A Study of LBP-EC01 in the Treatment of Acute Uncomplicated UTI Caused by Drug Resistant E. Coli (ELIMINATE Trial)

NCT05488340

Status	RECRUITING
Phase	Phase 2
Sponsor	Locus Biosciences
Enrollment	318 participants

Key Eligibility Criteria

Inclusion (10)

• History of UTI in the past 12 months and prior or current uUTI caused by AMR E. coli (as single pathogen or part of polymicrobial infection where E. coli is the predominant pathogen). Please note that the current infection can be used to meet the requirement of AMR E. coli documentation.

• Able to supply a mid-stream, clean catch urine sample for microbiological analysis.

• Active acute uUTI infection defined by:

• a. Evidence of pyuria: i. \>10 white blood cell (WBC)/mL3 on microscopic evaluation of spun, clean, mid-stream urine specimen or \>3 WBC/high power field on unspun clean, mid-stream urine specimen, AND/OR ii. Dipstick analysis of a clean, mid-stream urine specimen positive for leukocytes, AND b. At least 2 of the following signs or symptoms of UTI: dysuria, urinary frequency, urinary urgency, or suprapubic pain

• Willing to comply with all aspects of study design including study restrictions, blood, urine, and stool sampling, and scheduled study visits.

... and 5 more (see full listing online)

Exclusion (13)

• Signs or symptoms of systemic illness such as fever greater than 38° Centigrade/ Celsius, shaking chills, or other clinical manifestations suggestive of complicated UTI.

• Treatment with other antibacterial drugs including those that are effective for treatment of the acute uUTI or prevention of recurrent UTI in the 5 days prior to Screening unless the recovered pathogen demonstrates resistance to the initial antibiotic and clinical symptoms persist. In postmenopausal women vaginal estrogen replacement therapy is permitted so long as patient meets all other eligibility criteria, that the dose and regimen has be stable for \> 3 months from Screening (D1/V1), and that there is no planned change to therapy through the 6-month follow-up period or study discontinuation.

• Clinical symptoms for more than 5 days before Screening.

• Presence of indwelling urinary bladder catheters, urinary tract anatomical abnormalities that increase UTI risk or lead to a post void residual (PVR) urine volume \> 150mL, poorly controlled diabetes mellitus (diagnosed but is not being treated/managed by a physician's care or HbA1c \>8), current symptomatic or larger than 5mm renal calculi, or advanced renal dysfunction (determined by eGFR \< 45 mL/min/1.73 m2). Patients with vaginal prolapse beyond the hymen with Valsalva (e.g., when coughing).

• Individuals considered to be immunocompromised.

... and 8 more (see full listing online)

Locations (17 total)

Research Site 138, Fresno, California, United States
Research Site 131, Lancaster, California, United States
Research Site 123, Los Angeles, California, United States
... and 14 more locations

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