



Clinical trial results:

Open-Label Study to Evaluate the Efficacy and Safety of Ibrexafungerp in Patients with Fungal Diseases that are Refractory to, Resistant to or Intolerant of Standard Antifungal Treatment (FURI)

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2017-000381-29 |
| Trial protocol | DE AT ES GB |
| Global end of trial date | 25 August 2023 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 01 February 2025 |
| First version publication date | 01 February 2025 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | SCY-078-301 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03059992 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | SCYNEXIS, Inc. |
| Sponsor organisation address | 1 Evertrust Plaza, 13th floor, Jersey City, United States, NJ 07302 |
| Public contact | David Angulo, MD, SCYNEXIS, Inc., 001 2018845485, David.angulo@scynexis.com |
| Scientific contact | David Angulo, MD, SCYNEXIS, Inc., 001 2018845485, David.angulo@scynexis.com |

Notes:

Paediatric regulatory details

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|--|----|
| 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 | 24 July 2024 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 17 August 2023 |
| Global end of trial reached? | Yes |
| Global end of trial date | 25 August 2023 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

- To evaluate the efficacy of ibrexafungerp in the treatment of severe fungal diseases by a Data Review Committee (DRC) at the primary timepoint for the fungal disease
- To evaluate safety of ibrexafungerp

Protection of trial subjects:

The study will be conducted in accordance with the protocol, the ethical principles established by the Declaration of Helsinki (as amended in Fortaleza, Brazil, October 2013), the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, the United States Code of Federal Regulations (CFR) sections that address clinical research studies, applicable European Union regulations and/or other national and local ethical and legal requirements, as applicable.

Background therapy: -

Evidence for comparator:

not applicable

| | |
|---|-----------------|
| Actual start date of recruitment | 19 October 2017 |
| 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 | Netherlands: 4 |
| Country: Number of subjects enrolled | Spain: 10 |
| Country: Number of subjects enrolled | United Kingdom: 9 |
| Country: Number of subjects enrolled | Austria: 9 |
| Country: Number of subjects enrolled | Germany: 43 |
| Country: Number of subjects enrolled | United States: 124 |
| Country: Number of subjects enrolled | Pakistan: 11 |
| Country: Number of subjects enrolled | South Africa: 18 |
| Country: Number of subjects enrolled | Canada: 5 |
| Worldwide total number of subjects | 233 |
| EEA total number of subjects | 66 |

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) | 166 |
| From 65 to 84 years | 65 |
| 85 years and over | 2 |

Subject disposition

Recruitment

Recruitment details:

Screening/recruitment was active from October 19, 2017 to December 16, 2022. Subjects were screened at hospitals and medical clinics at 46 sites globally.

Pre-assignment

Screening details:

Subjects had to meet a set of criteria in order to enroll in the study; including being 18 years of age or older and being diagnosed with an eligible fungal disease.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Blinding implementation details:

NA

Arms

| | |
|-----------|-------------------------|
| Arm title | Ibrexafungerp (SCY-078) |
|-----------|-------------------------|

Arm description:

Ibrexafungerp (SCY-078), orally administered QD for up to 180 days.

| | |
|--|---------------|
| Arm type | Experimental |
| Investigational medicinal product name | Ibrexafungerp |
| Investigational medicinal product code | |
| Other name | SCY-078 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

For non-Vulvovaginal candidiasis cases: 750 mg BID on Day 1, Day2; 750 mg QD for the remainder of treatment

Vulvovaginal candidiasis cases: 750 mg QD on Day1, Day 3, Day 5

| Number of subjects in period 1 | Ibrexafungerp (SCY-078) |
|--------------------------------|-------------------------|
| Started | 233 |
| Completed | 177 |
| Not completed | 56 |
| Disease Relapse | 2 |
| Consent withdrawn by subject | 11 |
| Lost to follow up | 4 |
| Adverse Event | 10 |
| Physician Decision | 10 |
| Death | 11 |

| | |
|---------------------|---|
| Other | 5 |
| Progressive Disease | 3 |

Baseline characteristics

Reporting groups

| | |
|---|---------------|
| Reporting group title | Overall Trial |
| Reporting group description: | |
| Ibrexafungerp (SCY-078), orally administered QD for up to 180 days (ITT population) | |

| Reporting group values | Overall Trial | Total | |
|---|---------------|-------|--|
| Number of subjects | 233 | 233 | |
| Age categorical | | | |
| Ibrexafungerp (SCY-078), orally administered QD for up to 180 days (ITT population) | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 166 | 166 | |
| From 65-84 years | 65 | 65 | |
| 85 years and over | 2 | 2 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 128 | 128 | |
| Male | 105 | 105 | |
| Disease Category | | | |
| Units: Subjects | | | |
| Invasive Candidiasis including Candidemia | 104 | 104 | |
| Mucocutaneous Candidiasis | 75 | 75 | |
| Dimorphic Fungi | 3 | 3 | |
| Aspergillus Syndromes | 40 | 40 | |
| Other emerging fungi | 11 | 11 | |

End points

End points reporting groups

| | |
|---|-------------------------|
| Reporting group title | Ibrexafungerp (SCY-078) |
| Reporting group description: Ibrexafungerp (SCY-078), orally administered QD for up to 180 days. | |

Primary: Percentage of participants who achieve a Global Response as determined by the Data Review Committee (DRC) by Fungal Disease.

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|-----------------|---|
| End point title | Percentage of participants who achieve a Global Response as determined by the Data Review Committee (DRC) by Fungal Disease. ^[1] |
|-----------------|---|

End point description:

The percentage of participants who achieve Global Response (defined as complete or partial response) as determined by the DRC at disease specific timepoints by fungal disease. Global Response is measured by participant survival and overall effect of treatment on the disease. Complete response: Survival, all attributable signs/symptoms (including radiological) resolved and mycological eradication of disease; Partial response: Survival, improvement of attributable signs/symptoms (including radiological).

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other diseases.

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

End point timeframe:

Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline.

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: The number and percentage of subjects with Successful Global Response as determined by the DRC will be presented for each disease, disease category, enrollment category, and pathogen along with a 95% confidence interval (CI) for a single binomial proportion in the ITT and PP populations. The Clopper Pearson method will be used for the confidence interval. CI is not estimated when the subjects in a particular group is less than 5.

| End point values | Ibrexafungerp (SCY-078) | | | |
|---|-------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: 233 participants | | | | |
| Overall Study (ITT) Number Analyzed | 233 | | | |
| Overall Study (ITT) Success | 142 | | | |
| Overall Study (ITT) Failure | 69 | | | |
| Overall Study (ITT) Not Evaluable | 22 | | | |
| Overall Study (PP) Number Analyzed | 195 | | | |
| Overall Study (PP) Success | 131 | | | |
| Overall Study (PP) Failure | 59 | | | |
| Overall Study (PP) Not Evaluable | 5 | | | |
| Acute Inv Candidiasis incl Candidemia (ITT) Number | 61 | | | |
| Acute Inv Candidiasis incl Candidemia (ITT) Success | 40 | | | |

| | | | | |
|--|----|--|--|--|
| Acute Inv Candidiasis incl Candidemia (ITT) Failur | 13 | | | |
| Acute Inv Candidiasis incl Candidemia (ITT) Not Ev | 8 | | | |
| Acute Inv Candidiasis incl Candidemia (PP) Number | 49 | | | |
| Acute Inv Candidiasis incl Candidemia (PP) Success | 37 | | | |
| Acute Inv Candidiasis incl Candidemia (PP) Failure | 10 | | | |
| Acute Inv Candidiasis incl Candidemia (PP) Not Eva | 2 | | | |
| Chronic Invasive Candidiasis (ITT) Number Analyzed | 43 | | | |
| Chronic Invasive Candidiasis (ITT) Success | 30 | | | |
| Chronic Invasive Candidiasis (ITT) Failure | 9 | | | |
| Chronic Invasive Candidiasis (ITT) Not Evaluable | 4 | | | |
| Chronic Invasive Candidiasis (PP) Number Analyzed | 33 | | | |
| Chronic Invasive Candidiasis (PP) Success | 25 | | | |
| Chronic Invasive Candidiasis (PP) Failure | 7 | | | |
| Chronic Invasive Candidiasis (PP) Not Evaluable | 1 | | | |
| Esophageal Candidiasis (ITT) Number Analyzed | 16 | | | |
| Esophageal Candidiasis (ITT) Success | 9 | | | |
| Esophageal Candidiasis (ITT) Failure | 5 | | | |
| Esophageal Candidiasis (ITT) Not Evaluable | 2 | | | |
| Esophageal Candidiasis (PP) Number Analyzed | 14 | | | |
| Esophageal Candidiasis (PP) Success | 9 | | | |
| Esophageal Candidiasis (PP) Failure | 4 | | | |
| Esophageal Candidiasis (PP) Not Evaluable | 1 | | | |
| Oropharyngeal Candidiasis (ITT) Number Analyzed | 14 | | | |
| Oropharyngeal Candidiasis (ITT) Success | 9 | | | |
| Oropharyngeal Candidiasis (ITT) Failure | 5 | | | |
| Oropharyngeal Candidiasis (ITT) Not Evaluable | 0 | | | |
| Oropharyngeal Candidiasis (PP) Number Analyzed | 13 | | | |
| Oropharyngeal Candidiasis (PP) Success | 8 | | | |
| Oropharyngeal Candidiasis (PP) Failure | 5 | | | |
| Oropharyngeal Candidiasis (PP) Not Evaluable | 0 | | | |
| Chronic Mucocutaneous Candidiasis (ITT) Number Ana | 13 | | | |
| Chronic Mucocutaneous Candidiasis (ITT) Success | 8 | | | |
| Chronic Mucocutaneous Candidiasis (ITT) Failure | 5 | | | |
| Chronic Mucocutaneous Candidiasis (ITT) Not Evalua | 0 | | | |

| | | | | |
|---|----|--|--|--|
| Chronic Mucocutaneous Candidiasis (PP) Number Anal | 12 | | | |
| Chronic Mucocutaneous Candidiasis (PP) Success | 8 | | | |
| Chronic Mucocutaneous Candidiasis (PP) Failure | 4 | | | |
| Chronic Mucocutaneous Candidiasis (PP) Not Evaluab | 0 | | | |
| Vulvovaginal Candidiasis (ITT) Number Analyzed | 32 | | | |
| Vulvovaginal Candidiasis (ITT) Success | 26 | | | |
| Vulvovaginal Candidiasis (ITT) Failure | 4 | | | |
| Vulvovaginal Candidiasis (ITT) Not Evaluable | 2 | | | |
| Vulvovaginal Candidiasis (PP) Number Analyzed | 27 | | | |
| Vulvovaginal Candidiasis (PP) Success | 24 | | | |
| Vulvovaginal Candidiasis (PP) Failure | 3 | | | |
| Vulvovaginal Candidiasis (PP) Not Evaluable | 0 | | | |
| Disseminated/Inv Dimorphic Fungi (ITT) Number Ana | 3 | | | |
| Disseminated/Inv Dimorphic Fungi (ITT) Success | 1 | | | |
| Disseminated/Inv Dimorphic Fungi (ITT) Failure | 2 | | | |
| Disseminated/Inv Dimorphic Fungi (ITT) Not Evalua | 0 | | | |
| Disseminated/Inv Dimorphic Fungi (PP) Number Anal | 3 | | | |
| Disseminated/Inv Dimorphic Fungi (PP) Success | 1 | | | |
| Disseminated/Inv Dimorphic Fungi (PP) Failure | 2 | | | |
| Disseminated/Inv Dimorphic Fungi (PP) Not Evaluab | 0 | | | |
| Chronic Pulmonary Aspergillosis (ITT) Number Analy | 6 | | | |
| Chronic Pulmonary Aspergillosis (ITT) Success | 0 | | | |
| Chronic Pulmonary Aspergillosis (ITT) Failure | 6 | | | |
| Chronic Pulmonary Aspergillosis (ITT) Not Evaluabl | 0 | | | |
| Chronic Pulmonary Aspergillosis (PP) Number Analyz | 5 | | | |
| Chronic Pulmonary Aspergillosis (PP) Success | 0 | | | |
| Chronic Pulmonary Aspergillosis (PP) Failure | 5 | | | |
| Chronic Pulmonary Aspergillosis (PP) Not Evaluable | 0 | | | |
| Allergic Bronchopulmonary Aspergillosis (ITT) Numb | 5 | | | |
| Allergic Bronchopulmonary Aspergillosis (ITT) Succ | 0 | | | |
| Allergic Bronchopulmonary Aspergillosis (ITT) Fail | 3 | | | |
| Allergic Bronchopulmonary Aspergillosis (ITT) Not | 2 | | | |

| | | | | |
|--|----|--|--|--|
| Allergic Bronchopulmonary Aspergillosis (PP) Numbe | 3 | | | |
| Allergic Bronchopulmonary Aspergillosis (PP) Succe | 0 | | | |
| Allergic Bronchopulmonary Aspergillosis (PP) Failu | 3 | | | |
| Allergic Bronchopulmonary Aspergillosis (PP) Not E | 0 | | | |
| Invasive Pulmonary Aspergillosis (ITT) Number Anal | 29 | | | |
| Invasive Pulmonary Aspergillosis (ITT) Success | 12 | | | |
| Invasive Pulmonary Aspergillosis (ITT) Failure | 14 | | | |
| Invasive Pulmonary Aspergillosis (ITT) Not Evaluab | 3 | | | |
| Invasive Pulmonary Aspergillosis (PP) Number Analy | 26 | | | |
| Invasive Pulmonary Aspergillosis (PP) Success | 12 | | | |
| Invasive Pulmonary Aspergillosis (PP) Failure | 13 | | | |
| Invasive Pulmonary Aspergillosis (PP) Not Evaluabl | 1 | | | |
| Other Emerging Fungi (ITT) Number Analyzed | 11 | | | |
| Other Emerging Fungi (ITT) Success | 7 | | | |
| Other Emerging Fungi (ITT) Failure | 3 | | | |
| Other Emerging Fungi (ITT) Not Evaluable | 1 | | | |
| Other Emerging Fungi (PP) Number Analyzed | 10 | | | |
| Other Emerging Fungi (PP) Success | 7 | | | |
| Other Emerging Fungi (PP) Failure | 3 | | | |
| Other Emerging Fungi (PP) Not Evaluable | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who achieve a Global Response as Determined by the Data Review Committee (DRC) by Enrollment Category

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|-----------------|--|
| End point title | Percentage of Participants who achieve a Global Response as Determined by the Data Review Committee (DRC) by Enrollment Category |
|-----------------|--|

End point description:

The percentage of participants who achieve a Global Response (defined as complete or partial response) as determined by the DRC by enrollment category, at disease specific timepoints. Global Response is measured by participant survival and overall effect of treatment on the disease. Complete response: Survival, all attributable signs/symptoms (including radiological) resolved and mycological eradication of disease; Partial response: Survival, improvement of attributable signs/symptoms (including radiological).

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other

diseases. Participants may have been enrolled for more than 1 enrollment reason.

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|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline. | |

| End point values | Ibrexafungerp (SCY-078) | | | |
|--|-------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: 233 participants | | | | |
| Refractory Fungal Infection Number Analyzed | 128 | | | |
| Refractory Fungal Infection Success | 74 | | | |
| Refractory Fungal Infection Failure | 41 | | | |
| Refractory Fungal Infection Not Evaluable | 13 | | | |
| Resistance to standard of care antifungal Number A | 134 | | | |
| Resistance to standard of care antifungal Success | 95 | | | |
| Resistance to standard of care antifungal Failure | 29 | | | |
| Resistance to standard of care antifungal Not Eval | 10 | | | |
| Intolerance to standard of care antifungal Number | 29 | | | |
| Intolerance to standard of care antifungal Success | 13 | | | |
| Intolerance to standard of care antifungal Failure | 14 | | | |
| Intolerance to standard of care antifungal Not Eva | 2 | | | |
| Toxicities associated with SOC antifungal Number A | 17 | | | |
| Toxicities associated with SOC antifungal Success | 7 | | | |
| Toxicities associated with SOC antifungal Failure | 8 | | | |
| Toxicities associated with SOC antifungal Not Eval | 2 | | | |
| Relapse Number Analyzed | 18 | | | |
| Relapse Success | 12 | | | |
| Relapse Failure | 5 | | | |
| Relapse Not Evaluable | 1 | | | |
| Other Number Analyzed | 2 | | | |
| Other Success | 0 | | | |
| Other Failure | 1 | | | |
| Other Not Evaluable | 1 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieve a Global Response as Determined by the Data Review Committee (DRC) by Disease Category.

| | |
|-----------------|--|
| End point title | Percentage of Participants Who Achieve a Global Response as Determined by the Data Review Committee (DRC) by Disease Category. |
|-----------------|--|

End point description:

The percentage of participants who achieve Global Response (defined as complete or partial response) as determined by the DRC at disease specific timepoints by disease category. Global Response is measured by participant survival and overall effect of treatment on the disease. Complete response: Survival, all attributable signs/symptoms (including radiological) resolved and mycological eradication of disease; Partial response: Survival, improvement of attributable signs/symptoms (including radiological).

