



Clinical trial results:

A PHASE 2, MULTICENTER STUDY TO DETERMINE THE EFFICACY AND SAFETY OF BB2121 IN SUBJECTS WITH RELAPSED AND REFRACTORY MULTIPLE MYELOMA.

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2017-002245-29 |
| Trial protocol | DE BE FR ES IT |
| Global end of trial date | 20 December 2023 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 28 December 2024 |
| First version publication date | 28 December 2024 |

Trial information

Trial identification

| | |
|-----------------------|---------------|
| Sponsor protocol code | BB2121-MM-001 |
|-----------------------|---------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Bristol-Myers Squibb |
| Sponsor organisation address | Chaussée de la Hulpe 185, Brussels, Belgium, 1170 |
| Public contact | EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com |
| Scientific contact | Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.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 | 20 December 2023 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 20 December 2023 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to evaluate the efficacy, as defined as overall response rate (ORR), of bb2121 in subjects with relapsed and refractory multiple myeloma (RRMM)

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 04 December 2017 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Belgium: 3 |
| Country: Number of subjects enrolled | Canada: 1 |
| Country: Number of subjects enrolled | France: 8 |
| Country: Number of subjects enrolled | Germany: 6 |
| Country: Number of subjects enrolled | Italy: 3 |
| Country: Number of subjects enrolled | Japan: 9 |
| Country: Number of subjects enrolled | Spain: 13 |
| Country: Number of subjects enrolled | United States: 94 |
| Worldwide total number of subjects | 137 |
| EEA total number of subjects | 33 |

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) | 91 |
| From 65 to 84 years | 46 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

137 participants treated

Period 1

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

Arms

| | |
|------------------|--------|
| Arm title | BB2121 |
|------------------|--------|

Arm description:

BB2121

| | |
|--|-------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BB2121 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Dispersion for infusion |
| Routes of administration | Intravascular use |

Dosage and administration details:

dose ranging from 150 to 450 × 10⁶ CAR+ T cells/infusion.

| Number of subjects in period 1 | BB2121 |
|--------------------------------|--------|
| Started | 137 |
| Completed | 36 |
| Not completed | 101 |
| Adverse event, serious fatal | 77 |
| Consent withdrawn by subject | 20 |
| Lost to follow-up | 4 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--------|
| Reporting group title | BB2121 |
|-----------------------|--------|

| |
|------------------------------|
| Reporting group description: |
|------------------------------|

| |
|--------|
| BB2121 |
|--------|

| Reporting group values | BB2121 | Total | |
|---|--------|-------|--|
| Number of subjects | 137 | 137 | |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 91 | 91 | |
| From 65-84 years | 46 | 46 | |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 59.4 | | |
| standard deviation | ± 9.53 | - | |
| Sex: Female, Male | | | |
| Units: Participants | | | |
| Female | 54 | 54 | |
| Male | 83 | 83 | |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | |
| Asian | 12 | 12 | |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | |
| Black or African American | 6 | 6 | |
| White | 103 | 103 | |
| More than one race | 0 | 0 | |
| Unknown or Not Reported | 16 | 16 | |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 11 | 11 | |
| Not Hispanic or Latino | 112 | 112 | |
| Unknown or Not Reported | 14 | 14 | |

End points

End points reporting groups

| | |
|--|--------|
| Reporting group title | BB2121 |
| Reporting group description: BB2121 | |

Primary: Overall Response Rate

| | |
|--|--------------------------------------|
| End point title | Overall Response Rate ^[1] |
| End point description: Number of participants who achieved partial response (PR) or better according to IMWG Uniform Response Criteria for Multiple Myeloma as assessed by an independent response committee (IRC). | |
| End point type | Primary |
| End point timeframe: From first dose to 24 Months | |

