

For immediate release

Atox Bio granted orphan drug designation for AB103 for the treatment of necrotizing soft tissue infections (NSTI).

Ness Ziona, Israel – October 25, 2011 - Atox Bio today announced that the FDA Office of Orphan Products Development has granted orphan drug designation for AB103 for the treatment of necrotizing soft tissue infections.

Necrotizing soft tissue infections (NSTI) includes several distinctive clinical diagnoses that share clinical features representing the most severe types of infections involving the skin, skin structures and soft tissue and having a high mortality rate. Currently, there are no approved treatments for NSTI. The current principles of management include early diagnosis with prompt and repeated surgical debridement, aggressive resuscitation and physiologic support, in addition to antimicrobial drugs. NSTI is a fast progressing disease that develops when the initial, appropriate host response to an infection becomes amplified and is then dysregulated. As neither surgical debridement nor antibacterial therapy directly address the immunological pathogenesis of NSTI, reducing the host inflammatory response could lead to important clinical benefits in both morbidity and mortality.

AB103 is a rationally designed short peptide acting as a CD28 modulator regulating the host's inflammatory response. AB103 has successfully completed a phase 1 study and will shortly go into a phase 2 proof of concept study evaluating its clinical benefit when administered in addition to standard of care in up to 56 NSTI patients at 7 leading surgical trauma centers in the US.

"The FDA's decision to grant AB103 orphan drug designation is another important milestone for our clinical program and underscores the urgency of the need for new treatments for this life threatening infection. We look forward to continue working cooperatively with the agency to advance this potentially important new therapy through the clinical testing and regulatory process" said Dan Telem, Chief Executive Officer of Atox Bio.

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