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Atox Bio Announces Exercise by BARDA of Next Option Period to Support Continued Development of Reltecimod for NSTI

Durham, NC and Ness Ziona, Israel – June 18, 2019 - Atox Bio, a late stage clinical company developing immunotherapies for critically ill patients, today announced the Biomedical Advanced Research and Development Authority (BARDA) has exercised the next option on a performance-based contract with for the development of Reltecimod in patients with Necrotizing Soft Tissue Infections (NSTI). Reltecimod is the Company's lead product in development and is currently in late stage clinical trials for Necrotizing Soft Tissue Infections (NSTI,) and Sepsis-associated Acute Kidney Injury (AKI). Results of the ACCUTE NSTI Phase 3 study are expected by the end of 2019.

The exercise of this option brings the current commitment from BARDA to $22 million. The contract covers the pivotal Phase 3 study of Reltecimod, including manufacturing and regulatory activities.

“We appreciate and continue to benefit from BARDA’s ongoing support in the development of Reltecimod as a novel, host-based, immunomodulatory therapy to treat critically ill patients,” said Dan Teleman, Chief Executive Officer of Atox Bio. "Our Phase 3 trial for NSTI is on track to report data this year and assuming successful results, we look forward to continuing to work together with BARDA to bring this potentially important new therapy to patients."

About Reltecimod

Reltecimod is a rationally designed peptide that binds to the CD28 co-stimulatory receptor that modulates the host’s immune response to enhances the resolution of organ failure and other morbidities in condition associated with a severe acute inflammatory response. Reltecimod received Orphan Drug status from the FDA and EMA as well as Fast Track designation for the NSTI indication.

About Necrotizing Soft Tissue Infections (NSTI)

NSTI is a rapidly progressing condition that often result in significant tissue destruction and systemic disease leading to multiple organ failure and death. NSTI are rare, with an estimated 30,000 patients annually in the US. Currently, there are no approved treatments for NSTI. The standard of care includes prompt and repeated surgical debridement, aggressive resuscitation and physiologic support.

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About ACCUTE

The Phase 3 ACCUTE (AB103 Clinical Composite endpoint StUdy in necrotizing soft Tissue infEctions) is an ongoing randomized, placebo-controlled study, that plans to enroll 290 patients with NSTI at approximately 70 centers in the US and France. Patients receive Reltecimod or placebo, administered as a single dose during or shortly after surgical debridement, in addition to standard of care treatment. The primary end point is a clinical composite that evaluates both the local and systemic components of this disease.

About Acute Kidney Injury (AKI)

Acute Kidney Injury (AKI) involves inflammatory processes in the kidney which can lead to permanent reduction of kidney function and is also associated with an increased risk of death, extended hospitalization, and increased medical cost. There are currently no approved therapies to treat AKI and the only treatment options are dialysis and supportive care.

About REAKT

The REAKT (Reltecimod Efficacy for Acute Kidney Injury Trial) is an ongoing randomized, placebo-controlled study, that is enrolling patients with abdominal sepsis and severe AKI at approximately 70 centers in the US and Europe. Patients receive Reltecimod or placebo, administered as a single dose after the diagnosis of AKI, in addition to standard of care treatment. The primary endpoint is a composite end point assessing the durable loss of kidney function in patients.

About Atox Bio

Atox Bio is a late stage clinical company that develops immunotherapies for critically ill patients who have organ failure in conditions such as NSTI and sepsis. Atox Bio has an ongoing contract with the Biomedical Advanced Research and Development Authority (BARDA) supporting the development of Reltecimod in NSTI. 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 Yissum. For additional information http://www.atoxbio.com/.

About BARDA

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of

the necessary vaccines, drugs, therapies and diagnostic tools for public health medical emergencies. This ACCUTE study has been 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, under Contract No. HHSO100201400013C.

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