



Atox Bio Announces FDA Acceptance to File the NDA for Reltecimod to Treat Suspected Organ Dysfunction or Failure in Patients with Necrotizing Soft Tissue Infection (“Flesh-Eating Disease”)

**- PDUFA Date of September 30, 2021 -
- NDA Filed Under FDA Accelerated Approval Program -**

- Necrotizing soft tissue infection (NSTI) is a rare, life-threatening disease that involves significant necrosis and tissue destruction coupled with systemic organ failure
- If approved, reltecimod would be the first therapy to treat suspected organ dysfunction or failure in patients with NSTI

Durham, NC and Ness Ziona, Israel – December 10, 2020 – [Atox Bio](#) today announced that the U.S. Food and Drug Administration (FDA) has accepted to file the New Drug Application (NDA) for reltecimod with a Prescription Drug User Fee Act (PDUFA) date of September 30, 2021. The proposed indication is for the treatment of suspected organ dysfunction or failure in patients ≥ 12 years of age with NSTI, in conjunction with surgical debridement, antibiotic therapy, and supportive care. If approved, reltecimod could advance the standard of care for patients with NSTI by providing a novel treatment option for these patients.

“The FDA's decision to file the NDA for reltecimod marks another important step forward for Atox Bio in potentially bringing this innovative therapy to patients with NSTI,” said Dan Teleman, CEO of Atox Bio. “The development of reltecimod reinforces Atox Bio’s expertise in immunotherapy, our deep understanding of unmet needs in the critical care setting, and commitment to improving clinical outcomes for patients affected by this rare, life-threatening disease.”

Based on discussions with FDA, Atox Bio submitted an NDA under the Accelerated Approval Program. The Company believes reltecimod meets Accelerated Approval criteria as it treats a serious condition, provides meaningful therapeutic benefit over existing treatments, and demonstrates an effect on an intermediate clinical endpoint; resolution of organ dysfunction, that is reasonably likely to predict the clinical benefit of improved long-term survival.

Results from the ACCUTE study were previously announced [here](#).

About Reltecimod

Reltecimod is a small synthetic peptide that is host-oriented and pathogen-agnostic. With its novel mechanism of action, reltecimod leads to resolution of organ dysfunction or failure by

attenuating the dysregulated immune response frequently seen in patients with NSTI. It binds to the dimer interface of CD28 expressed on T-cells, thereby modulating the acute inflammation that leads to systemic organ failure. By acting on this early step in the host immune response, reltecimod avoids the ongoing concerns about bacterial resistance and is active independent of the pathogen type.

FDA granted reltecimod Fast Track status and orphan drug designation for NSTI. The European Commission granted orphan designation for reltecimod in the treatment of NSTI.

About Necrotizing Soft Tissue Infections (NSTI)

NSTI, commonly referred to as “flesh-eating disease” or “flesh-eating bacteria” is a rare, life-threatening disease that can travel quickly from the infection site and requires frequent, rapid surgical intervention to remove dead and infected tissue to stop further progression and the need for amputation. By their nature, these surgeries often leave patients significantly disfigured. In more serious cases, acute inflammation that results from the infection leads to systemic organ dysfunction in the heart, lungs and/or kidneys. Even with the best current standard of care that includes surgical debridement, broad spectrum antibiotics, and supportive intensive care, multi-organ failure frequently occurs. Mortality rates are significant in both the short- and intermediate-term, and patients who do survive often face long and expensive hospital and rehabilitation center stays.

Hospital discharge data indicate there are approximately 30,000 cases of NSTI in the US each year, with a similar number in Europe. There are currently no therapies specifically approved for NSTI.

About ACCUTE

ACCUTE (**A**B103 **C**linical **C**omposite endpoint **S**tudy in Necrotizing Soft **T**issue inf**E**ctions) was a Phase 3 randomized, placebo-controlled study that enrolled 290 patients across sites in the US and France. It evaluated the safety and efficacy of a single dose of intravenous reltecimod 0.5mg/kg versus placebo (0.9% saline) administered in conjunction with surgical debridement (removal of damaged skin, subcutaneous tissue, fascia, and sometimes muscle), antibiotic therapy, and supportive care in patients ≥12 years of age with NSTI. The trial also assessed hospital discharge status and impact on healthcare resource utilization.

About Atox Bio

Atox Bio is a late stage clinical company that develops immunotherapies for critically ill patients. The ACCUTE study was funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201400013C. 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 Yisum. Please visit www.AtoxBio.com for more information.

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