Clinical trial results:
A Multicenter, Double-Blind, Randomized, Phase 3 Study to Compare the Safety and Efficacy of Intravenous CXA-201 and Intravenous Levofloxacin in Complicated Urinary Tract Infection, Including Pyelonephritis

Summary

EudraCT number	2010-023453-11
Trial protocol	PL ES SI BG EE LV
Global end of trial date	04 September 2013

Results information

Result version number	v1
This version publication date	06 May 2016
First version publication date	06 May 2016
Summary attachment (see zip file)	statement regarding sister study results (7625A-005+6_2016-04-20_EudraCT_DualResultStatement.docx)

Trial information

Trial identification

Sponsor protocol code	CXA-cUTI-10-05

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Cubist Pharmaceuticals, Inc.
Sponsor organisation address	65 Hayden Avenue, Lexington, United States,
Public contact	Study Director, Cubist Pharmaceuticals, Inc., 1 7818608660,
Scientific contact	Study Director, Cubist Pharmaceuticals, Inc., 1 7818608660,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 September 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 September 2013
Global end of trial reached?	Yes
Global end of trial date	04 September 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a Phase 3, multicenter, prospective, randomized, double-blind, double dummy study of CXA-201 intravenous (IV) infusions (1500 milligrams [mg] total, including 1000 mg ceftolozane and 500 mg tazobactam, every 8 hours [q8h]) versus levofloxacin IV infusions (750 mg once a day [qd]) for the treatment of adults with a complicated urinary tract infection (cUTI; including pyelonephritis).

Two Phase 3 protocols were initiated (CXA-cUTI-10-04 and CXA-cUTI-10-05). Then, Cubist and the FDA agreed that integrated data from the 2 protocols could be analyzed and reported in a single Clinical Study Report. A total of 1083 subjects were enrolled: 558 to CXA-cUTI-10-04 and 525 to CXA-cUTI-10-05. Of these, 552 and 516 received treatment.

One subject’s age was unknown after enrollment, so this subject is counted in the “Adults (18-64 years)” age category for the purpose of this report.

Protection of trial subjects:

This study was conducted in compliance with institutional review board (IRB)/independent ethics committee (IEC) and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, in accordance with applicable regulations regarding clinical safety data management (E2A, E2B R3), with ICH guidelines regarding scientific integrity (E4, E8, E9, and E10), and with guidelines of local regulatory agencies. In addition, this study adhered to all local regulatory requirements, and requirements for data protection.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Brazil: 17
Country: Number of subjects enrolled	Bulgaria: 15
Country: Number of subjects enrolled	Chile: 1
Country: Number of subjects enrolled	Colombia: 41
Country: Number of subjects enrolled	Croatia: 12
Country: Number of subjects enrolled	Estonia: 27
Country: Number of subjects enrolled	Georgia: 60
Country: Number of subjects enrolled	Hungary: 71
Country: Number of subjects enrolled	India: 38
Country: Number of subjects enrolled	Israel: 24
Country: Number of subjects enrolled	Latvia: 53

Country: Number of subjects enrolled	Mexico: 27
Country: Number of subjects enrolled	Moldova, Republic of: 17
Country: Number of subjects enrolled	Peru: 32
Country: Number of subjects enrolled	Serbia: 5
Country: Number of subjects enrolled	Poland: 77
Country: Number of subjects enrolled	Romania: 115
Country: Number of subjects enrolled	Russian Federation: 188
Country: Number of subjects enrolled	Slovakia: 5
Country: Number of subjects enrolled	Slovenia: 7
Country: Number of subjects enrolled	South Africa: 13
Country: Number of subjects enrolled	Korea, Republic of: 16
Country: Number of subjects enrolled	Thailand: 39
Country: Number of subjects enrolled	Ukraine: 160
Country: Number of subjects enrolled	United States: 23
Worldwide total number of subjects	1083
EEA total number of subjects	382

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	802
From 65 to 84 years	261
85 years and over	20

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects enrolled in this study were at least 18 years of age with a complicated urinary tract infection. Subjects were eligible to participate in the study if they met all of the inclusion criteria and none of the exclusion criteria at the Screening visit.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	CXA-201 as treatment for cUTI

Arm description:

CXA-201 IV infusion (1000 mg of ceftolozane and 500 mg of tazobactam) every 8 hours for 7 days.

