Eleven Biotherapeutics Presents Clinical Data on EBI-005 for the Treatment of Dry Eye Disease and Allergic Conjunctivitis at ARVO 2015 Annual Meeting

**Clinically Relevant, Statistically Significant Improvements of Symptoms in the Late Phase of Allergic Conjunctivitis Supports Advancing to a Phase 3 Natural Environment Study**

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Eleven Biotherapeutics, Inc. (NASDAQ: EBIO), a clinical-stage biopharmaceutical company discovering and developing protein therapeutics to treat diseases of the eye, today announced the presentation of clinical data for EBI-005, its novel, protein therapeutic which is in late-stage clinical development for dry eye disease and allergic conjunctivitis, at the Association for Research in Vision and Ophthalmology (ARVO) 2015 Annual Meeting. Clinical data on Eleven's lead drug candidate, EBI-005, the first IL-1 (Interleukin-1) receptor inhibitor designed for topical ocular administration, demonstrated a clinically relevant effect in dry eye disease and clinically relevant, statistically significant improvements in ocular itching, ocular tearing and nasal symptoms associated with the late phase allergen response utilizing a modified direct conjunctival allergen model in patients with allergic conjunctivitis.

"We are pleased with these data, which further support the important role of interleukin-1 as a key target for ocular surface inflammation, offering a potential new therapy for the treatment of dry eye disease and allergic conjunctivitis," said Abbie Celniker, PhD, President and Chief Executive Officer of Eleven Biotherapeutics. "We are looking forward to reporting top-line pivotal Phase 3 results for EBI-005 in dry eye disease later this quarter and initiating a Phase 3 study with EBI-005 in allergic conjunctivitis in the second half of this year."

In an oral presentation entitled, "Comparison of Two Clinical Repeat Allergen Challenge Models to Evaluate EBI-005 in the Late Phase Inflammatory Response in Allergic Conjunctivitis," Michael H. Goldstein, MD, Chief Medical Officer of Eleven Biotherapeutics presented data from a Phase 2 study in subjects with moderate to severe allergic conjunctivitis in which EBI-005 was evaluated in two different clinical models adapted for the late phase inflammatory response, an area of high unmet need and the allergic conjunctivitis patient population for which EBI-005 is being developed. Based on these data, EBI-005 will be evaluated utilizing a natural environment model in a planned Phase 3 allergic conjunctivitis study of EBI-005 in the second half of this year. Highlights of the presentation include:

- EBI-005 demonstrated clinically relevant, statistically significant improvement in multiple symptoms associated with late phase allergen response in a modified direct conjunctival allergen model
- Clinically relevant improvements in ocular itching compared with vehicle in a modified direct conjunctival allergen model at the final two efficacy time points

In a poster presentation entitled, "Clinical Development of EBI-005, a Novel Interleukin-1 Receptor Inhibitor, for Patients with Ocular Surface Inflammation," Eleven Biotherapeutics researchers describe how data related to dosing, disease severity, patient selection, and endpoint selection from previously completed clinical studies shaped the design of pivotal, Phase 3 studies for EBI-005 in dry eye disease. Highlights of the poster include:

- EBI-005 demonstrated an effect in both dry eye disease and allergic conjunctivitis
- EBI-005 effect relative to vehicle was more apparent in moderate to severe patients with dry eye disease with patient Ocular Surface Disease Index (OSDI) of greater than 23 and less than 50
- EBI-005 reduced the need for rescue artificial tear use in dry eye disease
- EBI-005 is designed to provide a blockade of interleukin-1, a central driver for signs and symptoms of dry eye disease and allergic conjunctivitis. This mechanism is consistent with activity we have seen in two independent dry eye disease studies and in a Phase 2 study in patients with allergic conjunctivitis

**About EBI-005**

Eleven Biotherapeutics’ most advanced product candidate is EBI-005, a novel, topically-administered interleukin-1 (IL-1) receptor blocker in development as a protein therapeutic for dry eye disease and allergic conjunctivitis. The EBI-005 program is based on the role that elevated levels of the inflammatory cytokine IL-1 play in the initiation and maintenance of the inflammation and pain associated with dry eye disease and the itching and other symptoms associated with allergic conjunctivitis. EBI-005 has been evaluated in a Phase 2 study in patients with moderate to severe allergic conjunctivitis and is currently being evaluated in a pivotal Phase 3 study in dry eye disease.
About Eleven Biotherapeutics

Eleven Biotherapeutics, Inc. is a clinical-stage biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that it applies to the discovery and development of protein therapeutics to treat diseases of the eye. Eleven’s therapeutic approach is based on the role of cytokines in diseases of the eye, the company’s understanding of the structural biology of cytokines and the company’s ability to rationally design and engineer proteins to modulate the effects of cytokines. Cytokines are cell signaling molecules found in the body that can have important inflammatory effects.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company’s strategy, future operations, advancement or maturation of its product candidates and product pipeline, clinical development of the Company's therapeutic candidates, including expectations regarding timing of initiation of clinical trials, patient enrollment and availability of results, regulatory requirements for initiation of clinical trials and registration of product candidates, sufficiency of cash resources 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 clinical trials, availability and timing of data from ongoing clinical trials, whether results of early clinical trials will be indicative of the results of future trials, the adequacy of any clinical models, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals and other factors discussed in the "Risk Factors" section of the Company's most recent report on Form 10-Q filed with the Securities and Exchange Commission on April 30, 2015 and other reports on file 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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