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

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.

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 myoclogical 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) Succes	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

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 myoclogical 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.

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 myoclogical 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 Participnts With a Clinical Response (Signs and Symptoms) by Fungal Disease

End point title	Percentage of Participnts 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 Evaulab	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			
Resistence Number Analyzed	134			
Resistence Success	75			
Resistence Failure	23			
Resistence Not Evaluable	25			

Resistence 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			
Resistence Number Analyzed	134			
Resistence Success	28			
Resistence Failure	19			
Resistence 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 Recurre	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, Dat 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	1 / 233 (0.43%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Investigations				
Drug clearance decreased				
subjects affected / exposed	1 / 233 (0.43%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	1 / 233 (0.43%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Facial bones fracture				
subjects affected / exposed	1 / 233 (0.43%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	1 / 233 (0.43%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal anastomotic leak				
subjects affected / exposed	1 / 233 (0.43%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal anastomotic stenosis				
subjects affected / exposed	1 / 233 (0.43%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Kidney rupture				
subjects affected / exposed	1 / 233 (0.43%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	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 occurrences (all)	31 / 233 (13.30%) 56		
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) Abdominal pain upper subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	 26 / 233 (11.16%) 38 18 / 233 (7.73%) 27 163 / 233 (69.96%) 166 111 / 233 (47.64%) 119 53 / 233 (22.75%) 75		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all)	 13 / 233 (5.58%) 14 12 / 233 (5.15%) 14		
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	 13 / 233 (5.58%) 20		
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	 16 / 233 (6.87%) 16		
Infections and infestations COVID-19			

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 August 2019	Revised study objectives and endpoints to account for all eligible diseases/therapeutic area. Added disease-specific objectives and endpoints for selected fungal diseases. Added the following fungal diseases as eligible for inclusion in the study (as weil as eligibility criteria): • 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., sachromycetes, scopulariopsis) 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. Removed exclusion criteria for subjects with invasive fungal diseases of the bone and/or joint. Removed exclusion criteria based on absolute neutrophil count and QTcF interval. Added "legally authorized representative" as potential person giving consent. Developed two separate schedules: one for WC and a separate one for all other fungal diseases. Increased sample size to a total of 200 subjects. Updated to a total study duration of approximately 222 days for each subject (based on the prolongation of treatment to up to 180 days). Included table of efficacy timepoints and outcome definitions for primary and secondary endpoints for each fungal disease.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported