarter ended June 30, 2020 and reviewed business highlights.

"We have made important advances in our two cancer immunotherapy programs, GRANITE and SLATE, demonstrating early signals of clinical benefit together with a well-tolerated safety profile," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "Building upon our data presented 6 months ago, we have shown that GRANITE, our personalized 'N of 1' therapy, consistently elicited large numbers of Class I HLA-presented neoantigen-specific CD8+ T cells in all patients treated. Furthermore, we have shown that these very same T cells can expand within the tumor mass. Excitingly, we have seen signs of clinical benefit, with no GRANITE patient at dose level 3 or above having experienced disease progression to date. Most notably, in a microsatellite-stable colon cancer patient treated at dose level three, we are observing ongoing clinical response, corresponding with a decline in the tumor marker CEA and the normalization of liver function tests. We await further CT scans to assess for RECIST response. Further colorectal cancer patients with microsatellite-stable disease are on treatment at dose level 4, and we expect to present additional data from this dose level later this year. For SLATE, our shared neoantigen program, we are initiating Phase 2 expansion cohorts."

Recent Accomplishments

- Presented preliminary efficacy, immunogenicity, and safety data 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 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 signals 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
- Expanded the training dataset of HLA class II peptides and alleles for the EDGE platform
- Augmented its Scientific Advisory Board with the addition of Jean-Charles Soria, M.D., Ph.D., chief executive officer of Gustave Roussy Cancer Campus, the premier European comprehensive cancer center based in Villejuif, France
- Appointed Rahsaan W. Thompson, J.D., seasoned legal executive with over 20 years of corporate counsel experience, as executive vice president and general counsel
- Appointed Elaine V. Jones, Ph.D., an existing board member, to the position of chair of the board of directors

Anticipated Upcoming Milestones

- Present additional efficacy and safety data from the Phase 1 GRANITE study, including at the higher GRANITE dose level, in 2020
- Initiate single-arm Phase 2 expansion cohorts with GRANITE for patients with MSS CRC and gastroesophageal cancer in 2020
- Initiate single-arm Phase 2 expansion cohorts with SLATE for patients with NSCLC following previous therapy with checkpoint inhibitors and patients with TP53 mutations in 2020
- Nominate a lead bispecific antibody development candidate directed towards a novel solid tumor-specific HLA-peptide complex in 2020
- Present data from Phase 2 SLATE cohorts in the first half of 2021
- Present data from Phase 2 GRANITE cohorts in the second half of 2021
- Report data from SLATE cassette optimized for KRAS mutations in patients with NSCLC in the second half of 2021

Second Quarter 2020 Financial Results

For the three months ended June 30, 2020, Gritstone reported a net loss of \$25.9 million, compared to a net loss of \$21.2 million for the three months ended June 30, 2019.

Collaboration revenue was \$0.5 million for the three months ended June 30, 2020, compared to \$1.2 million for the three months ended June 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 \$21.3 million for the three months ended June 30, 2020, compared to \$18.5 million for the three months ended June 30, 2019. The increase was primarily attributable to an increase in personnel-related expenses driven by increased headcount, as well as an increase in facilities-related expenses to accommodate our manufacturing expansion and increased personnel.

General and administrative expenses were \$5.3 million for the three months ended June 30, 2020, compared to \$4.8 million for the three months ended June 30, 2019. The increase was primarily attributable to an increase in personnel-related expenses.

Cash, cash equivalents, marketable securities and restricted cash were \$92.9 million as of June 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 August 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		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Collaboration revenue	\$ 488	\$ 1,150	\$ 1,750	\$ 2,497
Operating expenses:				
Research and development	21,290	18,529	43,758	34,428

General and administrative	5,255	4,835	10,720	9,212
Total operating expenses	26,545	23,364	54,478	43,640
Loss from operations	(26,057)	(22,214)	(52,728)	(41,143)
Interest and other income, net	189	1,042	654	1,962
Net loss	\$ (25,868)	\$ (21,172)	\$ (52,074)	\$ (39,181)
Net loss per common share, basic and diluted	\$ (0.69)	\$ (0.63)	\$ (1.41)	\$ (1.25)
Shares used to compute for net loss per common share, basic and diluted	37,256,247	33,582,844	37,027,405	31,273,696

Gritstone Oncology, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 62,631	\$ 57,408
Marketable securities	29,282	70,368
Prepaid expenses and other current assets	2,584	3,497
Total current assets	94,497	131,273
Property and equipment, net	24,581	26,911
Operating lease right-of-use assets	23,909	23,427
Deposits and other long-term assets	2,679	2,778
Total assets	\$ 145,666	\$ 184,389
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,301	\$ 4,621
Accrued compensation	3,765	4,598
Accrued liabilities	138	1,041
Accrued research and development	953	1,779
Lease liabilities, current portion	4,240	2,505
Deferred revenue, current portion	5,778	4,956
Total current liabilities	19,175	19,500
Other non-current liabilities	375	-
Lease liabilities, net of current portion	22,258	20,985
Deferred revenue, net of current portion	7,630	9,560
Total liabilities	49,438	50,045
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	-	-
Common stock	17	17
Additional paid-in capital	369,223	355,291
Accumulated other comprehensive gain	50	24
Accumulated deficit	(273,062)	(220,988)
Total stockholders' equity	96,228	134,344
Total liabilities and stockholders' equity	\$ 145,666	\$ 184,389



Source: Gritstone Oncology, Inc