



Clinical trial results:

A Randomized, Double-Blind, Multi-Center Study to Evaluate the Efficacy and Safety of Intravenous to Oral Solithromycin (CEM-101) Compared to Intravenous to Oral Moxifloxacin in the Treatment of Adult Patients with Community-Acquired Bacterial Pneumonia

Summary

| | |
|--------------------------|----------------------------|
| EudraCT number | 2013-003453-13 |
| Trial protocol | HU BG LV DE ES RO SK NL SI |
| Global end of trial date | 07 September 2015 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 12 November 2016 |
| First version publication date | 12 November 2016 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | CE01-301 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01968733 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|----------------------------------------------------------------------------------|
| Sponsor organisation name | Cempra Pharmaceuticals, Inc. |
| Sponsor organisation address | 6320 Quadrangle Drive, Suite 360, Chapel Hill, United States, NC 27517 |
| Public contact | Clinical Trials Info, Cempra Pharmaceuticals, Inc., clinicaltrials@cempra.com |
| Scientific contact | Clinical Trials Info, Cempra Pharmaceuticals, Inc., clinicaltrials@cempra.com |

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 | 29 April 2016 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 07 September 2015 |
| Global end of trial reached? | Yes |
| Global end of trial date | 07 September 2015 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To determine noninferiority (NI) in the rate of Investigator assessment of clinical success of intravenous (IV) to oral solithromycin compared to IV to oral moxifloxacin at the Short-term Follow-Up Visit (SFU), 5 -10 days after the last dose of study drug in the Intent-To-Treat (ITT) and Clinically Evaluable (CE-SFU) populations for patients with a Pneumonia Outcomes Research Team (PORT) risk class of III/IV (ie, pneumonia severity index).

Protection of trial subjects:

This study was conducted in compliance with the protocol and all regulatory requirements, in accordance with GCP, including International Conference on Harmonisation (ICH) guidelines, and in general conformity with the most recent version of the Declaration of Helsinki.

Background therapy:

A single dose of a short-acting antibiotic (penicillins, cephalosporins [not ceftriaxone], tetracyclines, or trimethoprim-sulfamethoxazole) in the 7 days prior to enrolment was permitted (number of patient limited to 25% of the population).

Evidence for comparator:

Moxifloxacin was chosen as the active comparator for multiple reasons.

It has established efficacy in the treatment of CABP, with potent activity against key pathogens associated with CABP. Moxifloxacin is recommended empiric therapy for moderately severe CABP in the EU and USA. Additionally, moxifloxacin is available in IV and oral formulations, and thus is an appropriate comparator for both this study and Study CE01-300, the Phase 3 oral solithromycin CABP trial. It was also possible to define a common moxifloxacin regimen for all countries in which the study was conducted.

| | |
|-----------------------------------------------------------|-----------------|
| Actual start date of recruitment | 14 January 2014 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Poland: 51 |
| Country: Number of subjects enrolled | Romania: 102 |
| Country: Number of subjects enrolled | Slovakia: 2 |
| Country: Number of subjects enrolled | Slovenia: 16 |
| Country: Number of subjects enrolled | Spain: 17 |
| Country: Number of subjects enrolled | Bulgaria: 80 |
| Country: Number of subjects enrolled | Hungary: 29 |
| Country: Number of subjects enrolled | Latvia: 17 |
| Country: Number of subjects enrolled | Argentina: 5 |

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Canada: 7 |
| Country: Number of subjects enrolled | Chile: 2 |
| Country: Number of subjects enrolled | Georgia: 63 |
| Country: Number of subjects enrolled | Malaysia: 31 |
| Country: Number of subjects enrolled | Peru: 9 |
| Country: Number of subjects enrolled | Philippines: 79 |
| Country: Number of subjects enrolled | Russian Federation: 40 |
| Country: Number of subjects enrolled | Serbia: 88 |
| Country: Number of subjects enrolled | South Africa: 40 |
| Country: Number of subjects enrolled | Korea, Republic of: 10 |
| Country: Number of subjects enrolled | Taiwan: 3 |
| Country: Number of subjects enrolled | Ukraine: 76 |
| Country: Number of subjects enrolled | United States: 96 |
| Worldwide total number of subjects | 863 |
| EEA total number of subjects | 314 |

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) | 478 |
| From 65 to 84 years | 355 |
| 85 years and over | 30 |

Subject disposition

Recruitment

Recruitment details:

A total of 863 patients were enrolled from 147 centres worldwide.

