**Full Title**
A Phase III, Randomized, Multicenter, Parallel-Group, Double-Blind, Double-Dummy Study in Adolescent and Adult Female Participants Comparing the Efficacy and Safety of Gepotidacin to Nitrofurantoin in the Treatment of Uncomplicated Urinary Tract Infection (Acute Cystitis)

**Principal Investigator**
Stephen Fehnel, MD

**Sub-Investigators**
Xuezhi Jiang, MD
Mark Martens, MD
Christopher Pugh, DO

**Study Objectives**
To assess the combined clinical and microbiological efficacy of gepotidacin compared to nitrofurantoin, at the Test-of-Cure (TOC) Visit, in female participants with acute cystitis in the Microbiological Intent-to-Treat nitrofurantoin-Susceptible (micro-ITT NTF-S) Population

**Inclusion Criteria**
- Female at least 18 years of age and not pregnant, not breastfeeding, and is not of childbearing potential or agrees to follow contraceptive guidance from the Baseline Visit through completion
- Body weight ≥40 kg
- The participant has 2 or more of the following clinical signs and symptoms of acute cystitis with onset ≤72 hours prior to study entry: dysuria, frequency, urgency, or lower abdominal pain
- The participant has nitrite or pyuria (>15 WBC/HPF or the presence of 3+/moderate leukocyte esterase) from a pretreatment clean-catch midstream urine sample based on local laboratory procedures

**Exclusion Criteria**
- The participant has a body mass index ≥40.0 kg/m² or a body mass index ≥35.0 kg/m² and is experiencing obesity-related health conditions such as high blood pressure or uncontrolled diabetes
The participant is immunocompromised or has altered immune defenses that may predispose the participant to a higher risk of treatment failure and/or complications. Participants with a known CD4 count of <200 cells/mm³ should not be enrolled.

The participant has any of the following medical conditions that require medication that may be impacted by inhibition of acetylcholinesterase, such as:
  - Poorly controlled asthma or chronic obstructive pulmonary disease at Baseline and, in the opinion of the investigator, not stable on current therapy
  - Acute severe pain, uncontrolled with conventional medical management
  - Active peptic ulcer disease
  - Parkinson’s disease
  - Myasthenia gravis
  - A history of seizure disorder requiring medications for control

The participant has acute cystitis that is known or suspected to be due to fungal, parasitic, or viral pathogens; or known or suspected to be due to Pseudomonas aeruginosa or Enterobacteriaceae (other than E. coli) as the contributing pathogen.

**Affiliations & Sponsors**
- GSK

**Status**
- Open to Enrollment

**Keywords**
- Acute Cystitis, UTI, gepotidacin, nitrofurantoin