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ONCOLOGY

Gritstone Oncology Reports Second Quarter 2019 Financial Results and Recent Highlights

August 12, 2019

EMERYVILLE, Calif., Aug. 12, 2019 (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 recent business highlights and financial results for the second quarter ended June 30, 2019.

"Since our IPO at the end of September, we have advanced two novel neoantigen-based immunotherapies into clinical trials (GRANITE-001 and SLATE-001), expanded and published data validating our proprietary Gritstone EDGE™ artificial intelligence platform, and augmented our operations with the hiring of key senior leaders and the build out of our manufacturing facility," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "This momentum continues as we prepare to dose the first patient in our SLATE-001 Phase 1 trial, and as we generate clinical data from our ongoing GRANITE-001 Phase 1 clinical trial. Our goal is to confirm that true tumor-specific neoantigens within the right immunogenic vector can drive a profound neoantigen-specific T cell response that has clinical value for patients with cancer."

Recent Gritstone Oncology Highlights

- Received Investigational New Drug (IND) clearance from the Food and Drug Administration to initiate a Phase 1 clinical study of SLATE-001, our off-the-shelf immunotherapy product candidate, for certain patients with metastatic lung adenocarcinoma, pancreatic ductal carcinoma and microsatellite-stable colorectal cancer, as well as for patients with other solid tumor types who have relevant mutation/HLA (human leukocyte antigen) combinations
- Established a clinical trial collaboration and supply agreement with Bristol-Myers Squibb to use their immune checkpoint inhibitors nivolumab and ipilimumab in the Phase 1 study of SLATE-001
- Appointed Vijay Yabannavar, Ph.D., a biopharma leader with over 30 years of experience, as executive vice president of manufacturing and technical operations
- Completed a successful public offering of common stock, raising approximately \$74.8 million in gross proceeds
- Began dosing patients in a Phase 1 clinical study evaluating GRANITE-001, our personalized product candidate, in combination with immune checkpoint blockade for the treatment of patients with advanced solid tumors, including microsatellite stable colorectal cancer, gastroesophageal cancer, metastatic non-small cell lung cancer, and bladder cancer
- Delivered an oral presentation at the American Association for Cancer Research (AACR) Annual Meeting demonstrating that EDGE improved the positive predictive value for human leukocyte antigen class II (HLA-DR) peptide presentation over standard methods by approximately 20-fold
- Presented a poster at AACR showing Gritstone's capabilities to efficiently identify neoantigen-reactive T cells and T cell receptors, which have potential applications in cell therapy

Anticipated Near-term Milestones

- Dose the first patient in the Phase 1 SLATE-001 clinical study mid-year
- Present early immunogenicity and safety data from the first part of both the SLATE-001 and GRANITE-001 Phase 1 clinical trials in the fourth quarter of 2019 at a scientific congress
- Nominate a lead bispecific antibody development candidate directed towards a novel solid tumor-specific HLA-peptide complex in the fourth quarter of 2019
- Report clinical data from the first part of the SLATE-001 and GRANITE-001 Phase 1 trials at a scientific congress in mid-2020

Second Quarter 2019 Financial Results

For the three months ended June 30, 2019, Gritstone reported a net loss of \$22.2 million, compared to a net loss of \$15.5 million for the three months ended June 30, 2018.

Collaboration revenue was \$1.2 million for the three months ended June 30, 2019, with no collaboration revenue recognized for the three months ended June 30, 2018. The increase was due to revenue recognized under the Research Collaboration and License Agreement with bluebird bio, Inc., which was entered into in August 2018.

Total research and development expenses were \$18.5 million for the three months ended June 30, 2019, compared to \$12.7 million for the three months ended June 30, 2018. The increase was primarily attributable to an increase in personnel-related expenses driven by increased headcount, as well as an increase in outside services and consultants, in-house laboratory supplies and consumables, and facilities-related expenses to accommodate our manufacturing expansion.

General and administrative expenses were \$4.8 million for the three months ended June 30, 2019, compared to \$2.8 million for the three months ended June 30, 2018. The increase was primarily attributable to an increase in personnel-related expenses driven by an increase in headcount and an increase in legal and other outside professional services required to support the company's ongoing operations as a public company.

Cash, cash equivalents, and marketable securities were \$181.7 million as of June 30, 2019, compared to \$153.1 million as of December 31, 2018.

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 entering into a Phase 1 clinical study following recent IND acceptance. 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 expected timing for preliminary efficacy data from the Phase 1 GRANITE and SLATE studies and its investigational immunotherapies. 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 12, 2019 and any current and periodic reports filed with the Securities and Exchange Commission.

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Gritstone Oncology, Inc.

Condensed Statements of Operations

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Collaboration revenue	\$ 1,150	\$ -	\$ 2,497	\$ -
Operating expenses:				
Research and development	18,529	12,689	34,428	24,090
General and administrative	4,835	2,814	9,212	4,852
Total operating expenses	23,364	15,503	43,640	28,942
Loss from operations	(22,214)	(15,503)	(41,143)	(28,942)
Interest and other income, net	1,042	31	1,962	94

Net loss	\$ (21,172)	\$ (15,472)	\$ (39,181)	\$ (28,848)
Net loss per common share, basic and diluted	\$ (0.63)	\$ (6.57)	\$ (1.25)	\$ (12.62)
Shares used to compute for net income (loss) per common share, basic and diluted	33,582,844	2,353,337	31,273,696	2,285,906

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 107,728	\$ 52,183
Marketable securities	73,511	100,927
Prepaid expenses and other current assets	3,458	4,526
Total current assets	184,697	157,636
Property and equipment, net	18,966	29,494
Operating lease right-of-use assets	21,309	-
Deposits and other long-term assets	2,700	2,428
Long-term marketable securities	508	-
Total assets	\$ 228,180	\$ 189,558
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,253	\$ 4,825
Accrued compensation	2,621	3,951
Accrued liabilities	1,803	992
Lease liabilities, current portion	2,890	-
Deferred revenue, current portion	5,498	5,340
Total current liabilities	18,065	15,108
Deferred rent, net of current portion	-	1,353
Other non-current liabilities	-	12
Lease financing obligation, net of current portion	-	10,490
Lease liabilities, net of current portion	16,919	-
Deferred revenue, net of current portion	10,818	13,473
Total liabilities	45,802	40,436
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	-	-
Common stock	17	16
Additional paid-in capital	348,021	275,593
Accumulated other comprehensive loss	76	(85)
Accumulated deficit	(165,736)	(126,402)
Total stockholders' equity	182,378	149,122
Total liabilities and stockholders' equity	\$ 228,180	\$ 189,558



Source: Gritstone Oncology, Inc