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Atox Bio's Reltecimod Passes Futility Analysis in Phase 3 ACCUTE Study; Trial Continues as Planned

Ness Ziona, Israel and Chapel Hill, NC –May 23, 2017 – Atox Bio today announced that the Phase 3 ACCUTE study, evaluating Reltecimod (previously AB103) in patients with Necrotizing Soft Tissue Infections, will continue as planned without modification based on the successful completion of a pre-specified futility analysis. The recommendation was made by the independent Data Monitoring Committee (DMC) after evaluating efficacy and safety data from the first 102 patients enrolled.

"We're making significant progress in our mission to develop the first therapeutic specifically approved for NSTI patients," said Dan Teleman, Chief Executive Officer of Atox Bio. "We look forward to continued collaboration with all of the high caliber investigators and study coordinators who are participating in the trial."

About Reltecimod

Reltecimod (AB103) is a rationally designed peptide that binds to the CD28 co-stimulatory receptor to modulate the host's immune response to severe infections. By limiting, but not inhibiting, the body's acute inflammatory response, Reltecimod helps control the immune system in cases where an out of proportion response could otherwise quickly lead to morbidity and mortality.
Reltecimod received Orphan Drug status from the FDA and EMA as well as Fast Track designation.

About NSTI

NSTIs, commonly referred to as "flesh eating bacteria", represent the most severe, rare types of infections involving the skin, skin structure and soft tissues. NSTIs progress rapidly and often result in significant tissue destruction and systemic disease leading to multiple organ dysfunction, failure and death. Currently, there are no approved treatments for NSTIs - the standard of care includes prompt and repeated surgical debridement, aggressive resuscitation and physiologic support, in addition to antibiotics.

About ACCUTE

The phase 3 ACCUTE (AB103 Clinical Composite endpoint StUdy in necrotizing soft Tissue infEctions) study is an ongoing randomized, placebo-controlled study, that plans to enroll 290 patients with NSTI at approximately 60 level 1 trauma sites in the U.S. Patients receive Reltecimod 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.

About Atox Bio

Atox Bio is a late stage clinical biotechnology company with operations in the US and Israel that develops novel immune modulators for critically ill patients with severe infections. Atox Bio is exploring the potential of Reltecimod in NSTI ("Necrotizing Soft Tissue Infection" or "Flesh Eating Bacteria" infections) and additional critical care indications such as Acute Kidney Injury.

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 Reltecimod in NSTI. Atox Bio was established by Prof. Raymond Kaempfer and Dr. Gila Arad from the Hebrew University of Jerusalem and Yissum.