Arm type	Experimental
Investigational medicinal product name	CXA-201
Investigational medicinal product code	
Other name	Ceftolozane/Tazobactam
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

1500 mg (1000 mg of ceftolozane and 500 mg of tazobactam) every 8 hours for 7 days

Arm title	Levofloxacin as treatment for cUTI

Arm description:

Levofloxacin IV infusion (750 mg qd) for 7 days.

Arm type	Active comparator
Investigational medicinal product name	levofloxacin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

750 mg once daily for 7 days

Number of subjects in period 1	CXA-201 as treatment for cUTI	Levofloxacin as treatment for cUTI
Started	543	540
Completed	513	515
Not completed	30	25
Consent withdrawn by subject	13	10
Adverse event, non-fatal	-	1
Not specified	7	4
Lost to follow-up	9	10
Lack of Informed Consent	1	-

Baseline characteristics

Reporting groups	
Reporting group title	CXA-201 as treatment for cUTI
Reporting group description:	
CXA-201 IV infusion (1000 mg of ceftolozane and 500 mg of tazobactam) every 8 hours for 7 days.	
Reporting group title	Levofloxacin as treatment for cUTI
Reporting group description:	
Levofloxacin IV infusion (750 mg qd) for 7 days.	

Reporting group values	CXA-201 as treatment for cUTI	Levofloxacin as treatment for cUTI	Total
Number of subjects	543	540	
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	49.8	48.7	
standard deviation	± 19.6	± 20.1	-
Gender, Male/Female Units: participants			
Female			0
Male			0

Subject analysis sets	
Subject analysis set title	CXA-201 as treatment for cUTI - Safety Population
Subject analysis set type	Safety analysis
Subject analysis set description:	
All subjects who received any amount of the study drug. Subjects in the Safety population were categorised based on the actual treatment that the subjects received, irrespective of the treatment to which they were randomised.	
Subject analysis set title	Levofloxacin as treatment for cUTI - Safety Population
Subject analysis set type	Safety analysis
Subject analysis set description:	
All subjects who received any amount of the study drug. Subjects in the Safety population were categorised based on the actual treatment that the subjects received, irrespective of the treatment to which they were randomised.	
Subject analysis set title	CXA-201 as treatment for cUTI - ME Population
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
The microbiologically evaluable (ME) population is a subset of the clinically evaluable (CE) population who adhered to study procedures and had an appropriately collected urine culture specimen and interpretable urine culture result at the TOC visit. The CE population was a subset of the intention-to-treat (ITT) population of subjects who received an adequate amount of study drug, met the protocol-specific disease definition of cIAI, adhered to study procedures, and had a test-of-cure (TOC) visit within the specified visit window. Subjects in this population had no confounding factors that interfered with the assessment of outcome and met the key inclusion/exclusion criteria and additional protocol-defined criteria.	
Subject analysis set title	Levofloxacin as treatment for cUTI - ME Population
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The microbiologically evaluable (ME) population is a subset of the clinically evaluable (CE) population who adhered to study procedures and had an appropriately collected urine culture specimen and interpretable urine culture result at the TOC visit. The CE population was a subset of the intention-to-treat (ITT) population of subjects who received an adequate amount of study drug, met the protocol-specific disease definition of cIAI, adhered to study procedures, and had a test-of-cure (TOC) visit within the specified visit window. Subjects in this population had no confounding factors that interfered with the assessment of outcome and met the key inclusion/exclusion criteria and additional protocol-defined criteria.

Subject analysis set title	CXA-201 as treatment for cUTI - mMITT Population
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The microbiological modified intent-to-treat (mMITT) population was a subset of the modified intent-to-treat (MITT) population that included subjects who had at least 1 qualified uropathogen from a study-qualifying pretreatment baseline urine specimen. The MITT population consisted of all randomised subjects who received any amount of study drug.

