Clinical trial results:
A Phase 3 Study Comparing Pomalidomide and Dexamethasone With or Without Daratumumab in Subjects With Relapsed or Refractory Multiple Myeloma Who Have Received at Least One Prior Line of Therapy With Both Lenalidomide and a Proteasome Inhibitor.

Summary

EudraCT number	2017-001618-27
Trial protocol	GR ES BE DE CZ DK FR NL PL IT
Global end of trial date	30 November 2024

Results information

Result version number	v1 (current)
This version publication date	20 December 2025
First version publication date	20 December 2025

Trial information

Trial identification

Sponsor protocol code	EMN14/54767414MMY3013

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03180736
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	European Myeloma Network
Sponsor organisation address	Blaak 555, Rotterdam, Netherlands, 3011 GB
Public contact	Pieter Sonneveld, EMN, 0031 102687065,
Scientific contact	Pieter Sonneveld, EMN, 0031 102687065,

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	31 May 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 July 2020
Global end of trial reached?	Yes
Global end of trial date	30 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to compare PFS between treatment arms.

Protection of trial subjects:

Subjects provided their written consent to participate in the study after having been informed about the nature and purpose of the study, participation/termination conditions, and risks and benefits of treatment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 June 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Serbia: 9
Country: Number of subjects enrolled	Türkiye: 40
Country: Number of subjects enrolled	Netherlands: 9
Country: Number of subjects enrolled	Poland: 2
Country: Number of subjects enrolled	Spain: 37
Country: Number of subjects enrolled	Belgium: 16
Country: Number of subjects enrolled	Czechia: 10
Country: Number of subjects enrolled	Denmark: 2
Country: Number of subjects enrolled	France: 28
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Greece: 97
Country: Number of subjects enrolled	Italy: 39
Worldwide total number of subjects	304
EEA total number of subjects	255

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)	123
From 65 to 84 years	181
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled from 48 sites in 12 countries in Europe.
The study was fully enrolled in June 2019; therefore, there was no impact on enrollment due to COVID-19

Pre-assignment

Screening details:

Subjects were stratified by number of lines of prior therapy and ISS stage, and then randomized in a 1:1 ratio to receive either DPd or Pd.
The study consisted of Screening (within 28 days of randomization)

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Daratumumab + Pomalidomide + Dexamethasone

Arm description:

Daratumumab+Pomalidomide+Dexamethasone

Arm type	Experimental
Investigational medicinal product name	Dararumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion, Concentrate for solution for injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Daratumumab at a dose of 16 mg/kg administered as an IV infusion (Dara IV) or 1800 mg subcutaneously (Dara SC) at weekly intervals (QW) for 8 weeks, then every 2 weeks (Q2W) for an additional 16 weeks, then every 4 weeks (Q4W) thereafter

Investigational medicinal product name	pomaliomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Pomalidomide will be administered at full dose of 4 mg orally (PO) on Days 1 through 21 of each 28-day cycle.

Investigational medicinal product name	dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dexamethasone will be administered at a dose of 40 mg (20 mg for patients ≥75 years of age) orally, once daily on Days 1, 8, 15, and 22 of each 28-day treatment cycleta

Arm title	Pomalidomide + Dexamethasone

Arm description:	
Pomalidomide + Dexamethasone	
Arm type	Active comparator
Investigational medicinal product name	pomaliomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use
Dosage and administration details:	
Pomalidomide will be administered at full dose of 4 mg orally (PO) on Days 1 through 21 of each 28-day cycle.	
Investigational medicinal product name	dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Dexamethasone will be administered at a dose of 40 mg (20 mg for patients ≥75 years of age) orally, once daily on Days 1, 8, 15, and 22 of each 28-day treatment cycleta	

Number of subjects in period 1	Daratumumab + Pomalidomide + Dexamethasone	Pomalidomide + Dexamethasone
Started	151	153
Completed	60	33
Not completed	91	120
Adverse event, serious fatal	10	7
Physician decision	4	7
Adverse event, non-fatal	3	4
Non-compliance with study drug	-	12
Non-compliance with study drugb	5	-
Subjects randomized but not treated	2	3
Lost to follow-up	1	-
Lack of efficacy	66	87

Baseline characteristics

Reporting groups	
Reporting group title	Daratumumab + Pomalidomide + Dexamethasone
Reporting group description: Daratumumab+Pomalidomide+Dexamethasone	
Reporting group title	Pomalidomide + Dexamethasone
Reporting group description: Pomalidomide + Dexamethasone	

Reporting group values	Daratumumab + Pomalidomide + Dexamethasone	Pomalidomide + Dexamethasone	Total
Number of subjects	151	153	304
Age categorical Units: Subjects			
Adults (18-64 years)	63	60	123
From 65-84 years	88	93	181
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	72	71	143
Male	79	82	161

Subject analysis sets	
Subject analysis set title	Progression-free Survival
Subject analysis set type	Intention-to-treat
Subject analysis set description: Progression-free Survival based on Investigator Assessment	
Subject analysis set title	Summary of Progression-free Survival on Next Line of Therapy (
Subject analysis set type	Intention-to-treat
Subject analysis set description: Summary of Progression-free Survival on Next Line of Therapy (PFS2) based on Investigator Assessment;	

Reporting group values	Progression-free Survival	Summary of Progression-free Survival on Next Line of Therapy (	
Number of subjects	304	304	
Age categorical Units: Subjects			
Adults (18-64 years)	123	123	
From 65-84 years	181	181	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	Daratumumab + Pomalidomide + Dexamethasone
Reporting group description: Daratumumab+Pomalidomide+Dexamethasone	
Reporting group title	Pomalidomide + Dexamethasone
Reporting group description: Pomalidomide + Dexamethasone	
Subject analysis set title	Progression-free Survival
Subject analysis set type	Intention-to-treat
Subject analysis set description: Progression-free Survival based on Investigator Assessment	
Subject analysis set title	Summary of Progression-free Survival on Next Line of Therapy (
Subject analysis set type	Intention-to-treat
Subject analysis set description: Summary of Progression-free Survival on Next Line of Therapy (PFS2) based on Investigator Assessment;	

Primary: Comparison of Progression Free Survival between treatment arms (Daratumumab /Pomalidomide /Dexamethasone vs Pomalidomide / Dexamethasone)

End point title	Comparison of Progression Free Survival between treatment arms (Daratumumab /Pomalidomide /Dexamethasone vs Pomalidomide / Dexamethasone)

End point description:

Progression Free Survival (PFS) is defined as the time, in months, from randomization to the date of the first documented disease progression (PD) or death due to any cause, whichever comes first.
PFS2 is defined as the time, in months, from randomization to the date of the first documented disease progression (PD) or death due to any cause, whichever comes first, after the next line of therapy.
PD is assessed by the investigator based on the analysis of serum and urine protein electrophoresis (sPEP and uPEP), serum and urine immunofixation (sIFE and uIFE), serum free light chain protein (sFLC),corrected serum calcium assessment, imaging and bone marrow assessments as per modified IMWG guidelines.

End point type	Primary

End point timeframe:

PFS is assessed monthly from randomization until PD or death, whichever occurs first (approximately up to 3 years). PFS2 is assessed monthly from randomization until PD or death, whichever occurs first (approximately up to 5 years).

End point values	Daratumumab + Pomalidomide + Dexamethasone	Pomalidomide + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	153		
Units: month				
median (confidence interval 95%)				
Primary efficacy of PFS	12.42 (8.34 to 19.32)	6.93 (5.52 to 9.26)		

Statistical analyses

Statistical analysis title	The intent-to-treat (ITT)

Statistical analysis description:

Summary of Progression-free Survival on Next Line of Therapy (PFS2) based on Investigator Assessment;

Comparison groups	Daratumumab + Pomalidomide + Dexamethasone v Pomalidomide + Dexamethasone
Number of subjects included in analysis	304
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0.0038
Method	t-test, 2-sided

Notes:

[1] - intent to treat

Primary: pfs2

End point title	pfs2

End point description:

PFS2 is defined as the time, in months, from randomization to the date of the first documented disease progression (PD) or death due to any cause, whichever comes first, after the next line of therapy.
PD is assessed by the investigator based on the analysis of serum and urine protein electrophoresis (sPEP and uPEP), serum and urine immunofixation (sIFE and uIFE), serum free light chain protein (sFLC),corrected serum calcium assessment, imaging and bone marrow assessments as per modified IMWG guidelines.

End point type	Primary

End point timeframe:

PFS2 is assessed monthly from randomization until PD or death, whichever occurs first (approximately up to 5 years).