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other diseases.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline.

| End point values | Ibrexafungerp (SCY-078) | | | |
|--|-------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: 233 participants | | | | |
| Invasive Candidiasis including Candidemia Number A | 104 | | | |
| Invasive Candidiasis including Candidemia Success | 70 | | | |
| Invasive Candidiasis including Candidemia Failure | 22 | | | |
| Invasive Candidiasis including Candidemia Not Eval | 12 | | | |
| Mucocutaneous Candidiasis Number Analyzed | 75 | | | |
| Mucocutaneous Candidiasis Success | 52 | | | |
| Mucocutaneous Candidiasis Failure | 19 | | | |
| Mucocutaneous Candidiasis Not Evaluable | 4 | | | |
| Dimorphic Fungi Number Analyzed | 3 | | | |
| Dimorphic Fungi Success | 1 | | | |
| Dimorphic Fungi Failure | 2 | | | |
| Dimorphic Fungi Not Evaluable | 0 | | | |
| Aspergillus Syndromes Number Analyzed | 40 | | | |
| Aspergillus Syndromes Success | 12 | | | |
| Aspergillus Syndromes Failure | 23 | | | |
| Aspergillus Syndromes Not Evaluable | 5 | | | |
| Other emerging fungi Number Analyzed | 11 | | | |

| | | | | |
|------------------------------------|---|--|--|--|
| Other emerging fungi Success | 7 | | | |
| Other emerging fungi Failure | 3 | | | |
| Other emerging fungi Not Evaluable | 1 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Clinical Response (Based on Signs and Symptoms) by Disease Category

| | |
|-----------------|---|
| End point title | Percentage of Participants With a Clinical Response (Based on Signs and Symptoms) by Disease Category |
|-----------------|---|

End point description:

The percentage of participants with a Clinical Response as determined by the DRC at disease specific timepoints, by disease category. Clinical Response: resolution or improvement in attributable symptoms and signs of disease and radiological abnormalities (if applicable) .

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other diseases. Clinical response was evaluated based on disease signs (including radiological signs) and symptoms.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline.

| End point values | Ibrexafungerp (SCY-078) | | | |
|--|-------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: 233 | | | | |
| Invasive Candidiasis including Candidemia Number A | 401 | | | |
| Invasive Candidiasis including Candidemia Success | 57 | | | |
| Invasive Candidiasis including Candidemia Failure | 16 | | | |
| Invasive Candidiasis including Candidemia Not Eval | 29 | | | |
| Invasive Candidiasis including Candidemia No Respo | 2 | | | |
| Mucocutaneous Candidiasis (TOC) Number Analyzed | 75 | | | |
| Mucocutaneous Candidiasis (TOC) Success | 25 | | | |
| Failure | 5 | | | |
| Mucocutaneous Candidiasis (TOC) Not Evaluable | 2 | | | |
| Mucocutaneous Candidiasis (TOC) No Response | 43 | | | |
| Dimorphic Fungi Number Analyzed | 3 | | | |

| | | | | |
|---------------------------------------|----|--|--|--|
| Dimorphic Fungi Success | 3 | | | |
| Dimorphic Fungi Failure | 0 | | | |
| Dimorphic Fungi Not Evaluable | 0 | | | |
| Dimorphic Fungi No Response | 0 | | | |
| Aspergillus Syndromes Number Analyzed | 40 | | | |
| Aspergillus Syndromes Success | 18 | | | |
| Aspergillus Syndromes Failure | 14 | | | |
| Aspergillus Syndromes Not Evaluable | 6 | | | |
| Aspergillus Syndromes No Response | 2 | | | |
| Other emerging fungi Number Analyzed | 11 | | | |
| Other emerging fungi Success | 7 | | | |
| Other emerging fungi Failure | 3 | | | |
| Other emerging fungi Not Evaluable | 1 | | | |
| Other emerging fungi No Response | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Clinical Response (Signs and Symptoms) by Disease Category and Pathogen

| | |
|-----------------|---|
| End point title | Percentage of Participants With a Clinical Response (Signs and Symptoms) by Disease Category and Pathogen |
|-----------------|---|

End point description:

The percentage of participants with a Clinical Response as determined by the DRC by disease category and by pathogen isolated, at disease specific timepoints. Clinical Response: resolution or improvement in attributable symptoms and signs of disease and radiological abnormalities (if applicable) .

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other diseases. Clinical response was evaluated based on disease signs (including radiological signs) and symptoms.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline.

| | | | | |
|--|-------------------------|--|--|--|
| End point values | Ibrexafungerp (SCY-078) | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: 233 | | | | |
| Inv Candidiasis,incl Candidemia (C.albicans) Numbe | 26 | | | |
| Inv Candidiasis,incl Candidemia (C.albicans) Succe | 11 | | | |
| Inv Candidiasis,incl Candidemia (C.albicans) Failu | 7 | | | |

| | | | | |
|--|----|--|--|--|
| Inv Candidiasis,incl Candidemia (C.albicans) Not E | 8 | | | |
| Inv Candidiasis,incl Candidemia (C.auris) Number A | 10 | | | |
| Inv Candidiasis,incl Candidemia (C.auris) Success | 6 | | | |
| Inv Candidiasis,incl Candidemia (C.auris) Failure | 1 | | | |
| Inv Candidiasis,incl Candidemia (C.auris) Not Eval | 3 | | | |
| Inv Candidiasis,incl Candidemia (C. glabrata) Numb | 49 | | | |
| Inv Candidiasis,incl Candidemia (C. glabrata) Succ | 30 | | | |
| Inv Candidiasis,incl Candidemia (C. glabrata) Fail | 6 | | | |
| Inv Candidiasis,incl Candidemia (C. glabrata) Not | 13 | | | |
| Inv Candidiasis,incl Candidemia (C. krusei) Number | 8 | | | |
| Inv Candidiasis,incl Candidemia (C. krusei) Succes | 4 | | | |
| Inv Candidiasis,incl Candidemia (C. krusei) Failur | 2 | | | |
| Inv Candidiasis,incl Candidemia (C. krusei) Not Ev | 2 | | | |
| Inv Candidiasis, Candidemia (C.parapsilosis) Numbe | 9 | | | |
| Inv Candidiasis, Candidemia (C.parapsilosis) Succe | 5 | | | |
| Inv Candidiasis, Candidemia (C.parapsilosis) Failu | 1 | | | |
| Inv Candidiasis, Candidemia (C.parapsilosis) Not E | 3 | | | |
| Inv Candidiasis, Candidemia (C.tropicalis) Number | 9 | | | |
| Inv Candidiasis, Candidemia (C.tropicalis) Success | 6 | | | |
| Inv Candidiasis, Candidemia (C.tropicalis) Failure | 0 | | | |
| Inv Candidiasis, Candidemia (C.tropicalis) Not Eva | 3 | | | |
| Inv Candidiasis, Candidemia (other) Number Analyze | 5 | | | |
| Inv Candidiasis, Candidemia (other) Success | 3 | | | |
| Inv Candidiasis, Candidemia (other) Failure | 0 | | | |
| Inv Candidiasis, Candidemia (other) Not Evaluable | 2 | | | |
| Mucocutaneous Candidiasis (C. albicans) Number Ana | 47 | | | |
| Mucocutaneous Candidiasis (C. albicans) Success | 19 | | | |
| Mucocutaneous Candidiasis (C. albicans) Failure | 1 | | | |
| Mucocutaneous Candidiasis (C. albicans) Not Evalua | 27 | | | |
| Mucocutaneous Candidiasis (C. glabrata) Number Ana | 25 | | | |
| Mucocutaneous Candidiasis (C. glabrata) Success | 5 | | | |

| | | | | |
|--|----|--|--|--|
| Mucocutaneous Candidiasis (C. glabrata) Failure | 3 | | | |
| Mucocutaneous Candidiasis (C. glabrata) Not Evalua | 17 | | | |
| Mucocutaneous Candidiasis (C. krusei) Number Analy | 7 | | | |
| Mucocutaneous Candidiasis (C. krusei) Success | 2 | | | |
| Mucocutaneous Candidiasis (C. krusei) Failure | 1 | | | |
| Mucocutaneous Candidiasis (C. krusei) Not Evaluabl | 4 | | | |
| Mucocutaneous Candidiasis (C. tropicalis) Number A | 1 | | | |
| Mucocutaneous Candidiasis (C. tropicalis) Success | 0 | | | |
| Mucocutaneous Candidiasis (C. tropicalis) Failure | 0 | | | |
| Mucocutaneous Candidiasis (C. tropicalis) Not Eval | 1 | | | |
| Mucocutaneous Candidiasis (C. parapsilosis) Number | 1 | | | |
| Mucocutaneous Candidiasis (C. parapsilosis) Succes | 1 | | | |
| Mucocutaneous Candidiasis (C. parapsilosis) Failur | 0 | | | |
| Mucocutaneous Candidiasis (C. parapsilosis) Not Ev | 0 | | | |
| Mucocutaneous Candidiasis (other) Number Analyzed | 9 | | | |
| Mucocutaneous Candidiasis (other) Success | 3 | | | |
| Mucocutaneous Candidiasis (other) Failure | 1 | | | |
| Mucocutaneous Candidiasis (other) Not Evaluable | 5 | | | |
| Dimorphic Fungi (Histoplasmosis) Number Analyzed | 3 | | | |
| Dimorphic Fungi (Histoplasmosis) Success | 3 | | | |
| Dimorphic Fungi (Histoplasmosis) Failure | 0 | | | |
| Dimorphic Fungi (Histoplasmosis) Not Evaluable | 0 | | | |
| Aspergillus Syndromes (A. flavus) Number Analyzed | 2 | | | |
| Aspergillus Syndromes (A. flavus) Success | 2 | | | |
| Aspergillus Syndromes (A. flavus) Failure | 0 | | | |
| Aspergillus Syndromes (A. flavus) Not Evaluable | 0 | | | |
| Aspergillus Syndromes (A. fumigatus) Number Analyz | 18 | | | |
| Aspergillus Syndromes (A. fumigatus) Success | 8 | | | |
| Aspergillus Syndromes (A. fumigatus) Failure | 8 | | | |
| Aspergillus Syndromes (A. fumigatus) Not Evaluable | 2 | | | |
| Aspergillus Syndromes (other) Number Analyzed | 14 | | | |

| | | | | |
|--|---|--|--|--|
| Aspergillus Syndromes (other) Success | 9 | | | |
| Aspergillus Syndromes (other) Failure | 5 | | | |
| Aspergillus Syndromes (other) Not Evaluable/Missin | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Clinical Response (Signs and Symptoms) by Fungal Disease

| | |
|-----------------|--|
| End point title | Percentage of Participants With a Clinical Response (Signs and Symptoms) by Fungal Disease |
|-----------------|--|

End point description:

The percentage of participants with a Clinical Response as determined by the DRC by fungal disease, at disease specific timepoints. Clinical Response: resolution or improvement in attributable symptoms and signs of disease and radiological abnormalities (if applicable) .

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other diseases. Clinical response was evaluated based on disease signs (including radiological signs) and symptoms.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline.

| End point values | Ibrexafungerp (SCY-078) | | | |
|--|-------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: 233 participants | | | | |
| Acute Inv Candidiasis, incl Candidemia Number Anal | 61 | | | |
| Acute Inv Candidiasis, incl Candidemia Success | 30 | | | |
| Acute Inv Candidiasis, incl Candidemia Failure | 10 | | | |
| Acute Inv Candidiasis, incl Candidemia Not Evaluab | 19 | | | |
| Acute Inv Candidiasis, incl Candidemia No Respons | 2 | | | |
| Chronic Invasive Candidiasis Number Analyzed | 43 | | | |
| Chronic Invasive Candidiasis Success | 27 | | | |
| Chronic Invasive Candidiasis Failure | 6 | | | |
| Chronic Invasive Candidiasis Not Evaluable | 10 | | | |
| Chronic Invasive Candidiasis No Response | 0 | | | |

| | | | | |
|--|----|--|--|--|
| Vulvovaginal Candidiasis Number Analyzed | 32 | | | |
| Vulvovaginal Candidiasis Success | 25 | | | |
| Vulvovaginal Candidiasis Failure | 5 | | | |
| Vulvovaginal Candidiasis Not Evaluable | 2 | | | |
| Vulvovaginal Candidiasis No Response | 0 | | | |
| Esophageal Candidiasis Number Analyzed | 16 | | | |
| Esophageal Candidiasis Success | 10 | | | |
| Esophageal Candidiasis Failure | 4 | | | |
| Esophageal Candidiasis Not Evaluable | 2 | | | |
| Esophageal Candidiasis No Response | 0 | | | |
| Oropharyngeal Candidiasis Number Analyzed | 14 | | | |
| Oropharyngeal Candidiasis Success | 10 | | | |
| Oropharyngeal Candidiasis Failure | 4 | | | |
| Oropharyngeal Candidiasis Not Evaluable | 0 | | | |
| Oropharyngeal Candidiasis No Response | 0 | | | |
| Chronic Mucocutaneous Candidiasis Number Analyzed | 13 | | | |
| Chronic Mucocutaneous Candidiasis Success | 8 | | | |
| Chronic Mucocutaneous Candidiasis Failure | 5 | | | |
| Chronic Mucocutaneous Candidiasis Not Evaluable | 0 | | | |
| Chronic Mucocutaneous Candidiasis No Response | 0 | | | |
| Disseminated/Invasive Dimorphic Fungi Number Anal | 3 | | | |
| Disseminated/Invasive Dimorphic Fungi Success | 3 | | | |
| Disseminated/Invasive Dimorphic Fungi Failure | 0 | | | |
| Disseminated/Invasive Dimorphic Fungi Not Evalab | 0 | | | |
| Disseminated/Invasive Dimorphic Fungi No Response | 0 | | | |
| Chronic Pulmonary Aspergillosis Number Analyzed | 6 | | | |
| Chronic Pulmonary Aspergillosis Success | 3 | | | |
| Chronic Pulmonary Aspergillosis Failure | 2 | | | |
| Chronic Pulmonary Aspergillosis Not Evaluable | 1 | | | |
| Chronic Pulmonary Aspergillosis No Response | 0 | | | |
| Allergic Bronchopulmonary Aspergillosis Number Ana | 5 | | | |
| Allergic Bronchopulmonary Aspergillosis Success | 0 | | | |
| Allergic Bronchopulmonary Aspergillosis Failure | 2 | | | |
| Allergic Bronchopulmonary Aspergillosis Not Evalua | 2 | | | |
| Allergic Bronchopulmonary Aspergillosis No Respons | 1 | | | |
| Invasive Pulmonary Aspergillosis Number Analyzed | 29 | | | |

| | | | | |
|--|----|--|--|--|
| Invasive Pulmonary Aspergillosis Success | 15 | | | |
| Invasive Pulmonary Aspergillosis Failure | 10 | | | |
| Invasive Pulmonary Aspergillosis Not Evaluable | 3 | | | |
| Invasive Pulmonary Aspergillosis No Response | 1 | | | |
| Other Emerging Fungi Number Analyzed | 11 | | | |
| Other Emerging Fungi Success | 7 | | | |
| Other Emerging Fungi Failure | 3 | | | |
| Other Emerging Fungi Not Evaluable | 1 | | | |
| Other Emerging Fungi No Response | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Clinical Response (Signs and Symptoms) by Enrollment Category

| | |
|-----------------|---|
| End point title | Percentage of Participants With a Clinical Response (Signs and Symptoms) by Enrollment Category |
|-----------------|---|

End point description:

The percentage of participants with a Clinical Response as determined by the DRC by enrollment category, at disease specific timepoints. Clinical Response: resolution or improvement in attributable symptoms and signs of disease and radiological abnormalities (if applicable) .

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other diseases. Clinical response was evaluated based on disease signs (including radiological signs) and symptoms.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline.

| End point values | Ibrexafungerp (SCY-078) | | | |
|-----------------------------|-------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: Participants | | | | |
| Refractory Number Analyzed | 128 | | | |
| Refractory Success | 57 | | | |
| Refractory Failure | 29 | | | |
| Refractory Not Evaluable | 13 | | | |
| Refractory No Response | 29 | | | |
| Resistance Number Analyzed | 134 | | | |
| Resistance Success | 75 | | | |
| Resistance Failure | 23 | | | |
| Resistance Not Evaluable | 25 | | | |

| | | | | |
|-----------------------------|----|--|--|--|
| Resistance No Response | 11 | | | |
| Intolerance Number Analyzed | 29 | | | |
| Intolerance Success | 16 | | | |
| Intolerance Failure | 8 | | | |
| Intolerance Not Evaluable | 3 | | | |
| Intolerance No Response | 2 | | | |
| Toxicities Number Analyzed | 17 | | | |
| Toxicities Success | 12 | | | |
| Toxicities Failure | 3 | | | |
| Toxicities Not Evaluable | 1 | | | |
| Toxicities No Response | 1 | | | |
| Relapse Number Analyzed | 18 | | | |
| Relapse Success | 8 | | | |
| Relapse Failure | 4 | | | |
| Relapse Not Evaluable | 1 | | | |
| Relapse No Response | 5 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Mycological Response by Disease Category

| | |
|-----------------|--|
| End point title | Percentage of Participants With a Mycological Response by Disease Category |
|-----------------|--|

End point description:

The percentage of participants with a Mycological Response as determined by the DRC by disease category, at disease specific timepoints. Mycological Response: evidence of eradication or clearance of cultures or reduction of fungal burden, as assessed by a quantitative and validated laboratory marker.

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other diseases. Mycological response was evaluated based on culture, microscopy and other biomarkers of fungal infection.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline.

| | | | | |
|---|-------------------------|--|--|--|
| End point values | Ibrexafungerp (SCY-078) | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: Participants | | | | |
| Inv Candidiasis incl Candidemia Number Analyzed | 107 | | | |
| Inv Candidiasis incl Candidemia Success | 20 | | | |
| Inv Candidiasis incl Candidemia Failure | 14 | | | |

| | | | | |
|--|----|--|--|--|
| Inv Candidiasis incl Candidemia Not Evaluable/Miss | 70 | | | |
| Mucocutaneous Candidiasis (TOC) Number Analyzed | 75 | | | |
| Mucocutaneous Candidiasis (TOC) Success | 11 | | | |
| Mucocutaneous Candidiasis (TOC) Failure | 13 | | | |
| Mucocutaneous Candidiasis (TOC) Not Evaluable/Miss | 51 | | | |
| Dimorphic Fungi Number Analyzed | 3 | | | |
| Dimorphic Fungi Success | 0 | | | |
| Dimorphic Fungi Failure | 1 | | | |
| Dimorphic Fungi Not Evaluable/Missing | 2 | | | |
| Aspergillus Syndromes Number Analyzed | 40 | | | |
| Aspergillus Syndromes Success | 5 | | | |
| Aspergillus Syndromes Failure | 13 | | | |
| Aspergillus Syndromes Not Evaluable/Missing | 22 | | | |
| Other emerging fungi Number Analyzed | 11 | | | |
| Other emerging fungi Success | 2 | | | |
| Other emerging fungi Failure | 2 | | | |
| Other emerging fungi Not Evaluable/Missing | 7 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Mycological Response by Disease Category and Pathogen

| | |
|-----------------|---|
| End point title | Percentage of Participants With a Mycological Response by Disease Category and Pathogen |
|-----------------|---|

End point description:

The percentage of participants with a Mycological Response as determined by the DRC by disease category and by pathogen, at disease specific timepoints. Mycological Response: evidence of eradication or clearance of cultures or reduction of fungal burden, as assessed by a quantitative and validated laboratory marker.

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other diseases. Mycological response was evaluated based on culture, microscopy and other biomarkers of fungal infection.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline.

| End point values | Ibrexafungerp (SCY-078) | | | |
|---|----------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: Participants | | | | |
| Inv Candidiasis,incl Candidemia (C.albicans) Numbe | 26 | | | |
| Inv Candidiasis,incl Candidemia (C.albicans) Succe | 3 | | | |
| Inv Candidiasis,incl Candidemia (C.albicans) Failu | 6 | | | |
| Inv Candidiasis,incl Candidemia (C.albicans) Not E | 17 | | | |
| Inv Candidiasis, Candidemia (C.parapsilosis) Numbe | 9 | | | |
| Inv Candidiasis, Candidemia (C.parapsilosis) Succe | 1 | | | |
| Inv Candidiasis, Candidemia (C.parapsilosis) Failu | 2 | | | |
| Inv Candidiasis, Candidemia (C.parapsilosis) Not E | 6 | | | |
| Inv Candidiasis, Candidemia (C.auris) Number Analy | 10 | | | |
| Inv Candidiasis, Candidemia (C.auris) Success | 2 | | | |
| Inv Candidiasis, Candidemia (C.auris) Failure | 1 | | | |
| Inv Candidiasis, Candidemia (C.auris) Not Evaluabl | 7 | | | |
| Inv Candidiasis, Candidemia (C.glabrata) Number An | 49 | | | |
| Inv Candidiasis, Candidemia (C.glabrata) Success | 10 | | | |
| Inv Candidiasis, Candidemia (C.glabrata) Failure | 7 | | | |
| Inv Candidiasis, Candidemia (C.glabrata) Not Evalu | 32 | | | |
| Inv Candidiasis, Candidemia (C.krusei) Number Anal | 8 | | | |
| Inv Candidiasis, Candidemia (C.krusei) Success | 5 | | | |
| Inv Candidiasis, Candidemia (C.krusei) Failure | 0 | | | |
| Inv Candidiasis, Candidemia (C.krusei) Not Evaluab | 3 | | | |
| Inv Candidiasis, Candidemia (C.tropicalis) Number | 9 | | | |
| Inv Candidiasis, Candidemia (C.tropicalis) Success | 2 | | | |
| Inv Candidiasis, Candidemia (C.tropicalis) Failure | 0 | | | |
| Inv Candidiasis, Candidemia (C.tropicalis) Not Eva | 7 | | | |
| Inv Candidiasis, Candidemia (other) Number Analyze | 5 | | | |
| Inv Candidiasis, Candidemia (other) Success | 0 | | | |
| Inv Candidiasis, Candidemia (other) Failure | 0 | | | |
| Inv Candidiasis, Candidemia (other) Not Evaluable | 5 | | | |

| | | | | |
|---|----|--|--|--|
| Mucocutaneous Candidiasis (C.albicans) Number Anal | 47 | | | |
| Mucocutaneous Candidiasis (C.albicans) Success | 10 | | | |
| Mucocutaneous Candidiasis (C.albicans) Failure | 5 | | | |
| Mucocutaneous Candidiasis (C.albicans) Not Evaluab | 32 | | | |
| Mucocutaneous Candidiasis (C.glabrata) Number Anal | 25 | | | |
| Mucocutaneous Candidiasis (C.glabrata) Success | 0 | | | |
| Mucocutaneous Candidiasis (C.glabrata) Failure | 8 | | | |
| Mucocutaneous Candidiasis (C.glabrata) Not Evaluab | 17 | | | |
| Mucocutaneous Candidiasis (C.krusei) Number Analyz | 7 | | | |
| Mucocutaneous Candidiasis (C.krusei) Success | 2 | | | |
| Mucocutaneous Candidiasis (C.krusei) Failure | 1 | | | |
| Mucocutaneous Candidiasis (C.krusei) Not Evaluable | 4 | | | |
| Mucocutaneous Candidiasis (C.parapsilosis) Number | 1 | | | |
| Mucocutaneous Candidiasis (C.parapsilosis) Success | 0 | | | |
| Mucocutaneous Candidiasis (C.parapsilosis) Failure | 0 | | | |
| Mucocutaneous Candidiasis (C.parapsilosis) Not Eva | 1 | | | |
| Mucocutaneous Candidiasis (C.tropicalis) Number An | 1 | | | |
| Mucocutaneous Candidiasis (C.tropicalis) Success | 0 | | | |
| Mucocutaneous Candidiasis (C.tropicalis) Failure | 0 | | | |
| Mucocutaneous Candidiasis (C.tropicalis) Not Evalu | 1 | | | |
| Mucocutaneous Candidiasis (other) Number Analyzed | 9 | | | |
| Mucocutaneous Candidiasis (other) Success | 2 | | | |
| Mucocutaneous Candidiasis (other) Failure | 2 | | | |
| Mucocutaneous Candidiasis (other) Not Evaluable/Mi | 5 | | | |
| Dimorphic Fungi (Coccidioidomycosis) Number Analyz | 0 | | | |
| Dimorphic Fungi (Coccidioidomycosis) Success | 0 | | | |
| Dimorphic Fungi (Coccidioidomycosis) Failure | 0 | | | |
| Dimorphic Fungi (Coccidioidomycosis) Not Evaluable | 0 | | | |
| Dimorphic Fungi (Histoplasmosis) Number Analyzed | 3 | | | |
| Dimorphic Fungi (Histoplasmosis) Success | 0 | | | |
| Dimorphic Fungi (Histoplasmosis) Failure | 1 | | | |

| | | | | |
|--|----|--|--|--|
| Dimorphic Fungi (Histoplasmosis) Not Evaluable | 2 | | | |
| Aspergillus Syndromes (A.nidulans) Number Analyzed | 1 | | | |
| Aspergillus Syndromes (A.nidulans) Success | 0 | | | |
| Aspergillus Syndromes (A.nidulans) Failure | 1 | | | |
| Aspergillus Syndromes (A.nidulans) Not Evaluable/M | 0 | | | |
| Aspergillus Syndromes (A.fumigatus) Number Analyze | 18 | | | |
| Aspergillus Syndromes (A.fumigatus) Success | 1 | | | |
| Aspergillus Syndromes (A.fumigatus) Failure | 5 | | | |
| Aspergillus Syndromes (A.fumigatus) Not Evaluable | 12 | | | |
| Aspergillus Syndromes (A. flavus) Number Analyzed | 2 | | | |
| Aspergillus Syndromes (A. flavus) Success | 1 | | | |
| Aspergillus Syndromes (A. flavus) Failure | 1 | | | |
| Aspergillus Syndromes (A. flavus) Not Evaluable | 0 | | | |
| Aspergillus Syndromes (other) Number Analyzed | 14 | | | |
| Aspergillus Syndromes (other) Success | 2 | | | |
| Aspergillus Syndromes (other) Failure | 7 | | | |
| Aspergillus Syndromes (other) Not Evaluable/Missin | 5 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Mycological Response by Fungal Disease

| | |
|-----------------|--|
| End point title | Percentage of Participants With a Mycological Response by Fungal Disease |
|-----------------|--|

End point description:

The percentage of participants with a Mycological Response as determined by the DRC by fungal disease, at disease specific timepoints. Mycological Response: evidence of eradication or clearance of cultures or reduction of fungal burden, as assessed by a quantitative and validated laboratory marker.

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other diseases. Mycological response was evaluated based on culture, microscopy and other biomarkers of fungal infection.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline.

| End point values | Ibrexafungerp (SCY-078) | | | |
|---|----------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: Participants | | | | |
| Acute Inv Candidiasis,incl Candidemia Number Analy | 61 | | | |
| Acute Inv Candidiasis,incl Candidemia Success | 16 | | | |
| Acute Inv Candidiasis,incl Candidemia Failure | 10 | | | |
| Acute Inv Candidiasis,incl Candidemia Not Evaluabl | 35 | | | |
| Chronic Invasive Candidiasis Number Analyzed | 43 | | | |
| Chronic Invasive Candidiasis Success | 4 | | | |
| Chronic Invasive Candidiasis Failure | 4 | | | |
| Chronic Invasive Candidiasis Not Evaluable/Missing | 35 | | | |
| Esophageal Candidiasis Number Analyzed | 16 | | | |
| Esophageal Candidiasis Success | 2 | | | |
| Esophageal Candidiasis Failure | 5 | | | |
| Esophageal Candidiasis Not Evaluable/Missing | 9 | | | |
| Oropharyngeal Candidiasis Number Analyzed | 14 | | | |
| Oropharyngeal Candidiasis Success | 7 | | | |
| Oropharyngeal Candidiasis Failure | 4 | | | |
| Oropharyngeal Candidiasis Not Evaluable/Missing | 3 | | | |
| Chronic Mucocutaneous Candidiasis Number Analyzed | 13 | | | |
| Chronic Mucocutaneous Candidiasis Success | 6 | | | |
| Chronic Mucocutaneous Candidiasis Failure | 6 | | | |
| Chronic Mucocutaneous Candidiasis Not Evaluable | 1 | | | |
| Vulvovaginal Candidiasis Number Analyzed | 32 | | | |
| Vulvovaginal Candidiasis Success | 11 | | | |
| Vulvovaginal Candidiasis Failure | 13 | | | |
| Vulvovaginal Candidiasis Not Evaluable/Missing | 8 | | | |
| Disseminated/Invasive Dimorphic Fungi Number Anal | 3 | | | |
| Disseminated/Invasive Dimorphic Fungi Success | 0 | | | |
| Disseminated/Invasive Dimorphic Fungi Failure | 1 | | | |
| Disseminated/Invasive Dimorphic Fungi Not Evaluab | 2 | | | |
| Chronic Pulmonary Aspergillosis Number Analyzed | 6 | | | |

| | | | | |
|--|----|--|--|--|
| Chronic Pulmonary Aspergillosis Success | 1 | | | |
| Chronic Pulmonary Aspergillosis Failure | 4 | | | |
| Chronic Pulmonary Aspergillosis Not Evaluable/Miss | 1 | | | |
| Allergic Bronchopulmonary Aspergillosis Number Ana | 5 | | | |
| Allergic Bronchopulmonary Aspergillosis Success | 1 | | | |
| Allergic Bronchopulmonary Aspergillosis Failure | 2 | | | |
| Allergic Bronchopulmonary Aspergillosis Not Evalua | 2 | | | |
| Invasive Pulmonary Aspergillosis Number Analyzed | 29 | | | |
| Invasive Pulmonary Aspergillosis Success | 3 | | | |
| Invasive Pulmonary Aspergillosis Failure | 7 | | | |
| Invasive Pulmonary Aspergillosis Not Evaluable | 19 | | | |
| Other Emerging Fungi Number Analyzed | 11 | | | |
| Other Emerging Fungi Success | 2 | | | |
| Other Emerging Fungi Failure | 2 | | | |
| Other Emerging Fungi Not Evaluable | 7 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Mycological Response by Enrollment Category

| | |
|-----------------|---|
| End point title | Percentage of Participants With a Mycological Response by Enrollment Category |
|-----------------|---|

End point description:

The percentage of participants with a Mycological Response as determined by the DRC by enrollment category, at disease specific timepoints. Mycological Response: evidence of eradication or clearance of cultures or reduction of fungal burden, as assessed by a quantitative and validated laboratory marker.

Disease specific timepoints: End of Treatment (EoT) for invasive candidiasis, EoT or Day 84 for Chronic Mucocutaneous Candidiasis, Test of Cure (TOC) for Vulvovaginal Candidiasis, EoT or Day 90 for Chronic Pulmonary Aspergillosis, EoT or Day 90 Allergic Bronchopulmonary Aspergillosis and EoT for all other diseases. Mycological response was evaluated based on culture, microscopy and other biomarkers of fungal infection.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Vulvovaginal Candidiasis: Day 17. Chronic Mucocutaneous Candidiasis: EOT up to Day 84. Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis: EOT up to Day 90. All other diseases: EOT up to Day 180. All Days measured from Baseline.

| | | | | |
|-----------------------------------|-------------------------|--|--|--|
| End point values | Ibrexafungerp (SCY-078) | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: Participants | | | | |
| Refractory Number Analyzed | 128 | | | |
| Refractory Success | 21 | | | |
| Refractory Failure | 33 | | | |
| Refractory Not Evaluable/Failure | 74 | | | |
| Resistance Number Analyzed | 134 | | | |
| Resistance Success | 28 | | | |
| Resistance Failure | 19 | | | |
| Resistance Not Evaluable/Failure | 87 | | | |
| Intolerance Number Analyzed | 29 | | | |
| Intolerance Success | 7 | | | |
| Intolerance Failure | 10 | | | |
| Intolerance Not Evaluable/Failure | 12 | | | |
| Toxicities Number Analyzed | 17 | | | |
| Toxicities Success | 1 | | | |
| Toxicities Failure | 5 | | | |
| Toxicities Not Evaluable/Failure | 11 | | | |
| Relapse Number Analyzed | 18 | | | |
| Relapse Success | 5 | | | |
| Relapse Failure | 2 | | | |
| Relapse Not Evaluable/Failure | 11 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Recurrence of Baseline Fungal Disease

| | |
|-----------------|---|
| End point title | Percentage of Participants With a Recurrence of Baseline Fungal Disease |
|-----------------|---|

End point description:

The percentage of participants with a recurrence of their baseline fungal disease as assessed by the DRC at the 25-Day Follow Up (FU) for Vulvovaginal Candidiasis and at the 6-Week FU for all other diseases as assessed by the DRC. Recurrence is defined as having Global Response at end of treatment or test of cure, but re-emergence of the baseline fungal disease during the post treatment follow-up. Re-emergence is required to be with the same species and involving the same site identified at baseline.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

42 days for vulvovaginal candidiasis and 6 weeks after End of Treatment (up to 180 days after treatment start) for all other diseases.

| End point values | Ibrexafungerp (SCY-078) | | | |
|---|----------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: Participants | | | | |
| Acute Inv Candidiasis incl Candidemia Number Analy | 40 | | | |
| Acute Inv Candidiasis incl Candidemia Recurrence | 0 | | | |
| Acute Inv Candidiasis incl Candidemia No Recurrenc | 35 | | | |
| Acute Inv Candidiasis incl Candidemia Not Evaluabl | 5 | | | |
| Chronic Invasive Candidasis Number Analyzed | 30 | | | |
| Chronic Invasive Candidasis Recurrence | 0 | | | |
| Chronic Invasive Candidasis No Recurrence | 29 | | | |
| Chronic Invasive Candidasis Not Evaluable | 1 | | | |
| Candidemia only Number Analyzed | 13 | | | |
| Candidemia only Recurrence | 0 | | | |
| Candidemia only No Recurrence | 11 | | | |
| Candidemia only Not Evaluable | 2 | | | |
| Esophageal Candidiasis Number Analyzed | 9 | | | |
| Esophageal Candidiasis Recurrence | 3 | | | |
| Esophageal Candidiasis No Recurrence | 5 | | | |
| Esophageal Candidiasis Not Evaluable | 1 | | | |
| Oropharyngeal Candidiasis Number Analyzed | 9 | | | |
| Oropharyngeal Candidiasis Recurrence | 2 | | | |
| Oropharyngeal Candidiasis No Recurrence | 7 | | | |
| Oropharyngeal Candidiasis Not Evaluable | 0 | | | |
| Chronic Mucotaneous Candidiasis Number Analyzed | 7 | | | |
| Chronic Mucotaneous Candidiasis Recurrence | 4 | | | |
| Chronic Mucotaneous Candidiasis No Recurrence | 2 | | | |
| Chronic Mucotaneous Candidiasis Not Evaluable | 1 | | | |
| Vulvovaginal Candidiasis Number Analyzed | 28 | | | |
| Vulvovaginal Candidiasis Recurrence | 6 | | | |
| Vulvovaginal Candidiasis No Recurrence | 18 | | | |
| Vulvovaginal Candidiasis Not Evauable | 4 | | | |
| Disseminated/Invasive Dimorphic Fungi Number Anal | 1 | | | |
| Disseminated/Invasive Dimorphic Fungi Recurrence | 1 | | | |
| Disseminated/Invasive Dimorphic Fungi No Recurren | 0 | | | |
| Disseminated/Invasive Dimorphic Fungi Not Evaluab | 0 | | | |
| Chronic Pulmonary Aspergillosis Number Analyzed | 1 | | | |