Subject analysis set title	Levofloxacin as treatment for cUTI - mMITT Population
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The microbiological modified intent-to-treat (mMITT) population was a subset of the modified intent-to-treat (MITT) population that included subjects who had at least 1 qualified uropathogen from a study-qualifying pretreatment baseline urine specimen. The MITT population consisted of all randomised subjects who received any amount of study drug.

Reporting group values	CXA-201 as treatment for cUTI - Safety Population	Levofloxacin as treatment for cUTI - Safety Population	CXA-201 as treatment for cUTI - ME Population
Number of subjects	533	535	340
Age categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	±	±	±
Gender, Male/Female Units: participants			
Female	374	380	
Male	159	155	

Reporting group values	Levofloxacin as treatment for cUTI - ME Population	CXA-201 as treatment for cUTI - mMITT Population	Levofloxacin as treatment for cUTI - mMITT Population
Number of subjects	353	398	402
Age categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	±	±	±
Gender, Male/Female Units: participants			
Female			
Male			

End points

End points reporting groups

Reporting group title	CXA-201 as treatment for cUTI

Reporting group description:

CXA-201 IV infusion (1000 mg of ceftolozane and 500 mg of tazobactam) every 8 hours for 7 days.

Reporting group title	Levofloxacin as treatment for cUTI

Reporting group description:

Levofloxacin IV infusion (750 mg qd) for 7 days.

Subject analysis set title	CXA-201 as treatment for cUTI - Safety Population
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects who received any amount of the study drug. Subjects in the Safety population were categorised based on the actual treatment that the subjects received, irrespective of the treatment to which they were randomised.

Subject analysis set title	Levofloxacin as treatment for cUTI - Safety Population
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects who received any amount of the study drug. Subjects in the Safety population were categorised based on the actual treatment that the subjects received, irrespective of the treatment to which they were randomised.

Subject analysis set title	CXA-201 as treatment for cUTI - ME Population
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The microbiologically evaluable (ME) population is a subset of the clinically evaluable (CE) population who adhered to study procedures and had an appropriately collected urine culture specimen and interpretable urine culture result at the TOC visit. The CE population was a subset of the intention-to-treat (ITT) population of subjects who received an adequate amount of study drug, met the protocol-specific disease definition of cIAI, adhered to study procedures, and had a test-of-cure (TOC) visit within the specified visit window. Subjects in this population had no confounding factors that interfered with the assessment of outcome and met the key inclusion/exclusion criteria and additional protocol-defined criteria.

Subject analysis set title	Levofloxacin as treatment for cUTI - ME Population
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The microbiologically evaluable (ME) population is a subset of the clinically evaluable (CE) population who adhered to study procedures and had an appropriately collected urine culture specimen and interpretable urine culture result at the TOC visit. The CE population was a subset of the intention-to-treat (ITT) population of subjects who received an adequate amount of study drug, met the protocol-specific disease definition of cIAI, adhered to study procedures, and had a test-of-cure (TOC) visit within the specified visit window. Subjects in this population had no confounding factors that interfered with the assessment of outcome and met the key inclusion/exclusion criteria and additional protocol-defined criteria.

Subject analysis set title	CXA-201 as treatment for cUTI - mMITT Population
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The microbiological modified intent-to-treat (mMITT) population was a subset of the modified intent-to-treat (MITT) population that included subjects who had at least 1 qualified uropathogen from a study-qualifying pretreatment baseline urine specimen. The MITT population consisted of all randomised subjects who received any amount of study drug.

Subject analysis set title	Levofloxacin as treatment for cUTI - mMITT Population
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The microbiological modified intent-to-treat (mMITT) population was a subset of the modified intent-to-treat (MITT) population that included subjects who had at least 1 qualified uropathogen from a study-qualifying pretreatment baseline urine specimen. The MITT population consisted of all randomised subjects who received any amount of study drug.

Primary: The percentage of subjects who have both a per-subject microbiological outcome of eradication and a clinical outcome of cure at the Test of Cure (TOC) Visit in the Microbiologically Evaluable (ME) Population

End point title	The percentage of subjects who have both a per-subject microbiological outcome of eradication and a clinical outcome of cure at the Test of Cure (TOC) Visit in the Microbiologically Evaluable (ME) Population

End point description:

End point type	Primary

End point timeframe:

Test of Cure Visit (7 Days [± 2 days] after completion of study drug administration)

End point values	CXA-201 as treatment for cUTI - ME Population	Levofloxacin as treatment for cUTI - ME Population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	340	353		
Units: percentage of subjects				
number (not applicable)	84.7	75.4		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS
Comparison groups	CXA-201 as treatment for cUTI - ME Population v Levofloxacin as treatment for cUTI - ME Population
Number of subjects included in analysis	693
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Risk difference (RD)
Point estimate	9.4
Confidence interval	
level	Other: 99 %
sides	2-sided
lower limit	1.54
upper limit	17.12

Notes:

[1] - Non-inferiority was concluded if the lower bound of the 2-sided 99% CI was greater than -10%.

Secondary: The percentage of subjects who have both a per-subject microbiological outcome of eradication and a clinical outcome of cure at the TOC Visit in the microbiological modified intent to-treat (mMITT) population

End point title	The percentage of subjects who have both a per-subject microbiological outcome of eradication and a clinical outcome of cure at the TOC Visit in the microbiological modified intent to-treat (mMITT) population

End point description:

End point type	Secondary

End point timeframe:

Test of Cure Visit (7 Days [± 2 days] after completion of study drug administration)

End point values	CXA-201 as treatment for cUTI - mMITT Population	Levofloxacin as treatment for cUTI - mMITT Population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	398	402		
Units: percentage of subjects				
number (not applicable)	78.6	69.9		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	CXA-201 as treatment for cUTI - mMITT Population v Levofloxacin as treatment for cUTI - mMITT Population
Number of subjects included in analysis	800
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Risk difference (RD)
Point estimate	8.7
Confidence interval	
level	Other: 99 %
sides	2-sided
lower limit	0.77
upper limit	16.57

Notes:

[2] - Non-inferiority was concluded if the lower bound of the 2-sided 99% CI was greater than -10%.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were recorded for all subjects from the start of study drug administration through the last follow up visit, which occurred 28 to 35 days after the last dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	Levofloxacin as treatment for cUTI

Reporting group description:

Levofloxacin IV infusion (750 mg qd) for 7 days

Reporting group title	CXA-201 as treatment for cUTI

Reporting group description:

CXA-201 IV infusion (1500 mg q8) for 7 days

Serious adverse events	Levofloxacin as treatment for cUTI	CXA-201 as treatment for cUTI	
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 535 (3.36%)	15 / 533 (2.81%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	0 / 535 (0.00%)	2 / 533 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Injury, poisoning and procedural complications			
Pneumothorax traumatic			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Angina unstable			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Hernia obstructive			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Diabetic retinopathy			
subjects affected / exposed	0 / 535 (0.00%)	1 / 533 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastric ulcer			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 535 (0.00%)	1 / 533 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 535 (0.00%)	1 / 533 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular acidosis			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 535 (0.00%)	1 / 533 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Clostridium difficile colitis			
subjects affected / exposed	0 / 535 (0.00%)	1 / 533 (0.19%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 535 (0.00%)	1 / 533 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal abscess			
subjects affected / exposed	0 / 535 (0.00%)	1 / 533 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysematous pyelonephritis			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pseudomembranous colitis			
subjects affected / exposed	0 / 535 (0.00%)	1 / 533 (0.19%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 535 (0.00%)	2 / 533 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	0 / 535 (0.00%)	1 / 533 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	6 / 535 (1.12%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 535 (0.19%)	0 / 533 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 535 (0.00%)	2 / 533 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			

subjects affected / exposed	2 / 535 (0.37%)	3 / 533 (0.56%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Levofloxacin as treatment for cUTI	CXA-201 as treatment for cUTI	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 535 (4.86%)	31 / 533 (5.82%)	
Nervous system disorders			
Headache			
subjects affected / exposed	26 / 535 (4.86%)	31 / 533 (5.82%)	
occurrences (all)	26	35	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Two identical protocols were initiated (CXA-cUTI-10-04 and CXA-cUTI-10-05). Then, Cubist and the FDA agreed that integrated data from the 2 protocols could be analyzed and reported in a single Clinical Study Report. These analyses are presented here.

Notes: