

### 1 - ATOX/ Visit 1 - Screening - Eligibility

Subject Initials

  

Site #

 

Subject ID Number:

    

#### INCLUSION CRITERIA

**If the answer to any of these is "NO", the subject CANNOT continue in the study**

1. Age: >18 years  
 Yes  No
2. Surgical confirmation of NSTI by attending surgeon-Please complete the Screening NSTI information form  
 Yes  No
3. mSOFA score greater than or equal to 3  
 Yes  No

**Screening mSOFA score measurements must be performed prior to first surgery. It can be evaluated any time after arrival at study site hospital, although no more than 4 hours prior to anticipated first surgery. Sites are encouraged to re-evaluate mSOFA score as close to surgery as feasible for patients not meeting mSOFA  $\geq 3$  inclusion criteria during initial screening. Baseline mSOFA will include measurements of the score components in the following organ/systems (with one organ having a score of at least 2 at screening): respiratory, cardiovascular, renal, coagulation and CNS.**

4. IV drug administration within 6 hours from the clinical diagnosis and the decision at the study site, to have an urgent surgical exploration and debridement  
 Yes  No
5. If a woman is of childbearing potential, she must consistently use an acceptable method of contraception from baseline through Day 28. Women of childbearing potential must have a negative  $\beta$ -subunit hCG pregnancy test immediately prior to study entry.  
 Yes  No  Not applicable
6. If a male patient's sexual partner is of childbearing potential, the male patient must acknowledge that they will consistently use an acceptable method of contraception from baseline through Day 28.  
 Yes  No  Not applicable
7. Signed and dated ICF as defined by the IRB. If patient is unable to comprehend or sign the ICF, patient's legally acceptable representative may sign the ICF.  
 Yes  No

**\*\*Please be sure to record the consent process in the patient's chart.**

**\*\*Please be sure to provide a COPY of the consent to the patient/LAR.**

**\*\*Please maintain ORIGINAL ICF in patients study binder.**

#### EXCLUSION CRITERIA

**If the answer to any of these is "Yes", the subject is ineligible and CANNOT continue in the study**

1. BMI > 51  
 Yes  No Height \_\_\_\_\_ Weight \_\_\_\_\_
2. Patient who has been operated at least once for the current NSTI infection and had a curative deep tissue debridement.  
 Yes  No
3. Patients with overt peripheral vascular disease in the involved area - associated with ischemic wounds/ulcers or gangrene, and /or other significant symptoms of inadequate vascular supply or where limb amputation is considered likely within 7 days due to the peripheral vascular disease  
 Yes  No

4. Diabetic patients with peripheral vascular disease who present with below the ankle infection  
 Yes  No
5. Patient with burn wounds  
 Yes  No
6. Current condition of:  
(a) Intractable hypotension  
(b) a patient with respiratory failure such that an SaO<sub>2</sub> of 80% cannot be achieved  
(c) a patient with refractory coagulopathy  
 Yes  No
7. **Chronic neurological impairment that leads to a neuro mSOFA component  $\geq 2$**   
 Yes  No
8. Recent cerebrovascular accident in the last 3 months  
 Yes  No
9. Patients with cardiac arrest requiring cardiopulmonary resuscitation within the past 30 days  
 Yes  No
10. Patient is not expected to survive throughout 28 days of study due to underlying medical condition, such as poorly controlled neoplasm (e.g. Stage III or IV cancer)  
 Yes  No
11. Patient or patient's family are not committed to aggressive management of the patient's condition  
 Yes  No
12. Any concurrent medical condition, which in the opinion of the Investigator, may compromise the safety of the patient or the objectives of the study or the patient will not benefit from treatment such as:
- CHF {NYHA class III-IV}
  - Severe COPD {GOLD stage III-IV. or chronic hypoxemia (PaO<sub>2</sub> <55 mmHg) on room air, or chronic use of home ventilation, or unable to climb stairs or perform household duties due to chronic obstructive disease resulting in severe exercise restriction, or use of continuous home oxygen prior to hospital admission (sleep apnoea treated with continuous positive airway pressure or biphasic positive airway pressure oxygen during sleep is acceptable)}Severe COPD
  - Liver dysfunction {Childs-Pugh class C}
  - Immunosuppression (see Appendix F, Section 15.6 for list of excluded immunosuppressive medications)
  - Neutropenia < 1,000 cells/mm<sup>3</sup> not due to the underlying infection
  - **Idiopathic Thrombocytopenic Purpura**
  - Receiving or about to receive chemotherapy or biologic anti-cancer treatment although hormonal Manipulation therapies for breast and prostate malignancies are permitted
  - Hematological and lymphatic malignancies in the last 5 years
- Yes  No
13. Known HIV infection with CD4 count is less than 200 cells/mm<sup>3</sup> or is less than 14% of all Lymphocytes  
 Yes  No
14. Patients with known chronic kidney disease documented pre-illness creatinine value(s) greater than or equal to 2.0 or patients receiving renal replacement therapy for chronic kidney disease: either hemodialysis, peritoneal dialysis, hemofiltration such as Continuous Veno-Venous Hemofiltration (CVVH) or hemodiafiltration  
 Yes  No

15. Patients that are treated with continuous hemofiltration (e.g. Continuous Veno-Venous Hemofiltration) for acute kidney dysfunction, not due to NSTI, starting prior to study drug administration  
 Yes  No
16. Pregnant or lactating women  
 Yes  No  Not applicable
17. Previous enrollment in a clinical trial involving investigational drug or a medical device within 30 days before provision of written informed consent for the study or within five half-lives of the investigational drug, whichever is longer  
 Yes  No
18. Previous enrollment in this protocol, ATB-202 or the Phase 2 trial of AB103, ATB-201  
 Yes  No

**PLEASE ENSURE ALL OF THE INCLUSION AND EXCLUSION CRITERIA QUESTIONS HAVE BEEN ANSWERED COMPLETELY TO DETERMINE ELIGIBILITY**

IS THE SUBJECT ELIGIBLE TO CONTINUE IN THE STUDY?

Yes  No

Staff initials:

--	--	--

Physician signature\_\_\_\_\_

**PLEASE CONSIDER THAT DAY 1 (STUDY DRUG ADMINISTRATION DAY) ENDS AT MIDNIGHT. IF STUDY DRUG DOSING IS CLOSE TO MIDNIGHT AND STILL WITHIN THE 6 HOUR TREATMENT WINDOW, IF POSSIBLE PLEASE ADMINISTER STUDY DRUG AT 12:01. THIS WILL ALLOW 24 HOURS TO PERFORM/COLLECT DAY 1 ASSESSMENT DATA AS OPPOSED TO ADMINISTERING STUDY DRUG AT 23:45 AND HAVING 15 MINUTES FOR ALL DAY 1 ASSESSMENTS.**