| | | | | |
|---|----|--|--|--|
| Chronic Pulmonary Aspergillosis Recurrence | 0 | | | |
| Chronic Pulmonary Aspergillosis No Recurrence | 1 | | | |
| Chronic Pulmonary Aspergillosis Not Evaluable | 0 | | | |
| Allergic Bronchopulmonary Aspergillosis Number Ana | 0 | | | |
| Allergic Bronchopulmonary Aspergillosis Recurrence | 0 | | | |
| Allergic Bronchopulmonary Aspergillosis No Recurrence | 0 | | | |
| Allergic Bronchopulmonary Aspergillosis Not Evalua | 0 | | | |
| Invasive Pulmonary Aspergillosis Number Analyzed | 12 | | | |
| Invasive Pulmonary Aspergillosis Recurrence | 2 | | | |
| Invasive Pulmonary Aspergillosis No Recurrence | 10 | | | |
| Invasive Pulmonary Aspergillosis Not Evaluable | 0 | | | |
| Other Number Analyzed | 7 | | | |
| Other Recurrence | 0 | | | |
| Other No Recurrence | 6 | | | |
| Other Not Evaluable | 1 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Surviving at Day 30 or Day 42

| | |
|-----------------|--|
| End point title | Percentage of Participants Surviving at Day 30 or Day 42 |
|-----------------|--|

End point description:

Percentage of participants with invasive candidiasis surviving at Day 30 post-Baseline or percentage of participants with other fungal diseases surviving at Day 42 post-Baseline.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 30 post-Baseline for Invasive Candidiasis and Day 42 post-Baseline for all other fungal diseases.

| | | | | |
|--|-------------------------|--|--|--|
| End point values | Ibrexafungerp (SCY-078) | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 | | | |
| Units: Participants | | | | |
| Acute Invasive Candidiasis Number Analyzed | 41 | | | |
| Acute Invasive Candidiasis Alive | 39 | | | |
| Acute Invasive Candidiasis Dead | 1 | | | |
| Acute Invasive Candidiasis Unknown | 1 | | | |

| | | | | |
|--|----|--|--|--|
| Chronic Invasive Candidiasis Number Analyzed | 43 | | | |
| Chronic Invasive Candidiasis Alive | 43 | | | |
| Chronic Invasive Candidiasis Dead | 0 | | | |
| Chronic Invasive Candidiasis Unknown | 0 | | | |
| Candidemia Number Analyzed | 20 | | | |
| Candidemia Alive | 17 | | | |
| Candidemia Dead | 1 | | | |
| Candidemia Unknown | 2 | | | |
| Esophageal Candidiasis Number Analyzed | 16 | | | |
| Esophageal Candidiasis Alive | 15 | | | |
| Esophageal Candidiasis Dead | 0 | | | |
| Esophageal Candidiasis Unknown | 1 | | | |
| Oropharyngeal Candidiasis Number Analyzed | 14 | | | |
| Oropharyngeal Candidiasis Alive | 14 | | | |
| Oropharyngeal Candidiasis Dead | 0 | | | |
| Oropharyngeal Candidiasis Unknown | 0 | | | |
| Chronic Mucocutaneous Candidiasis Number Analyzed | 13 | | | |
| Chronic Mucocutaneous Candidiasis Alive | 13 | | | |
| Chronic Mucocutaneous Candidiasis Dead | 0 | | | |
| Chronic Mucocutaneous Candidiasis Unknown | 0 | | | |
| Vulvovaginal Candidiasis Number Analyzed | 32 | | | |
| Vulvovaginal Candidiasis Alive | 32 | | | |
| Vulvovaginal Candidiasis Dead | 0 | | | |
| Vulvovaginal Candidiasis Unknown | 0 | | | |
| Disseminated/Invasive Dimorphic Fungi Number Anal | 3 | | | |
| Disseminated/Invasive Dimorphic Fungi Alive | 3 | | | |
| Disseminated/Invasive Dimorphic Fungi Dead | 0 | | | |
| Disseminated/Invasive Dimorphic Fungi Unknown | 0 | | | |
| Chronic Pulmonary Aspergillosis Number Analyzed | 6 | | | |
| Chronic Pulmonary Aspergillosis Alive | 5 | | | |
| Chronic Pulmonary Aspergillosis Dead | 0 | | | |
| Chronic Pulmonary Aspergillosis Unknown | 1 | | | |
| Allergic Bronchopulmonary Aspergillosis Number Ana | 5 | | | |
| Allergic Bronchopulmonary Aspergillosis Alive | 5 | | | |
| Allergic Bronchopulmonary Aspergillosis Dead | 0 | | | |
| Allergic Bronchopulmonary Aspergillosis Unknown | 0 | | | |
| Invasive Pulmonary Aspergillosis Number Analyzed | 29 | | | |
| Invasive Pulmonary Aspergillosis Alive | 22 | | | |
| Invasive Pulmonary Aspergillosis Dead | 6 | | | |

| | | | | |
|---|----|--|--|--|
| Invasive Pulmonary Aspergillosis Unknown | 1 | | | |
| Other Emerging Fungi Number Analyzed | 11 | | | |
| Other Emerging Fungi Alive | 10 | | | |
| Other Emerging Fungi Dead | 0 | | | |
| Other Emerging Fungi Unknown | 1 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Death From Any Cause

| | |
|-----------------|------------------------------|
| End point title | Time to Death From Any Cause |
|-----------------|------------------------------|

End point description:

Time to death from any cause in days per Fungal Disease

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Six weeks after End of Treatment (EOT). EOT for Vulvovaginal Candidiasis is Day 7, Chronic Mucocutaneous Candidiasis is up to Day 84, Chronic Pulmonary Aspergillus and Allergic Bronchopulmonary Aspergillosis is up to Day 90 and up to Day 180 for other.

| End point values | Ibrexafungerp (SCY-078) | | | |
|----------------------------------|----------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0 ^[2] | | | |
| Units: Number of Days | | | | |
| median (confidence interval 95%) | (to) | | | |

Notes:

[2] - Not Evaluable: Insufficient number of participants with events

Statistical analyses

No statistical analyses for this end point

Secondary: Describe Ibrexafungerp Plasma Concentrations

| | |
|-----------------|--|
| End point title | Describe Ibrexafungerp Plasma Concentrations |
|-----------------|--|

End point description:

Ibrexafungerp plasma concentrations measured at specified timepoints prior to and after administration of study drug for participants that received the following dose regimen:

Day 1 and 2 loading dose - 750mg BID Day 3 onwards - 750mg QD

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 2 post-dose, Day 3-5 pre-dose, Day 7-10 pre-dose.

| | | | | |
|---------------------------------------|-------------------------|--|--|--|
| End point values | Ibrexafungerp (SCY-078) | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 233 ^[3] | | | |
| Units: ng/mL | | | | |
| median (full range (min-max)) | | | | |
| Day 2 post-dose Median (Full Range) | 479 (0 to 1790) | | | |
| Day 3-5 pre-dose Median (Full Range) | 644 (9.21 to 1980) | | | |
| Day 7-10 pre-dose Median (Full Range) | 571 (0 to 1810) | | | |

Notes:

[3] - Day 2 post-dose: 74 Participants

Day 3-5 pre-dose: 127 Participants

Day 7-10 pre-dose: 119 Partici

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AEs will be collected and evaluated from the time the informed consent is signed throughout the duration of the study and up to the last observation in the study.

