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Atox Bio Enrolls First Patient in Phase 3 Study of Potential Treatment for Necrotizing Soft Tissue Infection (Flesh Eating Bacteria)

Ness Ziona, Israel – Dec 7, 2015 – Atox Bio, developer of immunomodulatory therapeutics for rapidly-progressing infectious diseases in critically ill patients, today announced that it has enrolled the first patient in its Phase 3 study to evaluate AB103 – the first-ever candidate developed for the treatment of Necrotizing Soft Tissue Infections (NSTIs), also known as 'flesh eating bacteria'. The ACCUTE (AB103 **C**linical **C**omposite endpoint St**U**dy in necrotizing soft Tissue Inf**E**ctions) study is conducted at approximately 40 centers in the U.S. and expects to enroll 290 patients who will receive around the clock coverage by highly experienced surgical teams and critical care support.

NSTIs are caused by bacteria such as streptococcus, staphylococcus and others that enter the body via a minor cut, surgery, insect bite or other route and spread to the layer of connective tissue below the skin. The disease moves aggressively, causing significant destruction of tissue, and can quickly become systemic leading to multiple organ dysfunction. NSTIs are rare with 25-29,000 patients per year in the US. They are fatal in 15-20% of cases with major surgical care required for survivors. Currently, there are no approved treatments for NSTI. The standard of care includes prompt and repeated surgical debridement, resuscitation and physiologic support, in addition to antibiotics.

The previously conducted Phase 2 study demonstrated that patients treated with AB103 showed consistent and meaningful improvements. Results from the study were published in *JAMA Surgery*. In addition, the company has conducted a comprehensive retrospective study of NSTI that helped inform the design of the Phase 3 trial.

AB103 has received Orphan Drug status from the FDA and EMA as well as Fast Track designation. Development of AB103 is being supported by a contract with the Biomedical Advanced Research and Development Authority (BARDA).

“We are looking forward to working with the high-quality clinical sites in the ACCUTE study to evaluate AB103 in rapidly advancing NSTIs,” said Dan Teleman, CEO, Atox Bio. “This is the first drug candidate designed specifically to treat this devastating disease.”

Trial Design

Patients in the Phase 3 trial will receive AB103 or placebo, administered as a single dose during or shortly after initial surgical debridement, in addition to standard of care treatment. The primary endpoint is a clinical composite based on local and systemic components of this disease. Secondary endpoints include: time to resolution of organ dysfunction, recovery from acute kidney injury and health economic outcomes such as days on ventilation, days in the ICU and duration of hospital stay.

About AB103

AB103 is a rationally designed short peptide that modulates the patient’s inflammatory response through binding to the CD28 dimer interface. It offers a unique approach in the treatment of infectious diseases by modulating the patient’s own immune system and halting the uncontrolled response to pathogen detection. By targeting the host rather than the bacteria, AB103 has the potential to be effective across the spectrum of pathogen species and avoids public health issues associated with antibiotic resistance. AB103 is the first product candidate specifically developed for NSTI. Atox Bio is exploring the potential for AB103 in other critical care indications where severe acute inflammation is known to play a role in disease progression and pathogenesis.

About Atox Bio

Established by Prof. Raymond Kaempfer and Dr. Gila Arad from the Hebrew University of Jerusalem and Yissum, Atox Bio is a clinical stage biotechnology company that develops novel immune modulators for critically ill patients with severe infections. AB103, Atox Bio’s lead product candidate, is being developed for Necrotizing Soft Tissue Infections (NSTIs) and other indications where severe acute inflammation is a central issue. The company has offices in Israel and the U.S. Investors in Atox Bio include: SR One, OrbiMed and Lundbeckfond Ventures. www.atoxbio.com.