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Atox Bio Announces Enrollment of First Patient in Phase 2 Study of Acute Kidney Injury (AKI)

REAKT study to assess the efficacy of Reltecimod in patients with abdominal sepsis and AKI

Ness Ziona, Israel and Chapel Hill, NC – May 29, 2018 - Atox Bio, a clinical stage biotechnology company developing novel therapies for critically ill patients, today announced that the first patient has been enrolled in the Phase 2 REAKT (**R**eltecimod Efficacy for **A**cute **K**idney Injury **T**rial) study.

The Phase 2 randomized, placebo-controlled study, will enroll 120 patients with abdominal sepsis and stage 2/3 AKI (as described by KDIGO criteria) at approximately 50 level 1 trauma centers in the U.S. Patients will receive Reltecimod or placebo, administered as a single dose within 6 hours of the diagnosis of AKI, in addition to standard of care treatment. The primary endpoint is complete recovery from stage 2/3 AKI, defined as alive, free of dialysis and return of serum creatinine to <150% of reference baseline. Important secondary endpoints include survival, resolution of organ dysfunction and other health economic outcomes such as days on the ventilator, days in the ICU, duration of hospital stay and need for hospital readmission.

In parallel, Atox Bio is conducting the ACCUTE Phase 3 study evaluating Reltecimod in patients with Necrotizing Soft Tissue Infections.

Dan Teleman, CEO of Atox Bio, stated, "We are pleased to be initiating the Phase 2 REAKT study. With this study, we are expanding the potential uses of Reltecimod to additional indications in the critical care setting where severe acute inflammation plays a role in the morbidity and mortality of patients. We look forward to closely collaborating with all the high caliber clinical sites, all of which are participating in both the REAKT and ACCUTE studies."

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 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. AKI affects annually around 3 million patients in the US, Europe and Japan. There are currently no approved therapies to treat AKI and the only treatment options are dialysis and supportive care.

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 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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