For the MAA in EU, only PORT risk class of III/IV/V patients were studied and included 661 patients (ITT-EU); among them, 454 patients in Europe, 53 patients in North America, 12 patients in Latin America, 33 patients in South Africa and 109 patient in Asia Pacific.

Pre-assignment

Screening details:

Eligible patients were males or females ≥ 18 years of age with an acute onset or worsening of at least 3 of the following signs and symptoms of CABP: cough, production of purulent sputum, shortness of breath (dyspnea), chest pain.

And at least 1 of the following: fever, hypothermia, presence of pulmonary rales and/or pulmonary consolidation.

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, Monitor, Data analyst, Assessor |

Blinding implementation details:

A double-dummy design was utilized, with solithromycin placebo capsules identical in appearance to solithromycin capsules and moxifloxacin placebo over-encapsulated tablets identical in appearance to moxifloxacin over-encapsulated tablets. After dosing with IV study drug was completed, an exact number of capsules needed to complete 7 days of dosing were provided in blister packs to patients who met the switch criteria.

Arms

| | |
|------------------------------|-------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Solithromycin (PORT III/IV/V) |

Arm description:

Solithromycin treatment group

| | |
|----------------------------------------|------------------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Solithromycin |
| Investigational medicinal product code | CEM-101 |
| Other name | |
| Pharmaceutical forms | Powder for concentrate for solution for injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Day 1: Solithromycin 400 mg IV (250 mL over 60 [5/+20] minutes) followed by 400 mg IV daily until predefined oral switch criteria were met. First oral dose was 800 mg (4 x 200 mg capsules), followed by 400 mg (2 x 200 mg capsules) oral daily for the remainder of study (a total of 7 doses).

| | |
|------------------|------------------------------|
| Arm title | Moxifloxacin (PORT III/IV/V) |
|------------------|------------------------------|

Arm description:

Moxifloxacin treatment group

| | |
|----------------------------------------|---------------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Moxifloxacin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Day 1: Moxifloxacin 400 mg IV daily (250 mL over 60 [5/+20] minutes), followed by 400 mg IV daily until predefined oral switch criteria (clinical improvement) were met, followed by 400 mg (1×400 mg capsule) oral moxifloxacin daily for a total of 7 doses.

| Number of subjects in period 1^[1] | Solithromycin (PORT III/IV/V) | Moxifloxacin (PORT III/IV/V) |
|-----------------------------------------------------|--------------------------------------|-------------------------------------|
| Started | 328 | 333 |
| Completed | 308 | 318 |
| Not completed | 20 | 15 |
| Adverse event, serious fatal | 5 | 6 |
| Consent withdrawn by subject | 11 | 7 |
| Adverse event, non-fatal | 2 | - |
| randomised in error | - | 2 |
| clinical failure | 2 | - |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The reporting groups refer to PORT III/IV/V patients (EU analysis).

Baseline characteristics

Reporting groups

| | |
|---------------------------------------------------------------|-------------------------------|
| Reporting group title | Solithromycin (PORT III/IV/V) |
| Reporting group description: Solithromycin treatment group | |
| Reporting group title | Moxifloxacin (PORT III/IV/V) |
| Reporting group description: Moxifloxacin treatment group | |

| Reporting group values | Solithromycin (PORT III/IV/V) | Moxifloxacin (PORT III/IV/V) | Total |
|---------------------------------------|-------------------------------|------------------------------|-------|
| Number of subjects | 328 | 333 | 661 |
| Age categorical Units: Subjects | | | |
| Adults (18-64 years) | 152 | 151 | 303 |
| From 65-84 years | 161 | 169 | 330 |
| 85 years and over | 15 | 13 | 28 |
| Age continuous Units: years | | | |
| arithmetic mean | 64.2 | 64.3 | |
| standard deviation | ± 14.1 | ± 13.6 | - |
| Gender categorical Units: Subjects | | | |
| Female | 156 | 142 | 298 |
| Male | 172 | 191 | 363 |
| PORT risk class Units: Subjects | | | |
| Port III | 196 | 204 | 400 |
| Port IV | 130 | 125 | 255 |
| Port V | 2 | 4 | 6 |

