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Eleven Biotherapeutics Presents New Preclinical Data at AACR Supporting the Potential of the Company's Locally- and Systematically-Administered Drug Candidates

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 Targeting Protein Therapeutics (TPTs) platform, today announced new preclinical data with VB4-845, the active pharmaceutical ingredient used to formulate Vicinium™ and Proxinium™, and deBouganin, the de-immunized payload used in the Company's systemically-administered drug candidates. These data are being presented at the American Association of Cancer Research (AACR) Annual Meeting 2017 in Washington, D.C.

"Our TPTs are designed specifically to offer patients new therapies that improve upon, and overcome the challenges of, existing therapeutic options," said Stephen Hurly, President and Chief Executive Officer of Eleven Biotherapeutics. "The data reported today validate the potential of our proprietary compounds, both in combination and as monotherapies. The new preclinical results demonstrating that VB4-845 induces the expression of HMGB1 build on earlier observations, suggesting that VB4-845 induces all three damage-associated molecular patterns (DAMPs) indicative of immunogenic cell death (ICD), and thus is capable of promoting a local anti-tumor immune response. These data support our belief that compounds formulated with VB4-845 may work in tandem with checkpoint inhibitors, and we intend to initiate a Phase 1/2a combination trial of Proxinium with a checkpoint inhibitor later this year.

"We are also encouraged by the preclinical results with our proprietary de-immunized payload, deBouganin. These data suggest that deBouganin is not subject to the same multi-drug resistance mechanisms that hinder the efficacy of traditional ADCs and small molecule therapeutics. Coupled with its picomolar killing, broad therapeutic window and potential effect against cancer stem cells, we believe deBouganin has the potential to serve as the basis for next-generation therapies with activity in a broad spectrum of cancers."

Abstract 614: VB4-845 tumor cell killing in a combination study with the anti-PD1, nivolumab

Data suggest that VB4-845 induces the expression of HMGB1 in treated tumor cells. HMGB1 is one of three DAMPs markers that indicate that a tumor cell is undergoing ICD. Eleven has previously disclosed the observation of the two other DAMPs markers - cell surface expression of calreticulin and extracellular release of ATP - following treatment with VB4-845. Together, these results suggest that Eleven's product candidates formulated with VB4-845 (Vicinium and Proxinium) are capable of inducing host anti-tumor immune responses. In preclinical models, immunocompetent mice treated with both VB4-845 and the anti-PD1 nivolumab exhibited circulating T cells and intratumoral T cells, which suggests such an anti-tumor immune response.

Based on these data, Eleven believes that combination treatment with its product candidates formulated with VB4-845 (Vicinium and Proxinium) can facilitate and augment checkpoint inhibitor anti-tumor activity. These results support the Company's plans to initiate a Phase 1/2a clinical trial evaluating Proxinium in combination with a checkpoint inhibitor in the second half of 2017.

Abstract 79: Trastuzumab and C6.5 diabody armed with deBouganin overcome drug resistance to ADCs comprised of anti-microtubule agents

Data suggest that Eleven's deBouganin payload is capable of effectively killing tumor cells that are resistant to treatment with ADCs composed of the anti-mitotic payloads DM-1 and MMAE when conjugated to the same monoclonal antibody, trastuzumab. Preclinical data suggest that this is due, in part, to deBouganin's lack of sensitivity to the multidrug resistance pumps that allow some cancers to escape the action of anti-mitotic ADCs and to changes in the phosphorylation status of proteins involved in cell proliferation (JNK, MAPK, and AKT) or cell survival (BCl-xL and MCl-1).

Based on these findings, Eleven believes that deBouganin is capable of overcoming mechanisms of resistance being employed by cancer cells against ADC payloads and that it may therefore represent a more effective therapeutic option. The Company plans to file an investigational new drug application (IND) for VB6-845d, it's lead systemically-administered TPT, in the first quarter of 2018.

Both poster presentations are available on the "Investors & Media" page of Eleven's website under "Events & Presentations" at www.elevenbio.com.

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 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 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 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 uncertainties inherent in the initiation and conduct of pre-clinical studies and 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 pre-clinical studies and clinical trials, availability and timing of data from pre-clinical studies and clinical trials, whether interim results from a pre-clinical study or clinical trial will be predictive of the final results of the study or trial or results of early pre-clinical and clinical studies will be indicative of the results of future studies, the adequacy of any clinical models, expectations regarding regulatory approvals, 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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