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: No statistical analysis done for this endpoint

| | | | | |
|-----------------------------------|---------------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 74.5 (67.1 to 81.8) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Response Rate

| | |
|---|------------------------|
| End point title | Complete Response Rate |
| End point description: Percentage of participants who achieved CR or sCR according to IMWG Uniform Response Criteria for Multiple Myeloma as assessed by an IRC. | |
| End point type | Secondary |
| End point timeframe: From first dose to 24 Months | |

| | | | | |
|-----------------------------------|---------------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 47 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 34.3 (26.4 to 42.3) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

| | |
|--|----------------------|
| End point title | Duration of Response |
| End point description: Time from first documentation of response or PR or better to first documentation of disease progression or death from any cause, whichever occurs first. | |
| End point type | Secondary |
| End point timeframe: From first dose to 24 months after first dose | |

| | | | | |
|----------------------------------|-----------------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 11.04 (9.92 to 12.52) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to response

| | |
|--|------------------|
| End point title | Time to response |
| End point description: Time from first bb2121 infusion to first documentation of response of PR or better. | |
| End point type | Secondary |
| End point timeframe: From first dose to initial response (approximately on average 1.2 months, max of 8.8 months) | |

| | | | | |
|-------------------------------|------------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: Months | | | | |
| median (full range (min-max)) | 1.0 (0.5 to 8.8) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

| | |
|--|---------------------------------|
| End point title | Progression Free Survival (PFS) |
| End point description: Time from first bb2121 infusion to first documentation of progressive disease (PD), or death due to any cause, whichever occurs first. | |
| End point type | Secondary |
| End point timeframe: From first dose to 24 months after first dose | |

| | | | | |
|----------------------------------|----------------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 137 | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 8.90 (6.01 to 11.86) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with safety related events

| | |
|--|---|
| End point title | Number of participants with safety related events |
| End point description: Number of participants with adverse events (AEs), adverse events of special interest (AESI), serious adverse events (SAEs), cytokine release syndrome, neurotoxicity, infection and clinically significant laboratory abnormalities. | |
| End point type | Secondary |
| End point timeframe: From screening to the end of follow up (approximately 5 years and 2 months) | |

| | | | | |
|---|-----------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 137 | | | |
| Units: Participants | | | | |
| Any Grade AE | 137 | | | |
| Grade 3 or 4 AE | 136 | | | |
| SAEs | 98 | | | |
| AEs of Special Interest | 136 | | | |
| Cytokine Release Syndrome | 116 | | | |
| Neurotoxicity | 53 | | | |
| Infections | 95 | | | |
| Clinically Significant Laboratory Abnormalities | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Progression (TTP)

| | |
|--|---------------------------|
| End point title | Time to Progression (TTP) |
| End point description: Time from first bb2121 infusion to first documentation of progressive disease (PD), or death due to any cause, whichever occurs first. | |
| End point type | Secondary |
| End point timeframe: From first dose to 24 months after first dose | |

| | | | | |
|----------------------------------|-----------------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 137 | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 10.38 (6.11 to 12.06) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

| | |
|--|------------------|
| End point title | Overall Survival |
| End point description: Time from first bb2121 infusion to time of death due to any cause. | |
| End point type | Secondary |

End point timeframe:

From screening to the end of follow up (approximately 5 years and 2 months)

| | | | | |
|----------------------------------|------------------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 137 | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 28.25 (20.21 to 38.08) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax

| | |
|------------------------|---|
| End point title | Cmax |
| End point description: | Cmax |
| End point type | Secondary |
| End point timeframe: | From first dose to the end of follow up (Approximately 5 years) |

| | | | | |
|--------------------------------------|-------------------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 136 | | | |
| Units: copies/ug | | | | |
| arithmetic mean (standard deviation) | | | | |
| Total | 388150.65 (± 372280.64) | | | |
| 450x10 ⁶ cells | 449826.92 (± 375293.18) | | | |
| 300x10 ⁶ cells | 335916.20 (± 369546.39) | | | |
| 150x10 ⁶ cells | 317793.50 (± 284926.30) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUC 0-9M

| | |
|-----------------|----------|
| End point title | AUC 0-9M |
|-----------------|----------|

| | |
|---|-----------|
| End point description: | |
| Cmax | |
| End point type | Secondary |
| End point timeframe: | |
| From first dose to the end of follow up (Approximately 5 years) | |

| End point values | BB2121 | | | |
|--------------------------------------|-----------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 136 | | | |
| Units: copies*days/ug | | | | |
| arithmetic mean (standard deviation) | | | | |
| Total | 8634034.70 (± 9909488.82) | | | |
| 450x10 ⁶ cells | 10599751.18 (± 10833877.42) | | | |
| 300x10 ⁶ cells | 6604279.35 (± 8523928.48) | | | |
| 150x10 ⁶ cells | 10555200.59 (± 13555457.13) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax

| | |
|---|-----------|
| End point title | Tmax |
| End point description: | |
| Tmax | |
| End point type | Secondary |
| End point timeframe: | |
| From first dose to the end of follow up (Approximately 5 years) | |

| End point values | BB2121 | | | |
|--------------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 136 | | | |
| Units: Days | | | | |
| arithmetic mean (standard deviation) | | | | |
| Total | 12.07 (± 4.114) | | | |
| 450x10 ⁶ cells | 12.37 (± 4.513) | | | |
| 300x10 ⁶ cells | 11.74 (± 3.830) | | | |

| | | | | |
|---------------------------|-----------------|--|--|--|
| 150x10 ⁶ cells | 13.25 (± 1.500) | | | |
|---------------------------|-----------------|--|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-CAR-Antibodies

| | |
|-----------------|---|
| End point title | Number of Participants with Anti-CAR-Antibodies |
|-----------------|---|

End point description:

Number of Participants with Anti-CAR-Antibodies.

Pre-positive is defined by last value before or on bb2121 infusion date is positive

Post-positive is defined by at least one positive value post bb2121 infusion.

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

End point timeframe:

From first dose to the end of follow up (Approximately 5 years)

| End point values | BB2121 | | | |
|---|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 137 | | | |
| Units: Participants | | | | |
| Pre-Positive (pre-positive and post-positive) | 6 | | | |
| Pre-Positive (pre-positive and post-negative) | 0 | | | |
| Pre-Positive (missing post data) | 0 | | | |
| Pre-Negative (pre-negative and post-positive) | 69 | | | |
| Pre-Negative (pre-negative and post-negative) | 60 | | | |
| Pre-Negative (missing post data) | 1 | | | |
| Missing Pre data (post-positive) | 1 | | | |
| Missing Pre data (post-negative) | 0 | | | |
| Missing Pre Data (missing post data) | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who achieved ≥ VGPR and MRD negative status

| | |
|-----------------|--|
| End point title | Percentage of participants who achieved ≥ VGPR and MRD negative status |
|-----------------|--|

End point description:

Percentage of Subjects Who Achieved \geq VGPR and MRD Negative Status at Any Time Point from within 3 Months prior to Achieving VGPR or above to until Time of Progression/Death (Exclusive) based on IRC Review

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

End point timeframe:

From screening to the end of follow up (Approximately 5 years and 2 months)

| End point values | BB2121 | | | |
|-----------------------------------|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 137 | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| 10 ⁽⁻⁴⁾ Sensitivity | 41.6 (33.3 to 50.3) | | | |
| 10 ⁽⁻⁵⁾ Sensitivity | 40.9 (32.6 to 49.6) | | | |
| 10 ⁽⁻⁶⁾ Sensitivity | 24.8 (17.8 to 32.9) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline on the EORTC QLQ-C30 - Pain

| | |
|-----------------|---|
| End point title | Mean change from baseline on the EORTC QLQ-C30 - Pain |
|-----------------|---|

End point description:

Mean change from baseline on the EORTC QLQ-C30

Mean change from baseline on the EORTC QLQ-C30

The QLQ-C30 employs a week recall period for all items and a 4-point scale for the functional and symptom scales/items with response categories "Not at all", "A little", "Quite a bit" and "Very much". The two items assessing global health status/ HRQoL utilize a 7-point scale ranging from 1("Very Poor") to 7 ("Excellent")

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

End point timeframe:

At Day 1 and at specific time points up to month 24

| End point values | BB2121 | | | |
|--------------------------------------|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 126 | | | |
| Units: Score on a Scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Day 1 | -3.8 (\pm 19.46) | | | |
| Month 1 | -8.9 (\pm 26.02) | | | |

| | | | | |
|----------|-----------------|--|--|--|
| Month 3 | -12.0 (± 26.65) | | | |
| Month 6 | -14.5 (± 26.15) | | | |
| Month 9 | -17.5 (± 24.26) | | | |
| Month 12 | -17.3 (± 26.05) | | | |
| Month 18 | -16.7 (± 25.39) | | | |
| Month 24 | -13.1 (± 16.25) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline on the EORTC QLQ-C30 - Physical Functioning

| | |
|-----------------|---|
| End point title | Mean change from baseline on the EORTC QLQ-C30 - Physical Functioning |
|-----------------|---|

End point description:

Mean change from baseline on the EORTC QLQ-C30

Mean change from baseline on the EORTC QLQ-C30

The QLQ-C30 employs a week recall period for all items and a 4-point scale for the functional and symptom scales/items with response categories "Not at all", "A little", "Quite a bit" and "Very much". The two items assessing global health status/ HRQoL utilize a 7-point scale ranging from 1("Very Poor") to 7 ("Excellent")

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

End point timeframe:

At Day 1 and at specific time points up to month 24

| End point values | BB2121 | | | |
|--------------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 126 | | | |
| Units: Score on a Scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Day 1 | -0.4 (± 18.13) | | | |
| Month 1 | 2.1 (± 22.27) | | | |
| Month 3 | 9.8 (± 18.54) | | | |
| Month 6 | 13.9 (± 18.47) | | | |
| Month 9 | 13.1 (± 19.02) | | | |
| Month 12 | 13.3 (± 19.16) | | | |
| Month 18 | 12.8 (± 15.99) | | | |
| Month 24 | 3.8 (± 13.77) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline on the EORTC QLQ-C30 - Cognitive Functioning

| | |
|-----------------|--|
| End point title | Mean change from baseline on the EORTC QLQ-C30 - Cognitive Functioning |
|-----------------|--|

End point description:

Mean change from baseline on the EORTC QLQ-C30

Mean change from baseline on the EORTC QLQ-C30

The QLQ-C30 employs a week recall period for all items and a 4-point scale for the functional and symptom scales/items with response categories "Not at all", "A little", "Quite a bit" and "Very much". The two items assessing global health status/ HRQoL utilize a 7-point scale ranging from 1("Very Poor") to 7 ("Excellent")

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

End point timeframe:

At Day 1 and at specific time points up to month 24

| End point values | BB2121 | | | |
|--------------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 126 | | | |
| Units: Score on a Scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Day 1 | -0.4 (± 16.66) | | | |
| Month 1 | 2.8 (± 20.10) | | | |
| Month 3 | 5.4 (± 17.42) | | | |
| Month 6 | 6.4 (± 16.55) | | | |
| Month 9 | 6.8 (± 14.88) | | | |
| Month 12 | 4.2 (± 17.63) | | | |
| Month 18 | 3.8 (± 19.61) | | | |
| Month 24 | 3.6 (± 16.25) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline on the EORTC QLQ-C30 - Global health/QoL

| | |
|-----------------|--|
| End point title | Mean change from baseline on the EORTC QLQ-C30 - Global health/QoL |
|-----------------|--|

End point description:

Mean change from baseline on the EORTC QLQ-C30

Mean change from baseline on the EORTC QLQ-C30

The QLQ-C30 employs a week recall period for all items and a 4-point scale for the functional and symptom scales/items with response categories "Not at all", "A little", "Quite a bit" and "Very much". The two items assessing global health status/ HRQoL utilize a 7-point scale ranging from 1("Very Poor") to 7 ("Excellent")

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Day 1 and at specific time points up to month 24 | |

| | | | | |
|--------------------------------------|-----------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 126 | | | |
| Units: Score on a Scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Day 1 | -4.7 (± 17.03) | | | |
| Month 1 | 4.3 (± 19.95) | | | |
| Month 3 | 8.8 (± 20.31) | | | |
| Month 6 | 12.5 (± 19.12) | | | |
| Month 9 | 15.7 (± 20.88) | | | |
| Month 12 | 14.1 (± 21.57) | | | |
| Month 18 | 10.6 (± 17.25) | | | |
| Month 24 | 7.1 (± 14.93) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline on the EORTC QLQ-MY20 - Disease Symptoms

| | |
|-----------------|--|
| End point title | Mean change from baseline on the EORTC QLQ-MY20 - Disease Symptoms |
|-----------------|--|

End point description:

Mean change from baseline on the EORTC QLQ-MY20

The EORTC has developed a myeloma module referred to as QLQ- MY20, to be administered alongside the core QLQ-C30. The QLQ-MY20 is a 20-item myeloma module intended for use among patients varying in disease stage and treatment modality.

