PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A Phase 2, Multicenter, Randomized, Double-blind, Comparative Study to Evaluate the Efficacy and Safety of Intravenous Coadministered Ceftaroline Fosamil and NXL104 Versus Intravenous Doripenem in Adult Subjects With Complicated Urinary Tract Infection

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This is a study in adult subjects with complicated urinary tract infection (cUTI) comparing
treatment with intravenous (IV) coadministered ceftaroline fosamil and NXL104 versus
treatment with IV doripenem.

Brief Summary in Scientific Language

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Organizational Data

- DRKS-ID: **DRKS00010303**
- Date of Registration in DRKS: **2016/04/14**
- Date of Registration in Partner Registry or other Primary Registry: **2011/01/13**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01281462 (ClinicalTrials.gov)**
- Sponsor-ID: **CXL-MD-02 (Forest Laboratories)**

Health condition or Problem studied

- Free text: **Urinary Tract Infections**
- ICD10: **N39.0 - Urinary tract infection, site not specified**

Interventions/Observational Groups

- Arm 1: **Drug: Ceftaroline fosamil and NXL104 (q8h)**
- Arm 2: **Drug: Ceftaroline fosamil and NXL104 (q12h)**
- Arm 3: **Drug: Doripenem**
- Arm 4: **Drug: Placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Microbiological response of Microbiologically Evaluable (ME) at Test of Cure (TOC); time frame: 5 to 11 days after last dose of study drug; The number and percentage of subjects in each treatment group recorded as having a favorable microbiological response in the ME Population at Test-of-Cure (TOC)
- Evaluate safety; time frame: from administration of first dose of study drug to the Late -Follow -Up (LFU) visit (28 to 42 days after administration of the last dose of study drug); Evaluate the safety of coadministered IV ceftaroline fosamil and NXL104 in subjects with cUTI. Summaries of AEs, SAEs, deaths, laboratory evaluations (hematology and coagulation studies, comprehensive metabolic panel, and urinalysis), vital signs, ECGs, and physical examinations will be provided for each treatment group.

Secondary Outcome

- Clinical response in CE at Test of Cure; time frame: 5 to 11 days after last dose of study drug; The number and percentage of subjects in each treatment group classified as clinical cure Clinically Evaluable (CE) Population at TOC

Countries of recruitment

- BG **Bulgaria**
- DE **Germany**
- LB **Lebanon**
- PL **Poland**
- RU **Russian Federation**
- TR **Turkey**
- US **United States**

Locations of Recruitment

- **Investigational Site, Berlin**
- **Investigational Site, Freiburg**
- **Investigational Site, Gießen**
- **Investigational Site, Kassel**
- **Investigational Site, Minden**
- **Investigational Site, Muellheim**
- **Investigational Site, Paderborn**
- **Investigational Site, Planegg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/12/31**
- Target Sample Size: **217**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Subjects must meet the following inclusion criteria:

- Have pyuria (white blood cells in the urine)

- Clinical signs and/or symptoms of cUTI (including acute pyelonephritis)

- Have a pretreatment baseline urine culture specimen

- The subject's infection would require initial treatment with IV antibiotics

- The subject must require initial hospitalization to manage the cUTI by the standard of care.

Exclusion criteria

Subjects must NOT meet any of the following exclusion criteria:

- History of any hypersensitivity or allergic reaction to any β-lactam (eg, cephalosporins, penicillins, carbapenems)

- Confirmed fungal urinary tract infection

- Intractable UTI anticipated to require more than 10 days of study drug therapy

- Complete, permanent obstruction of the urinary tract

- Permanent indwelling bladder catheter or instrumentation (including nephrostomy) or current urinary catheter that will not be removed during IV study drug administration

- Suspected or confirmed perinephric or intrarenal abscess

- Suspected or confirmed prostatitis

- Ileal loops or vesico-ureteral reflux

- Impairment of renal function including a calculated CrCl of < 30 mL/min, requirement for peritoneal dialysis, hemodialysis or hemofiltration, or oliguria

- Renal transplantation

- Life expectancy less than 3 months

- Evidence of significant hepatic, hematological, or immunologic disease or

dysfunction

- **Past or current history of epilepsy or seizure disorder**
- **Women who are pregnant or nursing**

Addresses

■ **Primary Sponsor**

Forest Laboratories

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Forest Laboratories
Medical Monitor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Public Queries**

Forest Laboratories
Medical Monitor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

■ **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***

[---]*

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/07/01**

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 3
- Last processed date by ClinicalTrials.gov: 2016/07/17
Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.