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Gritstone Oncology Reports Third Quarter 2019 Financial Results and Recent Highlights

November 12, 2019

EMERYVILLE, Calif., Nov. 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 third quarter ended September 30, 2019.

"We are making good progress in advancing our ongoing Phase 1 dose escalation studies of GRANITE and SLATE, with preliminary immunogenicity data to be shown at the ESMO-IO meeting in December," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "We view a key outcome of this first-in-human data is to show that our immunotherapies can, uniquely, prime robust tumor-specific CD8+ T cell responses to neoantigens consistently across patients. If accomplished, this would be an important and de-risking step towards our goal of destroying tumors with neoantigen-specific T cells and, ultimately, offering transformative treatments for patients with cancer."

Recent Gritstone Oncology Highlights

- Continued dosing patients in a Phase 1 clinical study evaluating GRANITE, our personalized immunotherapy product candidate, for the treatment of patients with advanced solid tumors, including gastroesophageal cancer, microsatellite-stable colorectal cancer, metastatic non-small cell lung cancer, and bladder cancer
- Began dosing patients in a Phase 1 clinical study of SLATE, our off-the-shelf immunotherapy product candidate, for certain patients with advanced solid tumors, including metastatic non-small cell lung cancer, pancreatic ductal adenocarcinoma and microsatellite-stable colorectal cancer, as well as in patients with other solid tumor types who have relevant mutation/human leukocyte antigen (HLA) combinations
- Appointed a new board member, Elaine V. Jones, Ph.D., who has two decades of life science investing experience, has served on over 20 life science company boards, and has direct experience within biopharma research and business development
- Improved the performance of the EDGE artificial intelligence platform from a positive predictive value for HLA class I peptide presentation of approximately 55% initially to over 70% now, which is an estimated 10-fold improvement over leading public tools
- Presented a poster at the Society for Immunotherapy of Cancer's 34th Annual Meeting (SITC 2019) reviewing novel shared tumor-specific neoantigens (TSNA) derived from driver mutations (such as KRAS G12C) that were identified by Gritstone in an efficient process combining the EDGE platform with tumor HLA peptide sequencing. These neoantigens are contained within the first SLATE product candidate.

Anticipated Near-term Milestones

- Present early immunogenicity and safety data from the Gritstone Phase 1 program at the European Society for Medical Oncology's Immuno-Oncology Congress (ESMO-IO) in Geneva, Switzerland on December 12, 2019
- 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 Phase 1 clinical trials of GRANITE and SLATE at a scientific congress in mid-2020

Third Quarter 2019 Financial Results

For the three months ended September 30, 2019, Gritstone reported a net loss of \$27.5 million, compared to a net loss of \$18.6 million for the three months ended September 30, 2018.

Collaboration revenue was \$984 thousand for the three months ended September 30, 2019, compared to \$96 thousand for the three months ended September 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 \$24.9 million for the three months ended September 30, 2019, compared to \$15.6 million for the three months ended September 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 \$4.6 million for the three months ended September 30, 2019, compared to \$3.1 million for the three months ended September 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 \$151.5 million as of September 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, is a personalized neoantigen-based immunotherapy in Phase 1 clinical testing. Gritstone's second product candidate, SLATE, is a shared neoantigen, "off-the-shelf" immunotherapy which is also being evaluated in a Phase 1 clinical study. 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 of data from the Phase 1 GRANITE and SLATE studies. 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 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Collaboration revenue	\$ 984	\$ 96	\$ 3,481	\$ 96
Operating expenses:				
Research and development	24,886	15,622	59,314	39,712
General and administrative	4,582	3,088	13,794	7,940
Total operating expenses	29,468	18,710	73,108	47,652
Loss from operations	(28,484)	(18,614)	(69,627)	(47,556)
Interest and other income, net	936	26	2,898	120
Net loss	\$(27,548)	\$(18,588)	\$(66,729)	\$(47,436)
Net loss per common share, basic and diluted	\$(0.77)	\$(7.60)	\$(2.04)	\$(20.27)
Shares used to compute for net income (loss) per common share, basic and diluted	35,690,600	2,445,547	32,762,176	2,339,705

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 116,942	\$ 52,183
Marketable securities	32,523	100,927
Prepaid expenses and other current assets	5,318	4,526
Total current assets	154,783	157,636
Property and equipment, net	24,376	29,494
Operating lease right-of-use assets	24,780	-
Deposits and other long-term assets	2,709	2,428
Long-term marketable securities	2,003	-
Total assets	\$ 208,651	\$ 189,558
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,737	\$ 4,825
Accrued compensation	3,725	3,951
Accrued liabilities	2,147	740
Accrued research and development expenses	3,241	252
Lease liabilities, current portion	1,642	-
Deferred revenue, current portion	5,401	5,340
Total current liabilities	22,893	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	19,432	-
Deferred revenue, net of current portion	9,931	13,473
Total liabilities	52,256	40,436
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	-	-
Common stock	17	16
Additional paid-in capital	349,631	275,593
Accumulated other comprehensive loss	31	(85)
Accumulated deficit	(193,284)	(126,402)
Total stockholders' equity	156,395	149,122
Total liabilities and stockholders' equity	\$ 208,651	\$ 189,558



Source: Gritstone Oncology, Inc