



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 | Daratumumab |
| 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 | pomalidomide |
| 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 cycle

| | |
|------------------|------------------------------|
| 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 cycle

| 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 | - |
| Lost to follow-up | 1 | - |
| Subjects randomized but not treated | 2 | 3 |
| 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 occurrences (all) | 34 / 149 (22.82%) 34 | 23 / 150 (15.33%) 23 | |
| Pneumonia subjects affected / exposed occurrences (all) | 11 / 149 (7.38%) 11 | 10 / 150 (6.67%) 10 | |
| Lower respiratory tract infection subjects affected / exposed occurrences (all) | 12 / 149 (8.05%) 12 | 10 / 150 (6.67%) 10 | |
| Bronchitis subjects affected / exposed occurrences (all) | 21 / 149 (14.09%) 21 | 16 / 150 (10.67%) 16 | |
| Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all) | 17 / 149 (11.41%) 17 | 20 / 150 (13.33%) 20 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|---|
| 13 October 2017 | <ul style="list-style-type: none">- 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 | <ul style="list-style-type: none">- 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 | <ul style="list-style-type: none">- 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 | <ul style="list-style-type: none">- 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>