End points

End points reporting groups

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Reporting group title | Solithromycin (PORT III/IV/V) |
| Reporting group description: Solithromycin treatment group | |
| Reporting group title | Moxifloxacin (PORT III/IV/V) |
| Reporting group description: Moxifloxacin treatment group | |
| Subject analysis set title | Solithromycin -ITT Set (PORT III/IV/V) |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: All randomized patients with PORT III/IV/V regardless of whether or not the patient received study drug. A patient is considered randomized when the Investigator or Investigator's designee receives the IWRS-generated randomisation number. | |
| Subject analysis set title | Moxifloxacin - ITT Set (PORT III/IV/V) |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: All randomized patients with PORT III/IV/V regardless of whether or not the patient received study drug. A patient is considered randomized when the Investigator or Investigator's designee receives the IWRS-generated randomisation number. | |
| Subject analysis set title | Solithromycin - Clinically Evaluable Set (PORT III/IV/V) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: All patients in the ITT population who also met the criteria listed in the SAP, among them: met key inclusion criteria, did not meet the exclusion criteria, completed the TOC Visit 5-10 days after the last dose of study drug, received ≥ 2 doses of study drug during the first 48 hours if the patient was a clinical failure, received ≥ 3 doses of study drug during the first 72 hours if the patient was a clinical success, did not receive another systemic antibacterial from the first dose of study drug through EOT (End of treatment) or through TOC with likely or documented activity against confirmed or potential CABP pathogens, received the correct study drug based on randomization assignment. | |
| Subject analysis set title | Moxifloxacin - Clinically evaluable Set (PORT III/IV/V) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: All patients in the ITT population who also met the criteria listed in the SAP, among them: met key inclusion criteria, did not meet the exclusion criteria, completed the TOC Visit 5-10 days after the last dose of study drug, received ≥ 2 doses of study drug during the first 48 hours if the patient was a clinical failure, received ≥ 3 doses of study drug during the first 72 hours if the patient was a clinical success, did not receive another systemic antibacterial from the first dose of study drug through EOT (End of treatment) or through TOC with likely or documented activity against confirmed or potential CABP pathogens, received the correct study drug based on randomization assignment. | |

Primary: Clinical response-ITT at TOC: non-inferiority hypothesis

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| End point title | Clinical response-ITT at TOC: non-inferiority hypothesis |
| End point description: Proportion of patients with clinical success of CABP symptoms. Clinical response rate at the TOC visit (or SFU visit) for the ITT Population is a co-primary endpoint of the study. Clinical response (Investigator assessment) is classified as success, failure, or indeterminate according to the definitions in the SAP. | |
| End point type | Primary |
| End point timeframe: At Test of Cure (TOC), i.e. 5-10 days after last dose of study drug. | |

| End point values | Solithromycin (PORT III/IV/V) | Moxifloxacin (PORT III/IV/V) | | |
|-----------------------------|-------------------------------------|------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 328 | 333 | | |
| Units: number of patients | | | | |
| success | 281 | 293 | | |
| failure | 38 | 30 | | |
| indeterminate | 9 | 10 | | |

Statistical analyses

| Statistical analysis title | Non-inferiority analysis (success)-ITT |
|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Statistical analysis description: | |
| H0: Difference (Solithromycin treatment group minus Moxifloxacin treatment group) of clinical success rates $\leq -10\%$ | |
| Comparison groups | Solithromycin (PORT III/IV/V) v Moxifloxacin (PORT III/IV/V) |
| Number of subjects included in analysis | 661 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[1] |
| Method | non-inferiority test |
| Parameter estimate | Difference of clinical success rates |
| Point estimate | -2.32 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.8 |
| upper limit | 2.7 |

Notes:

[1] - A non-inferiority margin of 10% was used.

Primary: Clinical response - CE at TOC: non-inferiority hypothesis

| End point title | Clinical response - CE at TOC: non-inferiority hypothesis |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| End point description: | |
| Proportion of patients with clinical success of CABP symptoms at TOC for the Clinically Evaluable (CE) Population. | |
| This is a co-primary endpoint of the study. | |
| Clinical response (Investigator assessment) is classified as success, failure, or indeterminate according to the definitions in the SAP. | |
| End point type | Primary |
| End point timeframe: | |
| At TOC, i.e. 5-10 days after the last dose of study drug. | |

| End point values | Solithromycin (PORT III/IV/V) | Moxifloxacin (PORT III/IV/V) | | |
|-----------------------------|-------------------------------------|------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 292 ^[2] | 300 ^[3] | | |
| Units: number of patients | | | | |
| success | 257 | 276 | | |
| failure | 35 | 24 | | |
| indeterminate | 0 | 0 | | |

Notes:

[2] - Solithromycin- Modified Clinically Evaluable Population (PORT III/IV/V)

[3] - Moxifloxacin - Modified Clinically Evaluable Population (PORT III/IV/V)

Statistical analyses

| Statistical analysis title | Non-inferiority hypothesis test (success) - CE |
|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Statistical analysis description: | |
| H0: Differences (solithromycin minus Moxifloxacin treatment group) of clinical success rate \leq -10%. | |
| Comparison groups | Solithromycin (PORT III/IV/V) v Moxifloxacin (PORT III/IV/V) |
| Number of subjects included in analysis | 592 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[4] |
| Parameter estimate | Difference in clinical success rates |
| Point estimate | -3.99 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.2 |
| upper limit | 1.2 |

Notes:

[4] - A non-inferiority margin of 10% was used.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first study drug administration to late follow-up (Day 28-35 after first dose of study drug).

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 17.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------------------------------------------------|
| Reporting group title | Solithromycin - safety population (PORT III/IV/V) |
|-----------------------|---------------------------------------------------|

Reporting group description: -

| | |
|-----------------------|-------------------------------------------------|
| Reporting group title | Moxifloxacin- safety population (PORT III/IV/V) |
|-----------------------|-------------------------------------------------|

Reporting group description: -

| | |
|-----------------------|--------------------------------------------|
| Reporting group title | Solithromycin-safety population (All PORT) |
|-----------------------|--------------------------------------------|

Reporting group description:

All patients

| | |
|-----------------------|-------------------------------------------|
| Reporting group title | Moxifloxacin-safety population (All PORT) |
|-----------------------|-------------------------------------------|

Reporting group description:

All patients

| Serious adverse events | Solithromycin - safety population (PORT III/IV/V) | Moxifloxacin- safety population (PORT III/IV/V) | Solithromycin-safety population (All PORT) |
|---------------------------------------------------------------------|---------------------------------------------------|-------------------------------------------------|--------------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 25 / 327 (7.65%) | 20 / 331 (6.04%) | 30 / 432 (6.94%) |
| number of deaths (all causes) | 5 | 6 | 5 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute leukaemia | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Adrenal gland cancer | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Lung adenocarcinoma | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung adenocarcinoma metastatic | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small cell lung cancer | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertension | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 1 / 331 (0.30%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertensive crisis | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombophlebitis | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 0 / 331 (0.00%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute myocardial infarction | | | |

| | | | |
|------------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac arrest | | | |
| subjects affected / exposed | 2 / 327 (0.61%) | 0 / 331 (0.00%) | 2 / 432 (0.46%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 2 |
| Cardiac failure | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 1 / 331 (0.30%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Cardiovascular insufficiency | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 2 / 327 (0.61%) | 1 / 331 (0.30%) | 2 / 432 (0.46%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 2 |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Anaphylactic reaction | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 1 / 331 (0.30%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Large intestine perforation | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 4 / 331 (1.21%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 6 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Aspiration | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Asthmatic crisis | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic obstructive pulmonary disease | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 327 (0.31%) | 2 / 331 (0.60%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 2 / 327 (0.61%) | 0 / 331 (0.00%) | 2 / 432 (0.46%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Upper airway obstruction | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| Skin and subcutaneous tissue disorders | | | |
| Urticaria | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 327 (0.00%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Hydronephrosis | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal failure | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Empyema | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocarditis bacterial | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lobar Pneumonia | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung abscess | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 3 / 327 (0.92%) | 3 / 331 (0.91%) | 7 / 432 (1.62%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | 0 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 0 / 331 (0.00%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| sepsis | | | |
| subjects affected / exposed | 0 / 327 (0.00%) | 1 / 331 (0.30%) | 0 / 432 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 1 / 327 (0.31%) | 1 / 331 (0.30%) | 1 / 432 (0.23%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |

| Serious adverse events | Moxifloxacin-safety population (All PORT) | | |
|---------------------------------------------------|-------------------------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 23 / 426 (5.40%) | | |
| number of deaths (all causes) | 7 | | |
| number of deaths resulting from adverse events | 0 | | |

| | | | |
|---------------------------------------------------------------------|-----------------|--|--|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute leukaemia | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Adrenal gland cancer | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lung adenocarcinoma metastatic | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Small cell lung cancer | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypertension | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| Thrombophlebitis | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac arrest | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Cardiac failure | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Cardiovascular insufficiency | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Myocardial infarction | | | |

| | | | |
|------------------------------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Large intestine perforation | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 4 / 426 (0.94%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Aspiration | | | |

| | | | | |
|-------------------------------------------------|-----------------|--|--|--|
| subjects affected / exposed | 1 / 426 (0.23%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Asthmatic crisis | | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Chronic obstructive pulmonary disease | | | | |
| subjects affected / exposed | 2 / 426 (0.47%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Haemoptysis | | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pleural effusion | | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumothorax | | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary embolism | | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary oedema | | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory failure | | | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Upper airway obstruction | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Urticaria | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal failure | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Empyema | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Endocarditis bacterial | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | | |
|-------------------------------------------------|-----------------|--|--|--|
| Influenza | | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lobar Pneumonia | | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lung abscess | | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 3 / 426 (0.70%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary tuberculosis | | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory tract infection | | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory tract infection viral | | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| sepsis | | | | |
| subjects affected / exposed | 1 / 426 (0.23%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Septic shock | | | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 426 (0.23%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |

Frequency threshold for reporting non-serious adverse events: 2 %

| Non-serious adverse events | Solithromycin - safety population (PORT III/IV/V) | Moxifloxacin- safety population (PORT III/IV/V) | Solithromycin-safety population (All PORT) |
|-------------------------------------------------------|---------------------------------------------------|-------------------------------------------------|--------------------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 139 / 327 (42.51%) | 104 / 331 (31.42%) | 193 / 432 (44.68%) |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 19 / 327 (5.81%) | 1 / 331 (0.30%) | 28 / 432 (6.48%) |
| occurrences (all) | 38 | 1 | 57 |
| Vascular disorders | | | |
| hypertension | | | |
| subjects affected / exposed | 5 / 327 (1.53%) | 7 / 331 (2.11%) | 5 / 432 (1.16%) |
| occurrences (all) | 5 | 7 | 5 |
| Nervous system disorders | | | |
| dizziness | | | |
| subjects affected / exposed | 7 / 327 (2.14%) | 2 / 331 (0.60%) | 11 / 432 (2.55%) |
| occurrences (all) | 8 | 2 | 12 |
| headache | | | |
| subjects affected / exposed | 7 / 327 (2.14%) | 16 / 331 (4.83%) | 15 / 432 (3.47%) |
| occurrences (all) | 8 | 16 | 17 |
| General disorders and administration site conditions | | | |
| Infusion site pain | | | |
| subjects affected / exposed | 33 / 327 (10.09%) | 6 / 331 (1.81%) | 45 / 432 (10.42%) |
| occurrences (all) | 63 | 6 | 87 |
| Infusion site phlebitis | | | |
| subjects affected / exposed | 32 / 327 (9.79%) | 4 / 331 (1.21%) | 43 / 432 (9.95%) |
| occurrences (all) | 37 | 4 | 50 |
| Infusion site erythema | | | |
| subjects affected / exposed | 12 / 327 (3.67%) | 2 / 331 (0.60%) | 19 / 432 (4.40%) |
| occurrences (all) | 16 | 6 | 27 |
| Infusion site thrombosis | | | |

| | | | |
|--------------------------------------------------------------------------------------------------------|------------------------|------------------------|------------------------|
| subjects affected / exposed occurrences (all) | 9 / 327 (2.75%) 13 | 6 / 331 (1.81%) 10 | 9 / 432 (2.08%) 13 |
| Infusion site paraesthesia subjects affected / exposed occurrences (all) | 8 / 327 (2.45%) 8 | 0 / 331 (0.00%) 0 | 9 / 432 (2.08%) 9 |
| Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) | 11 / 327 (3.36%) 11 | 22 / 331 (6.65%) 23 | 19 / 432 (4.40%) 19 |
| Nausea subjects affected / exposed occurrences (all) | 8 / 327 (2.45%) 8 | 3 / 331 (0.91%) 3 | 14 / 432 (3.24%) 14 |
| Psychiatric disorders insomnia subjects affected / exposed occurrences (all) | 7 / 327 (2.14%) 7 | 3 / 331 (0.91%) 3 | 9 / 432 (2.08%) 9 |
| Metabolism and nutrition disorders Hypokalaemia subjects affected / exposed occurrences (all) | 10 / 327 (3.06%) 10 | 7 / 331 (2.11%) 7 | 11 / 432 (2.55%) 11 |

| | | | |
|------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--|--|
| Non-serious adverse events | Moxifloxacin-safety population (All PORT) | | |
| Total subjects affected by non-serious adverse events subjects affected / exposed | 125 / 426 (29.34%) | | |
| Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all) | 1 / 426 (0.23%) 1 | | |
| Vascular disorders hypertension subjects affected / exposed occurrences (all) | 9 / 426 (2.11%) 9 | | |
| Nervous system disorders dizziness subjects affected / exposed occurrences (all) headache | 5 / 426 (1.17%) 6 | | |

| | | | |
|------------------------------------------------------|------------------|--|--|
| subjects affected / exposed | 18 / 426 (4.23%) | | |
| occurrences (all) | 19 | | |
| General disorders and administration site conditions | | | |
| Infusion site pain | | | |
| subjects affected / exposed | 6 / 426 (1.41%) | | |
| occurrences (all) | 6 | | |
| Infusion site phlebitis | | | |
| subjects affected / exposed | 4 / 426 (0.94%) | | |
| occurrences (all) | 4 | | |
| Infusion site erythema | | | |
| subjects affected / exposed | 2 / 426 (0.47%) | | |
| occurrences (all) | 6 | | |
| Infusion site thrombosis | | | |
| subjects affected / exposed | 7 / 426 (1.64%) | | |
| occurrences (all) | 12 | | |
| Infusion site paraesthesia | | | |
| subjects affected / exposed | 0 / 426 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 25 / 426 (5.87%) | | |
| occurrences (all) | 26 | | |
| Nausea | | | |
| subjects affected / exposed | 7 / 426 (1.64%) | | |
| occurrences (all) | 7 | | |
| Psychiatric disorders | | | |
| insomnia | | | |
| subjects affected / exposed | 5 / 426 (1.17%) | | |
| occurrences (all) | 5 | | |
| Metabolism and nutrition disorders | | | |
| Hypokalaemia | | | |
| subjects affected / exposed | 9 / 426 (2.11%) | | |
| occurrences (all) | 9 | | |

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

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/27448679>