The QLQ-C30 employs a week recall period for all items and a 4-point scale for the functional and symptom scales/items with response categories "Not at all", "A little", "Quite a bit" and "Very much". The two items assessing global health status/ HRQoL utilize a 7-point scale ranging from 1("Very Poor") to 7 ("Excellent")

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Day 1 and at specific time points up to month 24 | |

| | | | | |
|--------------------------------------|-----------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 126 | | | |
| Units: Score on a Scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Day 1 | -0.8 (± 14.11) | | | |
| Month 1 | -10.2 (± 18.54) | | | |
| Month 3 | -10.8 (± 20.32) | | | |
| Month 6 | -12.6 (± 20.81) | | | |
| Month 9 | -14.4 (± 20.29) | | | |
| Month 12 | -15.7 (± 23.28) | | | |
| Month 18 | -12.0 (± 20.47) | | | |
| Month 24 | -13.1 (± 19.07) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline on the EORTC QLQ-MY20 - Side Effects

| | |
|-----------------|--|
| End point title | Mean change from baseline on the EORTC QLQ-MY20 - Side Effects |
|-----------------|--|

End point description:

Mean change from baseline on the EORTC QLQ-MY20

The EORTC has developed a myeloma module referred to as QLQ- MY20, to be administered alongside the core QLQ-C30. The QLQ-MY20 is a 20-item myeloma module intended for use among patients varying in disease stage and treatment modality.

The QLQ-C30 employs a week recall period for all items and a 4-point scale for the functional and symptom scales/items with response categories "Not at all", "A little", "Quite a bit" and "Very much". The two items assessing global health status/ HRQoL utilize a 7-point scale ranging from 1("Very Poor") to 7 ("Excellent")

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

End point timeframe:

At Day 1 and at specific time points up to month 24

| | | | | |
|--------------------------------------|-----------------|--|--|--|
| End point values | BB2121 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 126 | | | |
| Units: Score on a Scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Day 1 | 2.5 (± 9.51) | | | |
| Month 1 | 0.0 (± 11.95) | | | |
| Month 3 | -2.6 (± 11.45) | | | |

| | | | | |
|----------|---------------------|--|--|--|
| Month 6 | -4.7 (\pm 10.16) | | | |
| Month 9 | -6.5 (\pm 10.28) | | | |
| Month 12 | -4.0 (\pm 11.87) | | | |
| Month 18 | -3.4 (\pm 9.96) | | | |
| Month 24 | -3.2 (\pm 7.98) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline on the EQ-5D-5L Index

| | |
|-----------------|---|
| End point title | Mean change from baseline on the EQ-5D-5L Index |
|-----------------|---|

End point description:

Mean change from baseline on the EQ-5D-5L Index

EQ-5D is a standardized measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal. The descriptive system comprises dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension has 5 levels (no problems, slight problems, moderate problems, severe problems, extreme problems).

The lower the score the the better.

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

End point timeframe:

At Day 1 and at specific time points up to month 24

| End point values | BB2121 | | | |
|--------------------------------------|------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 126 | | | |
| Units: Score on a Scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Day 1 | 0.0314 (\pm 0.1760) | | | |
| Month 1 | 0.0528 (\pm 0.2473) | | | |
| Month 3 | 0.0998 (\pm 0.1956) | | | |
| Month 6 | 0.0974 (\pm 0.1798) | | | |
| Month 9 | 0.1067 (\pm 0.2334) | | | |
| Month 12 | 0.1097 (\pm 0.2287) | | | |
| Month 18 | 0.1101 (\pm 0.2027) | | | |
| Month 24 | 0.0383 (\pm 0.1604) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline on the EORTC QLQ-C30 - Fatigue.

