Atox Bio

Atox Bio Announces Independent Safety Monitoring Committee Recommendation To Continue Phase 3 Study Of AB103 In Necrotizing Soft Tissue Infections

Ness Ziona, Israel – Nov 3, 2016 – Atox Bio, a clinical stage company developing novel immunemodulators for critically ill patients with severe infections, today announced the independent Data Monitoring Committee (DMC) completed its pre-planned safety review of the first 50 patients enrolled in the company's ACCUTE trial and recommended that the study, evaluating novel candidate AB103 for the treatment of Necrotizing Soft Tissue Infections ("Flesh Eating Bacteria"), continue without modification.

"We appreciated our interaction with the DMC and are pleased that they have recommended the ACCUTE study continue as designed," said Dr. Wayne Dankner, Chief Medical Officer of Atox Bio. "A treatment is needed for this devastating condition and we are hopeful that AB103 will be the first product specifically approved for NSTI. We are continuing to enroll patients in this Phase 3 study at multiple centers throughout the U.S."

A DMC is a committee of independent clinical research experts who review data in ongoing clinical trials with particular attention to safety. As per the ACCUTE study protocol, the DMC reviews are designed to examine the safety data accumulated during the trial and are scheduled to occur after 50, 100, and 200 patients have completed 28 days of study follow-up.

About AB103

AB103 is a rationally-designed peptide binding to the CD28 co-stimulatory receptor that modulates the host's immune response. By modulating, but not inhibiting, the immune response, AB103 acts to significantly dampen the 'out-of-control' acute inflammatory response that leads to tissue and organ damage.

AB103 is currently being evaluated in the phase 3 ACCUTE (AB103 Clinical Composite endpoint Study in necrotizing soft Tissue Infections) study. ACCUTE is an ongoing randomized, placebo-controlled study, that plans to enroll 290 patients with NSTI at approximately 60 centers in the U.S. Patients are receiving AB103 or placebo, administered as a single dose during or shortly after surgical debridement, in addition to standard of care treatment. The primary end point is

a clinical composite that evaluates both the local and systemic components of this disease.

Atox Bio is exploring the potential for AB103 in NSTI ("Necrotizing Soft Tissue Infection" or "Flesh Eating Bacteria" infections) and additional critical care indications such as Acute Kidney Injury. AB103 has received Orphan Drug status from the FDA and EMA as well as Fast Track designation.

About Atox Bio

Atox Bio is a clinical stage biotechnology company with operations in the US and Israel that develops novel immune modulators for critically ill patients with severe infections. Atox Bio is supported by an investment syndicate including SR One, OrbiMed and Lundbeckfonden Ventures. Atox Bio has an ongoing contract with the Biomedical Advanced Research and Development Authority (BARDA) supporting the development of AB103 in NSTI. Atox Bio was established by Prof. Raymond Kaempfer and Dr. Gila Arad from the Hebrew University of Jerusalem and Yissum.

Atox Bio Contact:
Dan Teleman
+ 972 8-648-4111
dant@atoxbio.com