End point values	Daratumumab + Pomalidomide + Dexamethasone	Pomalidomide + Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	105		
Units: month				
median (confidence interval 95%)				
PFS2	24.41 (17.05 to 34.71)	17.58 (13.57 to 21.98)		

Statistical analyses

Statistical analysis title	The intent-to-treat (ITT)
Comparison groups	Daratumumab + Pomalidomide + Dexamethasone v Pomalidomide + Dexamethasone
Number of subjects included in analysis	193
Analysis specification	Pre-specified
Analysis type	other[2]
P-value	= 0.2077
Method	t-test, 2-sided
Confidence interval	
level	95 %
sides	2-sided

Notes:

[2] - intent-to -treat

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All adverse events and special reporting situations, whether serious or non-serious, were reported from the time informed consent was obtained until 30 days after the last day of study treatment.

Adverse event reporting additional description:

Adverse events are reported using MedDRA version 24.0

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Daratumumab+Pomalidomide+Dexamethasone
Reporting group description: -	
Reporting group title	Pomalidomide+Dexamethasone

Reporting group description: -

Serious adverse events	Daratumumab+Pomalidomide+Dexamethasone	Pomalidomide+Dexamethasone	
Total subjects affected by serious adverse events			
subjects affected / exposed	80 / 149 (53.69%)	60 / 150 (40.00%)	
number of deaths (all causes)	48	51	
number of deaths resulting from adverse events	11	11	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 149 (0.67%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac arrest			
subjects affected / exposed	0 / 149 (0.00%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 149 (0.00%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypertensive hydrocephalus			

subjects affected / exposed	0 / 149 (0.00%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Syncope			
subjects affected / exposed	3 / 149 (2.01%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	1 / 10	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	5 / 149 (3.36%)	4 / 150 (2.67%)	
occurrences causally related to treatment / all	9 / 9	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	4 / 149 (2.68%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	4 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow failure			
subjects affected / exposed	1 / 149 (0.67%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	1 / 149 (0.67%)	3 / 150 (2.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pyrexia			
subjects affected / exposed	3 / 149 (2.01%)	2 / 150 (1.33%)	
occurrences causally related to treatment / all	11 / 29	11 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	1 / 149 (0.67%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 149 (2.01%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	3 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Liver disorder			
subjects affected / exposed	1 / 149 (0.67%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 149 (2.01%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	6 / 16	2 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 149 (0.00%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory failure			
subjects affected / exposed	2 / 149 (1.34%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	1 / 2	1 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	1 / 149 (0.67%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 149 (0.67%)	5 / 150 (3.33%)	
occurrences causally related to treatment / all	7 / 20	7 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			

subjects affected / exposed	18 / 149 (12.08%)	14 / 150 (9.33%)	
occurrences causally related to treatment / all	7 / 29	12 / 24	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pneumonia			
subjects affected / exposed	23 / 149 (15.44%)	12 / 150 (8.00%)	
occurrences causally related to treatment / all	12 / 23	2 / 12	
deaths causally related to treatment / all	1 / 3	0 / 2	
Sepsis			
subjects affected / exposed	1 / 149 (0.67%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Septic shock			
subjects affected / exposed	1 / 149 (0.67%)	2 / 150 (1.33%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	1 / 1	0 / 2	
Systemic candida			
subjects affected / exposed	1 / 149 (0.67%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	3 / 149 (2.01%)	3 / 150 (2.00%)	
occurrences causally related to treatment / all	10 / 34	8 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	2 / 149 (1.34%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