| | |
|-----------------|---|
| End point title | Mean change from baseline on the EORTC QLQ-C30 - Fatigue. |
|-----------------|---|

End point description:

Mean change from baseline on the EORTC QLQ-C30

The QLQ-C30 employs a week recall period for all items and a 4-point scale for the functional and symptom scales/items with response categories "Not at all", "A little", "Quite a bit" and "Very much". The two items assessing global health status/ HRQoL utilize a 7-point scale ranging from 1("Very Poor") to 7 ("Excellent")

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

End point timeframe:

At Day 1 and at specific time points up to month 24

| End point values | BB2121 | | | |
|--------------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 126 | | | |
| Units: Score on a Scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Day 1 | 4.4 (± 18.56) | | | |
| Month 1 | 1.1 (± 24.38) | | | |
| Month 3 | -10.1 (± 24.32) | | | |
| Month 6 | -15.1 (± 24.39) | | | |
| Month 9 | -21.5 (± 24.58) | | | |
| Month 12 | -16.4 (± 25.02) | | | |
| Month 18 | -18.4 (± 19.10) | | | |
| Month 24 | -7.9 (± 15.97) | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From screening to the end of follow up (approximately 5 years and 2 months)

Adverse event reporting additional description:

The number at Risk for All-Cause Mortality represents all Randomized Participants. The number at Risk for Serious Adverse Events and Other (Not Including Serious) Adverse Events represents all participants that received at least 1 dose of study medication

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

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 26.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--------|
| Reporting group title | BB2121 |
|-----------------------|--------|

Reporting group description:

BB2121

| Serious adverse events | BB2121 | | |
|---|--------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 108 / 137 (78.83%) | | |
| number of deaths (all causes) | 82 | | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Plasmablastic lymphoma | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Plasma cell leukaemia | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Anal cancer | | | |

| | | | |
|--|-----------------|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 5 / 137 (3.65%) | | |
| occurrences causally related to treatment / all | 0 / 6 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Pelvic venous thrombosis | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypotension | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Distributive shock | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |

| | | | | |
|---|-------------------|--|--|--|
| Asthenia | | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | | |
| occurrences causally related to treatment / all | 2 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Chills | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Fatigue | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| General physical health deterioration | | | | |
| subjects affected / exposed | 30 / 137 (21.90%) | | | |
| occurrences causally related to treatment / all | 0 / 33 | | | |
| deaths causally related to treatment / all | 0 / 28 | | | |
| Localised oedema | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Mucosal inflammation | | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pain | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyrexia | | | | |
| subjects affected / exposed | 8 / 137 (5.84%) | | | |
| occurrences causally related to treatment / all | 2 / 11 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Immune system disorders | | | | |

| | | | |
|---|-------------------|--|--|
| Acute graft versus host disease subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemophagocytic lymphohistiocytosis subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cytokine release syndrome subjects affected / exposed | 22 / 137 (16.06%) | | |
| occurrences causally related to treatment / all | 27 / 27 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Reproductive system and breast disorders | | | |
| Benign prostatic hyperplasia subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Upper airway obstruction subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary embolism subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumothorax subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonitis | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lung disorder | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypoxia | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dyspnoea | | | |
| subjects affected / exposed | 4 / 137 (2.92%) | | |
| occurrences causally related to treatment / all | 2 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory failure | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Psychiatric disorders | | | |
| Confusional state | | | |
| subjects affected / exposed | 4 / 137 (2.92%) | | |
| occurrences causally related to treatment / all | 4 / 5 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Mood altered | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Mental status changes | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 3 / 137 (2.19%) | | |
| occurrences causally related to treatment / all | 1 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hallucination | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Disorientation | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Delirium | | | |
| subjects affected / exposed | 3 / 137 (2.19%) | | |
| occurrences causally related to treatment / all | 2 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 2 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 2 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 2 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood creatinine increased | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| C-reactive protein increased | | | |
| subjects affected / exposed | 3 / 137 (2.19%) | | |
| occurrences causally related to treatment / all | 3 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Coronavirus test positive | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Compression fracture | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyphaema | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Stress fracture | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Subdural haematoma | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Toxicity to various agents | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Vascular access complication | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Angina pectoris | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac arrest | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pericardial effusion | | | |
| subjects affected / exposed | 3 / 137 (2.19%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pericarditis | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tachycardia | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Syncope | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Spinal cord compression | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Seizure | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Paraesthesia | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Migraine | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolic encephalopathy | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lethargy | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 3 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypotonia | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hemiparesis | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Headache | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Encephalopathy | | | |
| subjects affected / exposed | 4 / 137 (2.92%) | | |
| occurrences causally related to treatment / all | 5 / 6 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dysarthria | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cognitive disorder | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 1 / 3 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Cerebral haematoma | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 1 / 3 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Cauda equina syndrome | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ataxia | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Aphasia | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 4 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Amnesia | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Disseminated intravascular coagulation | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Anaemia | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperviscosity syndrome | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Febrile neutropenia | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 12 / 137 (8.76%) | | |
| occurrences causally related to treatment / all | 5 / 16 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombotic microangiopathy | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 9 / 137 (6.57%) | | |
| occurrences causally related to treatment / all | 7 / 9 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancytopenia | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Neutropenia | | | |
| subjects affected / exposed | 6 / 137 (4.38%) | | |
| occurrences causally related to treatment / all | 8 / 9 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Diplopia | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diarrhoea | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 1 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Melaena | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nausea | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Urticaria | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rash | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Renal failure | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Acute kidney injury | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 5 / 137 (3.65%) | | |
| occurrences causally related to treatment / all | 1 / 5 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Back pain | | | |
| subjects affected / exposed | 3 / 137 (2.19%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bone pain | | | |
| subjects affected / exposed | 3 / 137 (2.19%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Muscular weakness | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pain in extremity | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pathological fracture | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Spinal pain | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Acute sinusitis | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sepsis | | | |
| subjects affected / exposed | 7 / 137 (5.11%) | | |
| occurrences causally related to treatment / all | 0 / 8 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Bacteraemia | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchopulmonary aspergillosis | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Coronavirus infection | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Device related bacteraemia | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Device related infection | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Enterococcal bacteraemia | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Erysipelas | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Escherichia bacteraemia | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis salmonella | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haemophilus infection | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatitis E | | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Herpes zoster | | | | |

| | | | | |
|---|-------------------|--|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypopyon | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infection | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Influenza | | | | |
| subjects affected / exposed | 5 / 137 (3.65%) | | | |
| occurrences causally related to treatment / all | 1 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Listeriosis | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lower respiratory tract infection viral | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 15 / 137 (10.95%) | | | |
| occurrences causally related to treatment / all | 4 / 19 | | | |
| deaths causally related to treatment / all | 0 / 2 | | | |
| Pneumonia aspiration | | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia cytomegaloviral | | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Pneumonia pneumococcal | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 3 / 137 (2.19%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rhinovirus infection | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 3 / 137 (2.19%) | | |
| occurrences causally related to treatment / all | 1 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Arthritis infective | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Septic shock | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Serratia bacteraemia | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Typhoid fever | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Acidosis | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Adult failure to thrive | | | |
| subjects affected / exposed | 2 / 137 (1.46%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tumour lysis syndrome | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 137 (0.73%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| | | | |
|---|---------------------|--|--|
| Non-serious adverse events | BB2121 | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 137 / 137 (100.00%) | | |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 24 / 137 (17.52%) | | |
| occurrences (all) | 35 | | |
| Hypertension | | | |
| subjects affected / exposed | 19 / 137 (13.87%) | | |
| occurrences (all) | 44 | | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 22 / 137 (16.06%) | | |
| occurrences (all) | 32 | | |
| Chills | | | |
| subjects affected / exposed | 20 / 137 (14.60%) | | |
| occurrences (all) | 22 | | |
| Fatigue | | | |
| subjects affected / exposed | 53 / 137 (38.69%) | | |
| occurrences (all) | 91 | | |
| Malaise | | | |
| subjects affected / exposed | 7 / 137 (5.11%) | | |
| occurrences (all) | 9 | | |
| Oedema peripheral | | | |
| subjects affected / exposed | 27 / 137 (19.71%) | | |
| occurrences (all) | 39 | | |
| Pain | | | |
| subjects affected / exposed | 9 / 137 (6.57%) | | |
| occurrences (all) | 9 | | |

