May 4, 2017

Eleven Biotherapeutics Reports First Quarter 2017 Financial Results

-- Continued Advancing Ongoing Phase 3 Registration Clinical Trial of Vicinium™ in Non-Muscle Invasive Bladder Cancer -

-- Presented Preclinical Data at AACR Suggesting that Lead Compounds Induce Anti-Tumor Immune Response That Can Potentiate the Activity of Immuno-Oncology Agents --

-- Expanded Clinical Development Team to Support Ongoing and Planned Trials --

-- Management to Host Conference Call Today at 8:00 a.m. ET --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Eleven Biotherapeutics, Inc. (NASDAQ:EBIO), a late-stage clinical oncology company advancing a broad pipeline of novel product candidates based on its Targeted Protein Therapeutics (TPTs) platform, today reported financial results for the quarter ended March 31, 2017, and provided a corporate update.

"During our first quarter of 2017, we made meaningful progress, advancing our Phase 3 registration clinical trial of Vicinium and continuing development efforts with Proxinium™ and VB6-845d," said Stephen Hurly, President and Chief Executive Officer of Eleven Biotherapeutics. "Importantly, we also presented new preclinical data supporting the potential of our locally- and systemically-administered drug candidates not just as monotherapies, but also in combination with immuno-oncology products, including checkpoint inhibitors. These results accord with our clinical development strategies, and we look forward to further exploring TPTs as new medicines with the potential to offer considerable improvements over existing options."

First Quarter and Recent Business Highlights and Anticipated Upcoming Milestones:

Vicinium: Vicinium is a single protein anti-epithelial cell adhesion molecule (anti-EpCAM) antibody fragment fused with *Pseudomonas* Exotoxin A (ETA) that is designed to specifically target and deliver a potent anti-cancer payload directly into tumor cells. Vicinium is currently in a Phase 3 registration clinical trial for the treatment of high-grade non-muscle invasive bladder cancer (NMIBC) in subjects who have previously received two courses of Bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive.

- Complete enrollment for Phase 3 registration clinical trial expected in second half of 2017
- Topline data from Phase 3 registration clinical trial expected in 2018

Proxinium: Proxinium is a single protein anti-EpCAM antibody fragment fused with ETA for the treatment of late-stage squamous cell carcinoma of the head and neck (SCCHN). Proxinium has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), and Fast Track designation from the FDA. Proxinium has demonstrated anti-tumor activity in prior Phase 1 and 2 clinical trials.

- Initiation of Phase 1/2a clinical trial evaluating Proxinium in combination with a checkpoint inhibitor expected in second half of 2017

At the American Association of Cancer Research (AACR) Annual Meeting in April, Eleven presented new preclinical results with VB4-845, the active pharmaceutical ingredient used to formulate both Vicinium and Proxinium. Data suggest that VB4-845 induces the expression of HMGB1 in tumor treated cells; HMGB1 is one of three damage-associated molecular patterns (DAMPs) indicative of immunogenic cell death (ICD). Eleven has previously disclosed observations of the other two DAMPs markers - cell surface expression of calreticulin and extracellular release of ATP - following treatment with VB4-845. Together, these results suggest that product candidates formulated with VB4-845 are capable of driving host anti-tumor immune responses that can potentiate the activity of immuno-oncology agents.

As part of the same poster presentation, Eleven shared data from a preclinical model in patient-derived xenograft tumor-bearing mice reconstituted with a human immune system, which was used to assess the combination of intratumoral injection of VB4-845 with the anti-PD1 antibody, nivolumab. Treatment with VB4-845 alone suppressed the growth of injected tumors, while monotherapy nivolumab had little effect. In contralateral, non-injected tumors, responses from mice treated with both VB4-845 and nivolumab were more pronounced than responses in mice treated with either product as a monotherapy. Based on these results, Eleven believes that VB4-845 killing of tumor cells could facilitate and augment checkpoint inhibitor

anti-tumor activity.

Systemically-administered TPT Pipeline: Eleven's initial systemically-administered TPTs leverage a proprietary, highly potent, de-immunized, plant toxin, deBouganin. DeBouganin has picomolar killing of cancer cells and may be effective against cancer stem cells. In preclinical studies, deBouganin demonstrated the ability to avoid multi-drug resistance mechanisms that can decrease the efficacy of small molecule payloads. Based on these results, Eleven believes that deBouganin-based therapies may be effective against a wide spectrum of cancers.

- Investigational New Drug Application (IND) submission for VB6-845d planned for first quarter of 2018

At the AACR Annual Meeting, Eleven presented preclinical data suggesting that its deBouganin payload is capable of effectively killing tumor cells that are resistant to treatment with antibody drug conjugates (ADCs) composed of DM-1 and MMAE payloads when conjugated to the same monoclonal antibody, trastuzumab. The Company believes this is due, in part, to deBouganin's lack of sensitivity to both the multidrug resistance pumps and the changes in phosphorylation status of proteins involved in cell proliferation and survival that allow some cancers to escape the action of anti-mitotic ADCs.

Corporate: Eleven further expanded its internal clinical development team with two key hires: Gary Conboy as Executive Director, Clinical Sciences and Mary Rohrer as Associate Director, Clinical Operations.

First Quarter 2017 Financial Results:

- **Cash Position**: Cash and cash equivalents were $20.3 million as of March 31, 2017, compared to $25.3 million as of December 31, 2016.
- **Revenue**: Revenue was $0.4 million for the three months ended March 31, 2017, compared to $0.2 million for the same period in 2016. This increase was due to revenue recognized from the License Agreement (License Agreement) with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche).
- **R&D Expenses**: Research and development expenses were $2.9 million for the three months ended March 31, 2017, compared to $4.6 million for the same period in 2016. The decrease was due primarily to a reduction in isunakinra and EBI-031 related development expenses, partially offset by an increase in Vicinium related development expenses.
- **G&A Expenses**: General and administrative expenses were $2.2 million for the three months ended March 31, 2017, compared to $2.1 million for the same period in 2016.
- **Net Loss**: Net loss was $6.1 million, or $0.25 per share, for the three months ended March 31, 2017, compared to net loss of $7.6 million, or $0.39 per share, for the same period in 2016.
- **Financial Guidance:** Based on current operating plans, Eleven expects to have cash to fund research and development programs and operations into early 2018.

Upcoming Events and Presentations:

- American Urological Association 2017 Annual Meeting, May 12-16, 2017 in Boston, Massachusetts

Conference Call Information:

Eleven Biotherapeutics' management team will host a conference call and audio webcast today at 8:00 a.m. ET to discuss the first quarter 2017 financial results and provide a corporate update. To access the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) at least five minutes prior to the start time and refer to conference ID 12752483.

An audio webcast of the call will also be available on the Investors & Media section of the Company's website, www.elevenbio.com. An archived webcast will be available on the Company's website approximately two hours after the event and will be available for 30 days.

About Eleven Biotherapeutics

Eleven Biotherapeutics, Inc. is a late-stage clinical oncology company advancing a broad pipeline of novel product candidates based upon the Company's TPT platform. The Company's TPTs incorporate a tumor-targeting antibody fragment and a protein cytotoxic payload into a single protein molecule in order to achieve focused tumor cell killing. The Company believes its TPT approach offers significant advantages in treating cancer over existing ADC technologies. The Company believes its TPTs provide effective tumor targeting with broader cancer cell-killing properties than are achievable

with small molecule payloads that require tumor cell proliferation and face multi-drug resistance mechanisms. Additionally, the Company believes that its TPT's cancer cell-killing properties promote an anti-tumor immune response that will potentially combine well with immuno-oncology drugs such as checkpoint inhibitors. For more information please refer to the Company's website at www.elevenbio.com.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the occurrence of any event change or other circumstances that could give rise to the termination of the License Agreement, the uncertainties inherent in receiving future payments pursuant to the License Agreement, the uncertainties inherent in the initiation and conduct of clinical trials, our ability to successfully develop our product candidates and complete our planned clinical programs, our ability to obtain marketing approvals for our product candidates, expectations regarding our ongoing clinical trials, availability and timing of data from clinical trials, whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical studies will be indicative of the results of future studies, the adequacy of any clinical models, expectations regarding regulatory approvals, our ability to obtain, maintain and protect our intellectual property for our technology and products, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements, other matters that could affect the financial performance of the Company, other matters that could affect the availability or commercial potential of the Company's product candidates and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

ELEVEN BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2017	**2016**
Total revenue	$ 425	$ 229
Operating expenses:		
Research and development	2,874	4,632
General and administrative	2,213	2,147
Loss from change in fair value of contingent consideration	1,500	-
Total operating expenses	6,587	6,779
Loss from operations	(6,162)	(6,550)
Other income (expense), net	101	(1,024)
Net loss	$ (6,061)	$ (7,574)
Net loss per share —basic and diluted	$ (0.25)	$ (0.39)
Weighted-average number of common shares used in net loss per share —basic and diluted	24,610	19,639

ELEVEN BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	March 31, 2017	**December 31, 2016**

Assets		
Current assets:		
Cash and cash equivalents	$ 20,268	$ 25,342
Prepaid expenses and other current assets	712	585
Total current assets	20,980	25,927
Property and equipment, net	714	796
Restricted cash	10	10
Intangible assets	60,500	60,500
Goodwill	16,864	16,864
Total assets	$ 99,068	$ 104,097
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,214	$ 1,667
Accrued expenses	1,897	1,774
Deferred revenue	-	425
Due to related party	115	114
Total current liabilities	3,226	3,980
Warrant liability	2	5
Deferred tax liability	16,335	16,335
Contingent consideration	46,600	45,100
Stockholders' equity:		
Common stock	25	25
Additional paid-in capital	162,243	161,963
Accumulated deficit	(129,363)	(123,311)
Total stockholders' equity	32,905	38,677
Total liabilities and stockholders' equity	$ 99,068	$ 104,097

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