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## For immediate release

# FDA grants Fast Track designation to Atox Bio's AB103 for the treatment of necrotizing soft tissue infections (NSTI)

## Atox Bio completed patient recruitment of a phase 2 clinical study with results expected by the end of the year.

Ness Ziona, Israel – September 10, 2012 – Atox Bio, a clinical stage biotechnology company engaged in the development of novel immunemodulators for severe infections in critically ill patients, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to AB103, its lead product, currently in development for the treatment of Necrotizing Soft Tissue Infections (NSTI).

Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track emphasizes the critical nature of close, early communication between the FDA and sponsors. The benefits of Fast Track include scheduled meetings to seek FDA input into development plans and the option of submitting a New Drug Application in sections rather than all components simultaneously. These meetings can help the FDA and sponsors reach early agreement on design of the clinical efficacy studies that will be needed to support approval.

Atox Bio completed recruitment of 40 patients in a phase 2 proof of concept study evaluating AB103's clinical benefit when administered in addition to standard of care. Efficacy data from these 40 patients is expected by the end of this year.

NSTI includes several distinctive clinical diagnoses that share clinical features representing the most severe types of infections involving the skin, skin structure and soft tissue with a high mortality rate. Currently, there are no approved treatments for NSTI. The existing principles of NSTI management include early diagnosis with prompt and repeated surgical debridement, aggressive resuscitation and physiologic support, in addition to antimicrobial drugs. As neither surgical debridement nor antibacterial therapy directly address the immunological pathogenesis of NSTI, modulating the host inflammatory response could lead to important clinical benefits in morbidity and mortality.

"Patients with necrotizing soft tissue infections have a devastating disease with a high risk of death. Those who survive require multiple surgeries and many require amputations" said Dr. Eileen Bulger, Professor of Surgery and Chief of Trauma at the University of Washington Harborview Medical Center. "We are excited to explore new treatment options to help manage these critically ill patients. It is our hope that AB103 will be a valuable adjunct in the management of this disease".

"The Fast Track designation recognizes the significant unmet need that exists in the treatment of NSTI and the important role that AB103 can play in treating these patients. This is a major milestone for Atox Bio that comes after the FDA has granted AB103 Orphan Drug designation in October 2011" said Dan Teleman, Atox Bio's CEO. "We look forward to working closely with the FDA to bring to market as quickly as possible what could be the first agent to help NSTI patients".

AB103 is a rationally designed short peptide acting as a CD28 modulator regulating the host's inflammatory response, improving the host's ability to effectively fight the infection. Atox Bio is implementing this novel mode of action into a unique approach to treating infectious diseases by targeting the host's immune system, rather than the pathogen, thereby providing solution for bacterial infections with broad-spectrum coverage, independent of pathogen type and eliminating the risk of drug resistance.

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## About Atox Bio

Established in 2003 by Prof. Raymond Kaempfer and Dr. Gila Arad from the faculty of Medicine of the Hebrew University of Jerusalem and Yissum, the technology transfer company of the Hebrew University of Jerusalem, Atox Bio is a clinical stage biotechnology company that develops novel immunemodulators for severe infections in critically ill patients.
AB103, Atox Bio's lead product, is initially being developed for necrotizing soft tissue infections.
Pre-clinical research is conducted in the areas of organ injury and inflammatory diseases.
Over $12 million were granted for biodefense research by DARPA and NIAID for the development of therapeutics against a broad family of bacterial toxins, the superantigens.
Atox Bio was included as one of the portfolio companies of Integra Holdings, a holding company formed by Yissum.

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