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

Non-serious adverse events	Daratumumab+Pomalidomide+Dexamethasone	Pomalidomide+Dexamethasone	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	144 / 149 (96.64%)	144 / 150 (96.00%)	
Nervous system disorders			
Peripheral sensory neuropathy			
subjects affected / exposed	19 / 149 (12.75%)	11 / 150 (7.33%)	
occurrences (all)	19	11	
Tremor			
subjects affected / exposed	15 / 149 (10.07%)	14 / 150 (9.33%)	
occurrences (all)	15	14	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	57 / 149 (38.26%)	67 / 150 (44.67%)	
occurrences (all)	57	67	
Neutropenia			
subjects affected / exposed	107 / 149 (71.81%)	80 / 150 (53.33%)	
occurrences (all)	107	80	
Thrombocytopenia			
subjects affected / exposed	49 / 149 (32.89%)	51 / 150 (34.00%)	
occurrences (all)	49	51	
Leukopenia			
subjects affected / exposed	39 / 149 (26.17%)	18 / 150 (12.00%)	
occurrences (all)	39	18	
Lymphopenia			
subjects affected / exposed	22 / 149 (14.77%)	12 / 150 (8.00%)	
occurrences (all)	22	12	
Febrile neutropenia			
subjects affected / exposed	9 / 149 (6.04%)	2 / 150 (1.33%)	
occurrences (all)	9	2	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	43 / 149 (28.86%)	37 / 150 (24.67%)	
occurrences (all)	43	37	
Asthenia			
subjects affected / exposed	33 / 149 (22.15%)	25 / 150 (16.67%)	
occurrences (all)	33	25	

Pyrexia			
subjects affected / exposed	28 / 149 (18.79%)	25 / 150 (16.67%)	
occurrences (all)	28	25	
Oedema peripheral			
subjects affected / exposed	25 / 149 (16.78%)	14 / 150 (9.33%)	
occurrences (all)	25	14	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	36 / 149 (24.16%)	22 / 150 (14.67%)	
occurrences (all)	36	22	
Constipation			
subjects affected / exposed	21 / 149 (14.09%)	22 / 150 (14.67%)	
occurrences (all)	21	22	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	18 / 149 (12.08%)	10 / 150 (6.67%)	
occurrences (all)	18	10	
Dyspnoea			
subjects affected / exposed	16 / 149 (10.74%)	12 / 150 (8.00%)	
occurrences (all)	16	12	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	13 / 149 (8.72%)	18 / 150 (12.00%)	
occurrences (all)	13	18	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	18 / 149 (12.08%)	15 / 150 (10.00%)	
occurrences (all)	18	15	
Bone pain			
subjects affected / exposed	17 / 149 (11.41%)	20 / 150 (13.33%)	
occurrences (all)	17	20	
Muscle spasms			
subjects affected / exposed	15 / 149 (10.07%)	7 / 150 (4.67%)	
occurrences (all)	15	7	
Infections and infestations			

Upper respiratory tract infection			
subjects affected / exposed	34 / 149 (22.82%)	23 / 150 (15.33%)	
occurrences (all)	34	23	
Pneumonia			
subjects affected / exposed	11 / 149 (7.38%)	10 / 150 (6.67%)	
occurrences (all)	11	10	
Lower respiratory tract infection			
subjects affected / exposed	12 / 149 (8.05%)	10 / 150 (6.67%)	
occurrences (all)	12	10	
Bronchitis			
subjects affected / exposed	21 / 149 (14.09%)	16 / 150 (10.67%)	
occurrences (all)	21	16	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	17 / 149 (11.41%)	20 / 150 (13.33%)	
occurrences (all)	17	20	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 October 2017	- To expand the study design to include the SC administration of daratumumab. - Other changes including update to IMWG criteria definition of progressive disease
03 April 2018	- To update the Pomalidomide Risk Evaluation Mitigation Strategy or Global Pregnancy Prevention Plan based on recommendations from a health authority. - To update exclusion criteria with regards to hepatitis and HIV testing, hypersensitivity, and prior vaccinations based on recommendations from a health authority
16 October 2020	- Following the positive primary analysis results, subjects continuing on treatment had a more limited schedule of assessments. - Long-term survival follow-up and data collection was defined to continue until 166 deaths were observed or 5 years after the last subject was randomized.
21 April 2024	- The end of the electronic case report form (eCRF) data collection was defined - The end of study was defined and the end of study assessments were clarified. - The long-term extension phase of this study was defined as beginning at the time of the CCO for the final OS analysis with the intention to provide ongoing access to study treatment for subjects who continue to benefit from such treatment. For these subjects, study treatment will be available through continued access within the current study until it is available through another source such as commercial availability with reimbursement, continued access through a long-term extension study, a patient access program, or after the last subject transitions into the long-term extension phase of the study up to 31 March 2024, whichever occurs first.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No notable study limitations were identified by the sponsor. Mitigation measures were taken to monitor and treat subjects during the COVID-19 pandemic. The COVID-19 pandemic did not limit the interpretation of study results.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/34087126