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Gritstone Oncology Reports Fourth Quarter and Full Year 2018 Financial Results and Recent Highlights

March 28, 2019

EMERYVILLE, Calif., March 28, 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 financial results for the fourth quarter and full year ended December 31, 2018 and reviewed 2018 highlights.

"Over this past year, we launched our novel immunotherapy program into clinical trials, enabling us to ask whether high-performance human tumor neoantigen prediction and expected profound CD8+ T cell elicitation can drive clinically relevant immune responses in solid tumor patients," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "As the first key step, we established EDGE™, our propriety artificial intelligence platform, as a best-in-class prediction model for the identification of human tumor neoantigens. The innovative approach and scientific rigor with which we built EDGE resulted in several important milestones in 2018: the publication of its powerful predictive capabilities in *Nature Biotechnology*, clinical partnerships with two leading biopharma companies, and patent issuance protecting our intellectual property. Novel tumor-specific antigens identified by EDGE are then targeted by our portfolio of product candidates, namely our personalized immunotherapy GRANITE-001, our off-the-shelf immunotherapy SLATE-001, and our targeted bispecific antibody program for solid tumors. We look forward this year to generating data with our pioneering clinical programs."

Key 2018 Accomplishments

Pipeline Portfolio

- Established a clinical research collaboration with Bristol-Myers Squibb (BMS) to evaluate Gritstone's GRANITE-001, a personalized immunotherapy using patient-specific neoantigens, in combination with BMS' immune checkpoint inhibitors nivolumab and ipilimumab in the Phase 1 study
- Initiated the Phase 1a portion of the GO-004 GRANITE Phase 1/2 clinical trial in patients with common solid tumors, including advanced non-small cell lung cancer, microsatellite stable colorectal cancer, gastroesophageal cancer and bladder cancer
- Granted Fast Track designation by the U.S. Food and Drug Administration for the use of GRANITE-001 as a potential treatment for microsatellite stable colorectal cancer
- Commenced IND-enabling work for its SLATE-001 product candidate, an "off-the-shelf" immunotherapy using shared neoantigens
- Advanced solid tumor bispecific antibody program into lead optimization phase
- Continued build-out of our own cGMP manufacturing facility wherein neoantigen-containing chimpanzee adenoviruses are produced and released

EDGE™ (Epitope Discovery in cancer Genomes) Artificial Intelligence Platform

- Published data in *Nature Biotechnology* demonstrating the predictive capabilities of the EDGE platform to identify major histocompatibility complex (MHC) class I neoantigens and neoantigen-reactive T cells, substantially outperforming public tools
- Entered into a strategic collaboration with bluebird bio to leverage Gritstone's EDGE platform to identify tumor-specific targets and natural T cell receptors for use in the development of bluebird's cancer cell therapies
- Issued patent coverage for EDGE describing neoantigen identification, manufacturing and use, including the use of mass spectrometry as a basis to improve neoantigen prediction

Corporate

- Completed a successful Initial Public Offering in October 2018, raising approximately \$92.6 million in net proceeds
- Appointed experienced financial executive, Steve E. Krognes, to Board of Directors

Anticipated Upcoming Near-term Milestones

- An oral presentation on April 2, 2019, at the American Association for Cancer Research (AACR) Annual Meeting on MHC class II antigen prediction capabilities of EDGE
- A poster presentation on April 2, 2019, at AACR on the identification of neoantigen reactive T cells and T cell receptors using EDGE
- The initiation of a first-in-human study with SLATE-001 in the second-half of 2019
- Preliminary data from the Phase 1a portion of the GO-004 GRANITE-001 study in the fourth quarter of 2019
- The identification of a lead bispecific antibody development candidate directed towards solid tumors

Fourth Quarter and Full Year 2018 Financial Results

For the three and twelve months ended December 31, 2018, Gritstone reported a net loss of \$17.3 million and \$64.8 million, respectively. This compares to a net loss of \$17.4 million and \$41.4 million, respectively, for the same periods in 2017.

Collaboration revenue was \$1.1 million for the three months ended December 31, 2018, and \$1.2 million for the full year 2018, compared to no collaboration revenue recognized in 2017. The increase was due to revenue recognized under the Research Collaboration and License Agreement with bluebird, which was entered into in August 2018.

Total research and development expenses were \$15.2 million for the three months ended December 31, 2018, and \$54.9 million for the full year 2018, compared to \$15.8 million and \$35.7 million, respectively, for the same periods in 2017. 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.

General and administrative expenses were \$3.9 million for the three months ended December 31, 2018, and \$11.8 million for the full year 2018, compared to \$1.8 million and \$6.1 million, respectively, for the same periods in 2017. 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 \$153.1 million as of December 31, 2018, compared to \$86.0 million as of December 31, 2017. The increase was primarily attributable to \$92.6 million received in net proceeds from the company's Initial Public Offering, as well as \$30.0 million in cash received related to the Research Collaboration and License Agreement and the Stock Purchase Agreement with bluebird, offset by operating and investing cash payments.

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 beginning Phase 1 clinical testing. Gritstone's second product candidate, SLATE-001, is a shared neoantigen ("off-the-shelf") immunotherapy which is advancing towards the clinic. 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 portion of GO-004, the planned initiation of SLATE-001, 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 Annual Report on Form 10-K filed on March 28, 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 December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Collaboration revenue	\$ 1,091	\$ -	\$ 1,187	\$ -
Operating expenses:				
Research and development	15,252	15,752	54,965	35,691
General and administrative	3,866	1,828	11,806	6,072
Total operating expenses	19,118	17,580	66,771	41,763
Loss from operations	(18,027)	(17,580)	(65,584)	(41,763)
Interest income, net	690	211	809	386
Net loss	\$ (17,337)	\$ (17,369)	\$ (64,775)	\$ (41,377)
Net loss per common share, basic and diluted	\$ (0.61)	\$ (8.18)	\$ (7.26)	\$ (20.70)
Shares used to compute for net loss per common share, basic and diluted	28,443,460	2,122,677	8,919,281	1,999,044

Gritstone Oncology, Inc.
Condensed Balance Sheets
(Unaudited)

(In thousands)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 52,183	\$ 39,007
Marketable securities	100,927	46,946
Prepaid expenses and other current assets	4,526	2,526
Total current assets	157,636	88,479
Property and equipment, net	29,494	27,211
Deposits and other long-term assets	2,428	1,610
Total assets	\$ 189,558	\$ 117,300
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,825	\$ 3,935
Accrued compensation	3,951	2,227
Accrued liabilities	992	1,490
Deverred revenue, current portion	5,340	-
Total current liabilities	15,108	7,652
Deferred rent, net of current portion	1,353	1,749
Other non-current liabilities	12	96
Lease financing obligation, net of current portion	10,490	10,521
Deferred revenue, net of current portion	13,473	-
Total liabilities	40,436	20,018
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	-	156,937

Common stock	16		1	
Additional paid-in capital	275,593		2,045	
Accumulated other comprehensive loss	(85)	(74)
Accumulated deficit	(126,402)	(61,627)
Total stockholders' equity	149,122		97,282	
Total liabilities and stockholders' equity	\$ 189,558		\$ 117,300	



Source: Gritstone Oncology, Inc