BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Atox Bio announces completion of pre-planned safety review

25 September 2018 | News

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

Atox Bio, a clinical stage biotechnology company developing novel therapies for critically ill patients has announced that the independent Data Monitoring Committee (DMC) has 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, 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.