Adverse event reporting additional description:

An AE is any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a study drug/study intervention, whether or not related to the s

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 26.0 |

Reporting groups

| | |
|-----------------------|-------------------------------------|
| Reporting group title | Adverse events in safety population |
|-----------------------|-------------------------------------|

Reporting group description:

Number of subjects who experienced an adverse event who received ibrexafungerp

| Serious adverse events | Adverse events in safety population | | |
|---|-------------------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 102 / 233 (43.78%) | | |
| number of deaths (all causes) | 15 | | |
| number of deaths resulting from adverse events | 15 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Disturbance in attention | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Acute lymphocytic leukaemia refractory | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| B-cell type acute leukaemia | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blastic plasmacytoid dendritic cell | | | |

| | | | |
|--|-----------------|--|--|
| neoplasia | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Shock | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Venoocclusive disease | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Surgical and medical procedures | | | |
| Hospitalisation | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 3 / 233 (1.29%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 3 | | |
| Pain | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Disease progression | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General physical health deterioration | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Graft versus host disease in gastrointestinal tract | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| Vaginal discharge | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vulvovaginal pruritus | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Respiratory failure | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 6 / 233 (2.58%) | | | |
| occurrences causally related to treatment / all | 0 / 6 | | | |
| deaths causally related to treatment / all | 0 / 3 | | | |
| Acute respiratory failure | | | | |
| subjects affected / exposed | 3 / 233 (1.29%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Dyspnoea | | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haemoptysis | | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pleural effusion | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Chronic obstructive pulmonary disease | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypoxia | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Interstitial lung disease | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonitis | | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary fibrosis | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary vein stenosis | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory distress | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Wheezing | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Confusional state | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hallucination | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Product issues | | | |

| | | | |
|---|-----------------------------------|--|--|
| Device dislocation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 233 (0.43%) 0 / 1 0 / 0 | | |
| Investigations Drug clearance decreased subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 233 (0.43%) 0 / 1 0 / 0 | | |
| Hepatic enzyme increased subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 233 (0.43%) 0 / 1 0 / 0 | | |
| Injury, poisoning and procedural complications Facial bones fracture subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 233 (0.43%) 0 / 1 0 / 0 | | |
| Fall subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 233 (0.43%) 0 / 1 0 / 0 | | |
| Gastrointestinal anastomotic leak subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 233 (0.43%) 0 / 1 0 / 0 | | |
| Gastrointestinal anastomotic stenosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 233 (0.43%) 0 / 1 0 / 0 | | |
| Kidney rupture subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 233 (0.43%) 0 / 1 0 / 0 | | |

| | | | |
|---|-----------------|--|--|
| Pelvic fracture | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Procedural pneumothorax | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thermal burn | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Weaning failure | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Cardiac disorders | | | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac arrest | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Cardiac failure | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac failure chronic | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Acute left ventricular failure | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pericardial effusion | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pericarditis | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Generalised tonic-clonic seizure | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemorrhage intracranial | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Headache | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypocalcaemic seizure | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Somnolence | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Myelosuppression | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancytopenia | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ear and labyrinth disorders | | | |

| | | | |
|---|-----------------|--|--|
| Deafness neurosensory | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 6 / 233 (2.58%) | | |
| occurrences causally related to treatment / all | 3 / 7 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ascites | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haematemesis | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancreatic pseudocyst | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancreatitis | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Upper gastrointestinal haemorrhage | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Intertrigo | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rash | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin mass | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin ulcer | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 7 / 233 (3.00%) | | |
| occurrences causally related to treatment / all | 0 / 8 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Haematuria | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue | | | |

| | | | | |
|---|-----------------|--|--|--|
| disorders | | | | |
| Osteonecrosis | | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Back pain | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Joint effusion | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myalgia | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Synovial cyst | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infections and infestations | | | | |
| COVID-19 | | | | |
| subjects affected / exposed | 5 / 233 (2.15%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sepsis | | | | |
| subjects affected / exposed | 5 / 233 (2.15%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 2 | | | |
| Urinary tract infection | | | | |
| subjects affected / exposed | 5 / 233 (2.15%) | | | |
| occurrences causally related to treatment / all | 0 / 6 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | | |
|---|-----------------|--|--|--|
| Pneumonia | | | | |
| subjects affected / exposed | 4 / 233 (1.72%) | | | |
| occurrences causally related to treatment / all | 0 / 4 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Septic shock | | | | |
| subjects affected / exposed | 4 / 233 (1.72%) | | | |
| occurrences causally related to treatment / all | 0 / 4 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bacteraemia | | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchopulmonary aspergillosis | | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Enterococcal bacteraemia | | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Liver abscess | | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Abdominal abscess | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Abdominal infection | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Abscess | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Acinetobacter infection | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Arthritis bacterial | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Atypical pneumonia | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchitis | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchopulmonary aspergillosis allergic | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Candida infection | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cellulitis | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cystitis | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cytomegalovirus infection reactivation | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Enterobacter bacteraemia | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Enterobacter pneumonia | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Escherichia bacteraemia | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Escherichia infection | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Escherichia urinary tract infection | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Extradural abscess | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis viral | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| HCoV-NL63 infection | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Influenza | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intervertebral discitis | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Klebsiella bacteraemia | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Mycobacterium avium complex infection | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Oral candidiasis | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia aspiration | | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia bacterial | | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia klebsiella | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pseudomonal sepsis | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pseudomonas infection | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psoas abscess | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rhinovirus infection | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Stenotrophomonas bacteraemia | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Streptococcal sepsis | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Urinary tract infection pseudomonal | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Wound sepsis | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 4 / 233 (1.72%) | | |
| occurrences causally related to treatment / all | 0 / 6 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 2 / 233 (0.86%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Failure to thrive | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gout | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypophagia | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypovolaemia | | | |
| subjects affected / exposed | 1 / 233 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | Adverse events in safety population | | |
|---|-------------------------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 215 / 233 (92.27%) | | |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 17 / 233 (7.30%) | | |
| occurrences (all) | 20 | | |
| Headache | | | |
| subjects affected / exposed | 38 / 233 (16.31%) | | |
| occurrences (all) | 50 | | |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 20 / 233 (8.58%) | | |
| occurrences (all) | 23 | | |
| Pyrexia | | | |

| | | | |
|---|--------------------|--|--|
| subjects affected / exposed | 31 / 233 (13.30%) | | |
| occurrences (all) | 56 | | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 26 / 233 (11.16%) | | |
| occurrences (all) | 38 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 18 / 233 (7.73%) | | |
| occurrences (all) | 27 | | |
| Diarrhoea | | | |
| subjects affected / exposed | 163 / 233 (69.96%) | | |
| occurrences (all) | 166 | | |
| Nausea | | | |
| subjects affected / exposed | 111 / 233 (47.64%) | | |
| occurrences (all) | 119 | | |
| Vomiting | | | |
| subjects affected / exposed | 53 / 233 (22.75%) | | |
| occurrences (all) | 75 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 13 / 233 (5.58%) | | |
| occurrences (all) | 14 | | |
| Dyspnoea | | | |
| subjects affected / exposed | 12 / 233 (5.15%) | | |
| occurrences (all) | 14 | | |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 13 / 233 (5.58%) | | |
| occurrences (all) | 20 | | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 16 / 233 (6.87%) | | |
| occurrences (all) | 16 | | |
| Infections and infestations | | | |
| COVID-19 | | | |

| | | | |
|--|---|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>14 / 233 (6.01%)</p> <p>15</p> | | |
| <p>Urinary tract infection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>22 / 233 (9.44%)</p> <p>39</p> | | |
| <p>Metabolism and nutrition disorders</p> <p>Decreased appetite</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hyperkalaemia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>13 / 233 (5.58%)</p> <p>15</p> <p>12 / 233 (5.15%)</p> <p>14</p> | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|----------------|--|
| 13 August 2019 | <p>Revised study objectives and endpoints to account for all eligible diseases/therapeutic area.</p> <p>Added disease-specific objectives and endpoints for selected fungal diseases.</p> <p>Added the following fungal diseases as eligible for inclusion in the study (as well as eligibility criteria):</p> <ul style="list-style-type: none">• vulvovaginal candidiasis (VVC)• disseminated/invasive dimorphic fungi (coccidioidomycosis, histoplasmosis, blastomycosis)• chronic pulmonary aspergillosis (CPA)• allergic bronchopulmonary aspergillosis (ABPA)• invasive pulmonary aspergillosis (IPA)• other emerging fungi including yeasts and molds (e.g., saccharomycetes, scopulariopsis) <p>Clarify that subjects will be excluded if they have an invasive fungal disease with central nervous system involvement, unless it is planned to receive combination therapy with ibrexafungerp and another antifungal.</p> <p>Removed exclusion criteria for subjects with invasive fungal diseases of the bone and/or joint.</p> <p>Removed exclusion criteria based on absolute neutrophil count and QTcF interval.</p> <p>Added "legally authorized representative" as potential person giving consent.</p> <p>Developed two separate schedules: one for WC and a separate one for all other fungal diseases.</p> <p>Increased sample size to a total of 200 subjects.</p> <p>Updated to a total study duration of approximately 222 days for each subject (based on the prolongation of treatment to up to 180 days).</p> <p>Included table of efficacy timepoints and outcome definitions for primary and secondary endpoints for each fungal disease.</p> |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported