Clinical trial results:
An Open-Label, Rollover Protocol for Participants Previously Enrolled in Takeda-Sponsored Ixazomib Studies

Summary

EudraCT number	2016-001681-28
Trial protocol	ES BE SE GR PL
Global end of trial date	03 July 2024

Results information

Result version number	v1 (current)
This version publication date	13 March 2025
First version publication date	13 March 2025

Trial information

Trial identification

Sponsor protocol code	C16027

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02924272
WHO universal trial number (UTN)	U1111-1184-2041

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 Hayden Avenue, Lexington, MA, United States, 02421
Public contact	Study Director, Takeda, TrialDisclosures@takeda.com
Scientific contact	Study Director, Takeda, TrialDisclosures@takeda.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	03 July 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to provide continued access of ixazomib and to evaluate the long-term safety profile of ixazomib.

Protection of trial subjects:

All study participants were required to read and sign an informed consent form (ICF).

Background therapy:

NA

Evidence for comparator:

NA

Actual start date of recruitment	16 December 2016
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	Belgium: 1
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Greece: 4
Country: Number of subjects enrolled	Poland: 8
Country: Number of subjects enrolled	Singapore: 1
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	Sweden: 4
Country: Number of subjects enrolled	United States: 7
Country: Number of subjects enrolled	Korea, Republic of: 1
Country: Number of subjects enrolled	Japan: 1
Worldwide total number of subjects	32
EEA total number of subjects	21

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)	7
From 65 to 84 years	25
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at various investigative sites globally from 16 December 2016 to 03 July 2024.

Pre-assignment

Screening details:

Participants who had previously received and tolerated treatment in ixazomib parent studies (C16003, C16005, C16006, C16007, C16008, C16010 Global, C16011, C16013, C16014 Global and Korean Continuation, C16017, C16020, C16029, or C16047), and in investigator's opinion could benefit from continued therapy were enrolled.

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Ixazomib Monotherapy

Arm description:

Participants received ixazomib capsule, orally, at same dose and schedule as they were receiving in the parent study until disease progression, clinical deterioration in the investigator's judgment, experienced an unacceptable toxicity, withdrew consent, pursued an alternative therapy, meet other study-specified reasons for discontinuation of study drug, or until the participant was transitioned to ixazomib through commercial channels, including reimbursement for the participant's indication, or up to a maximum of 7 years whichever was sooner.

Arm type	Experimental
Investigational medicinal product name	Ixazomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received ixazomib capsule, orally at the same doses as they were receiving in the parent study.

Arm title	Ixazomib Combination Therapy

Arm description:

Participants received combination therapy with ixazomib capsule, orally and another medication(s) (1 or more of the anticancer agents dexamethasone, lenalidomide or cyclophosphamide) at same dose and schedule as they were receiving in the parent study until disease progression, clinical deterioration in the investigator's judgment, experienced an unacceptable toxicity, withdrew consent, pursued an alternative therapy, met other study-specified reasons for discontinuation of study drug, or until the participant was transitioned to ixazomib through commercial channels, including reimbursement for the participant's indication, or up to a maximum of 6.5 years whichever was sooner.

Arm type	Experimental
Investigational medicinal product name	Ixazomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received combination therapy with ixazomib capsule, orally and another medication(s) (1 or

more of the anticancer agents dexamethasone, lenalidomide or cyclophosphamide) at same dose as they were receiving in the parent study.

Number of subjects in period 1	Ixazomib Monotherapy	Ixazomib Combination Therapy
Started	23	9
Completed	0	0
Not completed	23	9
Adverse event, serious fatal	1	-
Consent withdrawn by subject	2	-
Clinical Deterioration	1	-
Adverse event, non-fatal	3	-
Reason Not Specified	1	-
Progressive Disease	11	8
Site Terminated by Sponsor	4	1

Baseline characteristics

Reporting groups	
Reporting group title	Ixazomib Monotherapy
Reporting group description:	
Participants received ixazomib capsule, orally, at same dose and schedule as they were receiving in the parent study until disease progression, clinical deterioration in the investigator's judgment, experienced an unacceptable toxicity, withdrew consent, pursued an alternative therapy, meet other study-specified reasons for discontinuation of study drug, or until the participant was transitioned to ixazomib through commercial channels, including reimbursement for the participant's indication, or up to a maximum of 7 years whichever was sooner.	
Reporting group title	Ixazomib Combination Therapy
Reporting group description:	
Participants received combination therapy with ixazomib capsule, orally and another medication(s) (1 or more of the anticancer agents dexamethasone, lenalidomide or cyclophosphamide) at same dose and schedule as they were receiving in the parent study until disease progression, clinical deterioration in the investigator's judgment, experienced an unacceptable toxicity, withdrew consent, pursued an alternative therapy, met other study-specified reasons for discontinuation of study drug, or until the participant was transitioned to ixazomib through commercial channels, including reimbursement for the participant's indication, or up to a maximum of 6.5 years whichever was sooner.	

Reporting group values	Ixazomib Monotherapy	Ixazomib Combination Therapy	Total
Number of subjects	23	9	32
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	75.1	64.6	
standard deviation	± 6.45	± 9.53	-
Gender categorical Units: Subjects			
Female	11	5	16
Male	12	4	16

End points

End points reporting groups

Reporting group title	Ixazomib Monotherapy

Reporting group description:

Participants received ixazomib capsule, orally, at same dose and schedule as they were receiving in the parent study until disease progression, clinical deterioration in the investigator's judgment, experienced an unacceptable toxicity, withdrew consent, pursued an alternative therapy, meet other study-specified reasons for discontinuation of study drug, or until the participant was transitioned to ixazomib through commercial channels, including reimbursement for the participant's indication, or up to a maximum of 7 years whichever was sooner.

Reporting group title	Ixazomib Combination Therapy

Reporting group description:

Participants received combination therapy with ixazomib capsule, orally and another medication(s) (1 or more of the anticancer agents dexamethasone, lenalidomide or cyclophosphamide) at same dose and schedule as they were receiving in the parent study until disease progression, clinical deterioration in the investigator's judgment, experienced an unacceptable toxicity, withdrew consent, pursued an alternative therapy, met other study-specified reasons for discontinuation of study drug, or until the participant was transitioned to ixazomib through commercial channels, including reimbursement for the participant's indication, or up to a maximum of 6.5 years whichever was sooner.

Primary: Number of Participants With Serious Adverse Events (SAEs)

End point title	Number of Participants With Serious Adverse Events (SAEs)[1]

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a participant administered a pharmaceutical product; the untoward medical occurrence does not necessarily have a causal relationship with this treatment. 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 medicinal (investigational) product whether or not it is related to the medicinal product. An SAE is any untoward medical occurrence that at any dose: a) results in death; b) is life-threatening; c) requires inpatient hospitalization or prolongation of an existing hospitalization; d) results in persistent or significant disability or incapacity; e) is a congenital anomaly/birth defect; f) is a medically important event. Safety Population included all enrolled participants who received at least 1 dose of ixazomib.

End point type	Primary

End point timeframe:

Up to 7 years

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analyses were planned for this endpoint.

End point values	Ixazomib Monotherapy	Ixazomib Combination Therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	9		
Units: participants	12	4		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With ≥ Grade 3 AEs

End point title	Number of Participants With ≥ Grade 3 AEs[2]

End point description:

An AE is defined as any untoward medical occurrence in a clinical investigation participant administered a drug; it does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (e.g., a clinically significant abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, whether or not it is considered related to the drug. The severity grade was evaluated as per the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0. Grade 3: severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living (ADL), Grade 4: life-threatening consequences; urgent intervention indicated. Grade 5 was: death related to AE. Safety Population included all enrolled participants who received at least 1 dose of ixazomib.

End point type	Primary

End point timeframe:

Up to 7 years

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analyses were planned for this endpoint.

End point values	Ixazomib Monotherapy	Ixazomib Combination Therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	9		
Units: participants	13	5		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With ≥ Grade 2 Peripheral Neuropathy

End point title	Number of Participants With ≥ Grade 2 Peripheral

End point description:

Severity grade was evaluated based on CTCAE version 5.0. Grade 2: moderate symptoms; limiting instrumental activities of daily living. Grade 3: severe or medically significant; limiting self-care activities of daily living. Grade 4: life threatening consequences; urgent intervention indicated. Safety Population included all enrolled participants who received at least 1 dose of ixazomib.

End point type	Primary

End point timeframe:

Up to 7 years

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analyses were planned for this endpoint.

End point values	Ixazomib Monotherapy	Ixazomib Combination Therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	9		
Units: participants	2	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With New Primary Malignancies

End point title	Number of Participants With New Primary Malignancies[4]

End point description:

Safety Population included all enrolled participants who received at least 1 dose of ixazomib.

End point type	Primary

End point timeframe:

Up to 7 years

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analyses were planned for this endpoint.

End point values	Ixazomib Monotherapy	Ixazomib Combination Therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	9		
Units: participants	3	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With any AE Resulting in Dose Modification or Discontinuation of any Study Drug

End point title	Number of Participants With any AE Resulting in Dose Modification or Discontinuation of any Study Drug[5]

End point description:

An AE means any untoward medical occurrence in a participant administered a pharmaceutical product; the untoward medical occurrence does not necessarily have a causal relationship with this treatment. 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 medicinal (investigational) product whether or not it is related to the medicinal product. Safety Population included all enrolled participants who received at least 1 dose of ixazomib.

End point type	Primary

End point timeframe:

Up to 7 years

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analyses were planned for this endpoint.

End point values	Ixazomib Monotherapy	Ixazomib Combination Therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	9		
Units: participants				
AE Resulting in Dose Modification	12	7		
AE Resulting in Discontinuation of Study Drug	4	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 7 years

Adverse event reporting additional description:

The Safety Population included all enrolled participants who received at least 1 dose of ixazomib.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Ixazomib Monotherapy

Reporting group description:

Participants received ixazomib capsule, orally, at same dose and schedule as they were receiving in the parent study until disease progression, clinical deterioration in the investigator's judgment, experienced an unacceptable toxicity, withdrew consent, pursued an alternative therapy, meet other study-specified reasons for discontinuation of study drug, or until the participant was transitioned to ixazomib through commercial channels, including reimbursement for the participant's indication, or up to a maximum of 7 years whichever was sooner.

Reporting group title	Ixazomib Combination Therapy

Reporting group description:

Participants received combination therapy with ixazomib capsule, orally and another medication(s) (1 or more of the anticancer agents dexamethasone, lenalidomide or cyclophosphamide) at same dose and schedule as they were receiving in the parent study until disease progression, clinical deterioration in the investigator's judgment, experienced an unacceptable toxicity, withdrew consent, pursued an alternative therapy, met other study-specified reasons for discontinuation of study drug, or until the participant was transitioned to ixazomib through commercial channels, including reimbursement for the participant's indication, or up to a maximum of 6.5 years whichever was sooner.

Serious adverse events	Ixazomib Monotherapy	Ixazomib Combination Therapy	
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 23 (52.17%)	4 / 9 (44.44%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Sebaceous carcinoma			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			

subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Bladder injury			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Femur fracture			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac failure congestive			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Rectal haemorrhage			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 23 (8.70%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 23 (8.70%)	3 / 9 (33.33%)	
occurrences causally related to treatment / all	0 / 3	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculous pleurisy			
subjects affected / exposed	1 / 23 (4.35%)	0 / 9 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Ixazomib Monotherapy	Ixazomib Combination Therapy	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 23 (39.13%)	6 / 9 (66.67%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 23 (0.00%)	2 / 9 (22.22%)	
occurrences (all)	0	2	
Neutrophil count decreased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	2 / 23 (8.70%)	0 / 9 (0.00%)	
occurrences (all)	2	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 23 (17.39%)	0 / 9 (0.00%)	
occurrences (all)	6	0	
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
Anaemia			
subjects affected / exposed	1 / 23 (4.35%)	3 / 9 (33.33%)	
occurrences (all)	1	3	
Neutropenia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	2	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 23 (8.70%)	0 / 9 (0.00%)	
occurrences (all)	2	0	
Gastrointestinal pain			

subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	2 / 23 (8.70%)	0 / 9 (0.00%)	
occurrences (all)	2	0	
Hepatobiliary disorders			
Hepatotoxicity			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	2	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 23 (8.70%)	0 / 9 (0.00%)	
occurrences (all)	2	0	
Pain in extremity			
subjects affected / exposed	2 / 23 (8.70%)	0 / 9 (0.00%)	
occurrences (all)	3	0	
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	2	
Herpes zoster			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
Gastroenteritis viral			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	1	
Pneumonia			
subjects affected / exposed	1 / 23 (4.35%)	1 / 9 (11.11%)	
occurrences (all)	1	1	
Tooth infection			
subjects affected / exposed	0 / 23 (0.00%)	1 / 9 (11.11%)	
occurrences (all)	0	2	

Tooth abscess subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 9 (11.11%) 1	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 3	3 / 9 (33.33%) 3	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 March 2017	The following changes were made as per Amendment 01: 1. Added allowance for study drug administration to be rounded and/or converted from body surface area (BSA)-based dosing to fixed dosing with approval from the medical monitor. 2. Specified that local safety-related laboratory and vital signs assessments would be performed as presented in this study, rather than in the parent study. 3. Provided additional dose administration instructions. 4. Updated storage and handling instructions to be consistent with current ixazomib investigator's brochure (IB). 5. Added allowance for on-site monitoring visits. 6. Added allowance for study drug to be dispensed for up to 3 cycles at a distribution at the discretion of the investigator.
03 June 2021	The following changes were made as per Amendment 03: 1. Updated the background information on other ixazomib clinical trials. 2. Updated the criteria for withdrawing participants from study. 3. Added information about alternative monitoring approaches, such as remote source data verification, in the event a monitor could not visit the site in a timely manner due to the coronavirus disease 2019 (COVID-19) pandemic.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported