



Eleven Biotherapeutics Announces Completion of Vicinium Manufacturing for Ongoing Clinical Trials in Non-Muscle Invasive Bladder Cancer

September 22, 2017

-- Topline Three-Month Data from Phase 3 Registration Trial Expected in Mid-2018 --

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 22, 2017-- Eleven Biotherapeutics, Inc. (NASDAQ:EBIO), a late-stage clinical oncology company advancing novel product candidates based on its Targeted Protein Therapeutics (TPTs) platform, today announced that it has completed the manufacturing of all Vicinium necessary for its ongoing Phase 3 registration trial in patients with non-muscle invasive bladder cancer (NMIBC), and for its Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute. In conjunction with this achievement, Eleven is ending its large-scale manufacturing activities and redirecting resources toward completing its Phase 3 trial and preparing for discussions with the U.S. Food and Drug Administration (FDA) regarding, as appropriate, the submission of a Biologics License Application (BLA) for Vicinium in patients with NMIBC. This change will include a reduction of headcount and associated cost savings. For commercialization, the Company plans to engage an external, Current Good Manufacturing Practice (cGMP) compliant, contract manufacturer.

"We are pleased to have completed the manufacture of all Vicinium necessary for our clinical trials, which marks another key achievement on our path to registration," said Stephen Hurly, Chief Executive Officer of Eleven Biotherapeutics. "Ending our large-scale manufacturing operations will result in significant cost savings and enable a refocus of our resources toward completing our clinical trials and preparing to meet with the FDA. We are very thankful to our manufacturing team for their hard work and dedicated service, which played a key role in maturing Eleven into a late-stage company, and brought us closer to our goal of delivering transformational medicines to patients."

About Vicinium™

Vicinium is manufactured as a single protein anti-epithelial cell adhesion molecule (anti-EpCAM) fusion protein fused with *Pseudomonas* Exotoxin A (ETA) designed to specifically target and deliver a potent anti-cancer payload directly into tumor cells. It is constructed with a stable, genetically-engineered linker to ensure its potent protein payload remains attached until it is internalized by the cancer cell, which is believed to decrease the risk of toxicity to healthy tissues thereby improving the compound's safety. Vicinium's one-step manufacturing process offers significant cost advantages and results in the production of a homogenous product, with less batch-to-batch variability than most antibody drug conjugates. Vicinium is currently in a Phase 3 registration clinical trial for the treatment of high-grade non-muscle invasive bladder cancer (NMIBC) in patients who have previously received two courses of Bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Eleven Biotherapeutics intends to enroll 134 subjects in the trial, including 77 subjects with carcinoma *in situ* (CIS), at over 70 centers in the United States and Canada. Primary and secondary endpoints include complete response (CR) in CIS subjects, time to disease recurrence and event free survival. The Company expects to complete patient enrollment in the first quarter of 2018 and to report topline three-month data in mid-2018.

About Eleven Biotherapeutics:

Eleven Biotherapeutics, Inc. is a late-stage, clinical oncology company advancing novel product candidates based upon the Company's targeted protein therapeutics (TPTs) 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 antibody drug conjugate 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 resistant 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 immune 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 timing and cost related to the cessation of the Company's large-scale manufacturing activities, the ability to engage external cGMP compliant contract manufacturers for future drug supply, 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, expectations regarding regulatory approvals, 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.

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