



Clinical trial results:

Voriconazole in High-Risk Patients With Invasive Fungal Infections in Slovakia. An Open, Prospective, Non-Comparative Study. (Ve-RIFI)

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2017-000501-20 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 16 November 2009 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 09 June 2017 |
| First version publication date | 09 June 2017 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | A1501082 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01137292 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Pfizer, Inc. |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017 |
| Public contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.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? | Yes |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 15 April 2010 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 November 2009 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To collect data on treatment outcomes (clinical and mycological cure), safety and tolerability of treatment with voriconazole in subjects with invasive fungal infections in Slovakia.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 12 April 2007 |
| 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 | Slovakia: 177 |
| Worldwide total number of subjects | 177 |
| EEA total number of subjects | 177 |

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) | 3 |
| Children (2-11 years) | 8 |
| Adolescents (12-17 years) | 6 |
| Adults (18-64 years) | 134 |
| From 65 to 84 years | 26 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study was conducted from 12 April 2007 to 16 November 2009 in Slovakia.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|-----------|--------------|
| Arm title | Voriconazole |
|-----------|--------------|

Arm description:

Subjects received Voriconazole intravenously at a loading dose of 6 milligram per kilogram (mg/kg) every 12 hours (during the first 24 hours) followed by the maintenance dose of 4 mg/kg twice daily up to 2 weeks. Subjects weighing greater than (>) 40 kg, received oral formulation at a loading dose of 400 mg twice during the first 24 hours followed by maintenance dose of 200 mg twice daily up to 2 weeks. Subjects weighing less than (<) 40 kg received oral formulation at a loading dose of 200 mg twice during the first 24 hours followed by maintenance dose of 100 mg twice daily up to 2 weeks. Paediatric subjects <12 years received 7 mg/kg intravenously or 200 mg orally twice daily up to 2 weeks.

| | |
|--|-----------------|
| Arm type | Experimental |
| Investigational medicinal product name | Voriconazole |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects received Voriconazole at a loading dose of 6 mg/kg every 12 hours (during the first 24 hours) followed by the maintenance dose of 4 mg/kg twice daily up to 2 weeks. Paediatric subjects <12 years received 7 mg/kg or 200 mg twice daily up to 2 weeks.

| | |
|--|---------------|
| Investigational medicinal product name | Voriconazole |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral solution |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects weighing >40 kg, received formulation at a loading dose of 400 mg twice during the first 24 hours followed by maintenance dose of 200 mg twice daily up to 2 weeks. Subjects weighing <40 kg received formulation at a loading dose of 200 mg twice during the first 24 hours followed by maintenance dose of 100 mg twice daily up to 2 weeks.

| Number of subjects in period 1 | Voriconazole |
|---------------------------------------|--------------|
| Started | 177 |
| Completed | 123 |
| Not completed | 54 |
| Other unspecified | 7 |
| Death | 30 |
| Adverse event | 3 |
| Lost to follow-up | 1 |
| Lack of efficacy | 13 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | Voriconazole |
|-----------------------|--------------|

Reporting group description:

Subjects received Voriconazole intravenously at a loading dose of 6 milligram per kilogram (mg/kg) every 12 hours (during the first 24 hours) followed by the maintenance dose of 4 mg/kg twice daily up to 2 weeks. Subjects weighing greater than (>) 40 kg, received oral formulation at a loading dose of 400 mg twice during the first 24 hours followed by maintenance dose of 200 mg twice daily up to 2 weeks. Subjects weighing less than (<) 40 kg received oral formulation at a loading dose of 200 mg twice during the first 24 hours followed by maintenance dose of 100 mg twice daily up to 2 weeks. Paediatric subjects <12 years received 7 mg/kg intravenously or 200 mg orally twice daily up to 2 weeks.

| Reporting group values | Voriconazole | Total | |
|------------------------|--------------|-------|--|
| Number of subjects | 177 | 177 | |
| Age Categorical | | | |
| Units: Subjects | | | |
| <2 years | 3 | 3 | |
| 2 to 18 years | 16 | 16 | |
| 19 to 44 years | 52 | 52 | |
| 45 to 64 years | 80 | 80 | |
| >=65 years | 26 | 26 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 45.9 | | |
| standard deviation | ± 19.1 | - | |
| Gender, Male/Female | | | |
| Units: Subjects | | | |
| Female | 73 | 73 | |
| Male | 104 | 104 | |

End points

End points reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | Voriconazole |
|-----------------------|--------------|

Reporting group description:

Subjects received Voriconazole intravenously at a loading dose of 6 milligram per kilogram (mg/kg) every 12 hours (during the first 24 hours) followed by the maintenance dose of 4 mg/kg twice daily up to 2 weeks. Subjects weighing greater than (>) 40 kg, received oral formulation at a loading dose of 400 mg twice during the first 24 hours followed by maintenance dose of 200 mg twice daily up to 2 weeks. Subjects weighing less than (<) 40 kg received oral formulation at a loading dose of 200 mg twice during the first 24 hours followed by maintenance dose of 100 mg twice daily up to 2 weeks. Paediatric subjects <12 years received 7 mg/kg intravenously or 200 mg orally twice daily up to 2 weeks.

Primary: Number of Subjects With Clinical and/or Mycological Efficacy by Response at the End of Treatment (EOT) Visit

| | |
|-----------------|---|
| End point title | Number of Subjects With Clinical and/or Mycological Efficacy by Response at the End of Treatment (EOT) Visit ^[1] |
|-----------------|---|

End point description:

Clinical, mycological responses: clinical cure, clinical improvement, no clinical cure, mycological cure, no mycological cure and no mycological culture performed. Subjects could have more than one responses. Responses were based on the investigator's judgement according to the Infectious Disease Society of America, European Conference on Infections in Leukemia, and European Committee on Antimicrobial Susceptibility Testing guidelines. Full analysis set (FAS) included all enrolled subjects who were administered the study medication and had post baseline documentation of efficacy available.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Baseline up to 2 Weeks (EOT visit)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned to be analysed in this end point.

| End point values | Voriconazole | | | |
|----------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 177 | | | |
| Units: subjects | | | | |
| Clinical Cure | 64 | | | |
| Clinical Improvement | 64 | | | |
| No Clinical Cure | 36 | | | |
| Mycological Cure | 34 | | | |
| No Mycological Cure | 10 | | | |
| No Mycological Culture Performed | 40 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Clinical and/or Mycological Efficacy by Response at the Test-of-Cure Visit

| | |
|-----------------|---|
| End point title | Number of Subjects With Clinical and/or Mycological Efficacy by Response at the Test-of-Cure Visit ^[2] |
|-----------------|---|

End point description:

Clinical, mycological responses: clinical cure, clinical improvement, no clinical cure, mycological cure, no mycological cure, no mycological culture performed, death, and lost from follow-up. Subjects could have more than one responses. Responses were based on the investigator's judgement according to the Infectious Disease Society of America, European Conference on Infections in Leukemia, and European Committee on Antimicrobial Susceptibility Testing guidelines. FAS included all enrolled subjects who were administered the study medication and had post baseline documentation of efficacy available.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

6 weeks after last dose of study drug

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned to be analysed in this end point.

| End point values | Voriconazole | | | |
|----------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 177 | | | |
| Units: subjects | | | | |
| Clinical Cure | 54 | | | |
| Clinical Improvement | 46 | | | |
| No Clinical Cure | 7 | | | |
| Mycological Cure | 31 | | | |
| No Mycological Cure | 1 | | | |
| No Mycological Culture Performed | 19 | | | |
| Death | 41 | | | |
| Lost From Follow-Up | 11 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Investigator's Satisfaction with the Efficacy of Voriconazole Assessment at the End of Treatment (EOT) Visit

| | |
|-----------------|---|
| End point title | Number of Subjects With Investigator's Satisfaction with the Efficacy of Voriconazole Assessment at the End of Treatment (EOT) Visit ^[3] |
|-----------------|---|

End point description:

Investigator's Satisfaction Responses: very good, good, moderate, poor. Responses were based on the investigator's judgement. FAS included all enrolled subjects who were administered the study medication and had post baseline documentation of efficacy available. Here, 'number of subjects analyzed' signifies the subjects who were evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Baseline up to 2 weeks (EOT visit)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned to be analysed in this end point.

| End point values | Voriconazole | | | |
|-----------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 172 | | | |
| Units: subjects | | | | |
| Very Good | 85 | | | |
| Good | 49 | | | |
| Moderate | 33 | | | |
| Poor | 5 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Investigator's Satisfaction with the Tolerability of Voriconazole Assessment at the End of Treatment (EOT) Visit

| | |
|-----------------|---|
| End point title | Number of Subjects With Investigator's Satisfaction with the Tolerability of Voriconazole Assessment at the End of Treatment (EOT) Visit ^[4] |
|-----------------|---|

End point description:

Investigator's Satisfaction Responses: very good, good, moderate, poor. Responses were based on the investigator's judgement. Safety population included subjects who received at least 1 dose of the study medication. Here, 'number of subjects analyzed' signifies the subjects who were evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Baseline up to 2 weeks (EOT visit)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned to be analysed in this end point.

| End point values | Voriconazole | | | |
|-----------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 174 | | | |
| Units: subjects | | | | |
| Very Good | 105 | | | |
| Good | 61 | | | |
| Moderate | 8 | | | |
| Poor | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 28 days after the last dose of study drug

Adverse event reporting additional description:

The same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one subject and as nonserious in another subject, or one subject may have experienced both a serious and nonserious event during the study.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 12.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | Voriconazole |
|-----------------------|--------------|

Reporting group description:

Subjects received Voriconazole intravenously at a loading dose of 6 milligram per kilogram (mg/kg) every 12 hours (during the first 24 hours) followed by the maintenance dose of 4 mg/kg twice daily up to 2 weeks. Subjects weighing greater than (>) 40 kg, received oral formulation at a loading dose of 400 mg twice during the first 24 hours followed by maintenance dose of 200 mg twice daily up to 2 weeks. Subjects weighing less than (<) 40 kg received oral formulation at a loading dose of 200 mg twice during the first 24 hours followed by maintenance dose of 100 mg twice daily up to 2 weeks. Paediatric subjects <12 years received 7 mg/kg intravenously or 200 mg orally twice daily up to 2 weeks.

| Serious adverse events | Voriconazole | | |
|---|-------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 34 / 177 (19.21%) | | |
| number of deaths (all causes) | 41 | | |
| number of deaths resulting from adverse events | 0 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute myeloid leukaemia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Lymphocytic leukaemia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Neoplasm | | | |

| | | | |
|--|-----------------|--|--|
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Neoplasm malignant | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Non-Hodgkin's lymphoma | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Injury, poisoning and procedural complications | | | |
| Multiple injuries | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 2 / 177 (1.13%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 2 | | |
| Subdural haematoma | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Traumatic brain injury | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Cardiac disorders | | | |
| Acute myocardial infarction | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Cardiac failure | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 5 / 177 (2.82%) | | |
| occurrences causally related to treatment / all | 0 / 6 | | |
| deaths causally related to treatment / all | 0 / 4 | | |
| Cardiopulmonary failure | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 177 (2.26%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Nervous system disorders | | | |
| Haemorrhage intracranial | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 3 / 177 (1.69%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 3 | | |
| Haemorrhagic stroke | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Locked-in syndrome | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Bone marrow disorder | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|--|-----------------|--|--|
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Pancytopenia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| General disorders and administration site conditions | | | |
| Disease progression | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Multi-organ failure | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 8 / 177 (4.52%) | | |
| occurrences causally related to treatment / all | 0 / 12 | | |
| deaths causally related to treatment / all | 0 / 6 | | |
| Sudden death | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory distress syndrome | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Respiratory failure | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 3 / 177 (1.69%) | | |
| occurrences causally related to treatment / all | 0 / 5 | | |
| deaths causally related to treatment / all | 0 / 3 | | |
| Renal and urinary disorders | | | |
| Crush syndrome | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Nephropathy toxic | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Aspergillosis | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 5 / 177 (2.82%) | | |
| occurrences causally related to treatment / all | 0 / 5 | | |
| deaths causally related to treatment / all | 0 / 3 | | |
| Sepsis | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 177 (2.26%) | | |
| occurrences causally related to treatment / all | 0 / 5 | | |
| deaths causally related to treatment / all | 0 / 3 | | |
| Septic shock | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 2 / 177 (1.13%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 1 | | |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Voriconazole | | |
|---|-----------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 6 / 177 (3.39%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Lymphoma | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences (all) | 1 | | |
| Vascular disorders | | | |
| Hypertensive crisis | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences (all) | 1 | | |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences (all) | 1 | | |
| Hepatobiliary disorders | | | |
| Liver disorder | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences (all) | 1 | | |
| Skin and subcutaneous tissue disorders | | | |
| Acrodermatitis | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences (all) | 1 | | |
| Rash pruritic | | | |
| alternative assessment type: | | | |

| | | | |
|------------------------------|-----------------|--|--|
| Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences (all) | 1 | | |
| Infections and infestations | | | |
| Bronchitis | | | |
| alternative assessment type: | | | |
| Systematic | | | |
| subjects affected / exposed | 1 / 177 (0.56%) | | |
| occurrences (all) | 1 | | |

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