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

Chapel Hill, NC and Ness Ziona, Israel – September 25, 2018 - Atox Bio, a clinical stage biotechnology company developing novel therapies for critically ill patients, today announced the independent Data Monitoring Committee (DMC) completed its pre-planned safety review of the first 200 patients enrolled in the company's ACCUTE trial and recommended that the study, evaluating novel candidate Reltecimod for the treatment of Necrotizing Soft Tissue Infections ("Flesh Eating Bacteria"), continue without modification through completion.

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 Reltecimod 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 and France and look forward to completing the study in 2019".

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 after patients have completed 28 days of study follow-up.

In parallel, Atox Bio is conducting the REAKT Phase 2 study evaluating Reltecimod in patients with Abdominal sepsis induced Acute Kidney Injury.

About Reltecimod

Reltecimod (AB103) is a rationally designed peptide that binds to the CD28 co-stimulatory receptor and restores the host's appropriate immune response to severe infections. By modulating, but not inhibiting, the body's acute inflammatory response, Reltecimod is designed to help control the cytokine storm that could otherwise quickly lead to morbidity and mortality. Reltecimod received Orphan Drug status from the FDA and EMA as well as Fast Track designation for the NSTI indication.

About Necrotizing Soft Tissue Infections (NSTI)

NSTI, commonly referred to as "flesh eating bacteria", represent the most severe types of infections involving soft tissues. NSTI progress rapidly and often result in significant tissue destruction and systemic disease leading to multiple organ failure and death. NSTI are rare with approximately 28,000 patients annually in the US. Currently, there are no approved treatments for NSTI. 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 70 level 1 trauma sites in the US. 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 Acute Kidney Injury (AKI)

Acute Kidney Injury (AKI) involves inflammatory processes in the kidney which can lead to permanent reduction of kidney function and is also associated with an increased risk of death, extended hospitalization, and increased medical cost. There are currently no approved therapies to treat AKI and the only treatment options are dialysis and supportive care.

About Atox Bio

Atox Bio is a late stage clinical biotechnology company that develops novel immune modulators for critically ill patients with severe infections. Atox Bio has an ongoing contract with the Biomedical Advanced Research and Development Authority (BARDA) supporting the development of Reltecimod in NSTI. Major investors in the company include SR One, OrbiMed, Lundbeckfonden Ventures, Arix Bioscience plc and Adams Street Partners. The Company was established by Prof. Raymond Kaempfer and Dr. Gila Arad from the Hebrew University of Jerusalem and Yissum. For additional information http://www.atoxbio.com/

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