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AB103 granted orphan medicinal product designation in the European Union for the treatment of necrotizing soft tissue infections (NSTI).

Ness Ziona, Israel – August 5, 2014 - Atox Bio today announced that the European Commission has granted AB103 (Sodium acetate salt of the synthetic peptide H-D-Ala-Ser-Pro-Met-Leu-Val-Ala-Tyr-Asp-D-Ala-OH) orphan medicinal product designation (EU/3/14/1294) for the treatment of necrotizing soft tissue infections. Atox Bio is represented in the EU by Dr. Ulrich Granzer as agent.
In addition to a 10-year period of marketing exclusivity in the EU after product approval, orphan designation provides fee reduction for companies seeking protocol assistance from the EMA, direct access to centralized marketing authorization as well as fee reduction for the centralized marketing authorization.

NSTI are rare, fast progressing infections that result in significant tissue destruction and systemic disease leading to multiple organ dysfunction. Currently, there are no approved treatments for NSTI and the standard of care includes prompt and repeated surgical debridement, aggressive resuscitation and physiologic support, in addition to antibiotics.

AB103, a novel immunomodulator, is a short peptide that modulates the host's inflammatory response through binding to the CD28 dimer interface. It offers a unique approach in the treatment of infectious diseases by modulating, but not inhibiting, the host immune system. This approach of targeting the host response rather than the pathogen precludes the rapid generation of drug resistance and provides a multisystem solution for bacterial infections with broad-spectrum coverage, independent of pathogen type.

AB103 successfully completed a Phase 2 study in patients with NSTI. The results demonstrated that patients treated with AB103 had a meaningful improvement across multiple end points. Patients treated with AB103 had a faster resolution of organ dysfunction, spent fewer days in the intensive care unit, required fewer days of assisted ventilation and needed fewer surgical procedures to remove infected tissue. A pivotal study is planned for the second half of 2015.

"Obtaining orphan designation for AB103 in the European Union is an important regulatory milestone for Atox Bio, supporting our global development plan after having received Orphan Drug designation and Fast Track status from the FDA. We are continuing development to bring to patients what could be the first therapy for this devastating and rare disease" said Dan Teleman, Chief Executive Officer of Atox Bio.