| | | | |
|--|---------------------------|--|--|
| Pyrexia subjects affected / exposed occurrences (all) | 36 / 137 (26.28%) 77 | | |
| Immune system disorders Cytokine release syndrome subjects affected / exposed occurrences (all) | 110 / 137 (80.29%) 170 | | |
| Hypogammaglobulinaemia subjects affected / exposed occurrences (all) | 32 / 137 (23.36%) 36 | | |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 34 / 137 (24.82%) 47 | | |
| Dyspnoea subjects affected / exposed occurrences (all) | 14 / 137 (10.22%) 20 | | |
| Dyspnoea exertional subjects affected / exposed occurrences (all) | 8 / 137 (5.84%) 10 | | |
| Epistaxis subjects affected / exposed occurrences (all) | 11 / 137 (8.03%) 12 | | |
| Nasal congestion subjects affected / exposed occurrences (all) | 11 / 137 (8.03%) 11 | | |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 13 / 137 (9.49%) 14 | | |
| Pleural effusion subjects affected / exposed occurrences (all) | 8 / 137 (5.84%) 10 | | |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 7 / 137 (5.11%) 7 | | |
| Psychiatric disorders | | | |

| | | | |
|---|-------------------|--|--|
| Anxiety | | | |
| subjects affected / exposed | 19 / 137 (13.87%) | | |
| occurrences (all) | 27 | | |
| Confusional state | | | |
| subjects affected / exposed | 16 / 137 (11.68%) | | |
| occurrences (all) | 20 | | |
| Insomnia | | | |
| subjects affected / exposed | 14 / 137 (10.22%) | | |
| occurrences (all) | 15 | | |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 7 / 137 (5.11%) | | |
| occurrences (all) | 14 | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 22 / 137 (16.06%) | | |
| occurrences (all) | 33 | | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 26 / 137 (18.98%) | | |
| occurrences (all) | 40 | | |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 18 / 137 (13.14%) | | |
| occurrences (all) | 36 | | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 8 / 137 (5.84%) | | |
| occurrences (all) | 14 | | |
| C-reactive protein increased | | | |
| subjects affected / exposed | 15 / 137 (10.95%) | | |
| occurrences (all) | 29 | | |
| International normalised ratio increased | | | |
| subjects affected / exposed | 7 / 137 (5.11%) | | |
| occurrences (all) | 9 | | |
| Weight decreased | | | |
| subjects affected / exposed | 19 / 137 (13.87%) | | |
| occurrences (all) | 38 | | |
| Weight increased | | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed occurrences (all) | 8 / 137 (5.84%) 16 | | |
| Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all) | 9 / 137 (6.57%) 9 | | |
| Cardiac disorders Tachycardia subjects affected / exposed occurrences (all) | 22 / 137 (16.06%) 44 | | |
| Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Somnolence subjects affected / exposed occurrences (all) Tremor subjects affected / exposed occurrences (all) | 23 / 137 (16.79%) 27 47 / 137 (34.31%) 68 10 / 137 (7.30%) 11 12 / 137 (8.76%) 14 | | |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) Leukopenia subjects affected / exposed occurrences (all) Lymphopenia subjects affected / exposed occurrences (all) Neutropenia subjects affected / exposed occurrences (all) | 104 / 137 (75.91%) 706 70 / 137 (51.09%) 531 49 / 137 (35.77%) 284 130 / 137 (94.89%) 1018 | | |

| | | | |
|---|--------------------------|--|--|
| Thrombocytopenia subjects affected / exposed occurrences (all) | 95 / 137 (69.34%) 719 | | |
| Febrile neutropenia subjects affected / exposed occurrences (all) | 19 / 137 (13.87%) 24 | | |
| Gastrointestinal disorders | | | |
| Constipation subjects affected / exposed occurrences (all) | 45 / 137 (32.85%) 63 | | |
| Diarrhoea subjects affected / exposed occurrences (all) | 61 / 137 (44.53%) 81 | | |
| Dry mouth subjects affected / exposed occurrences (all) | 10 / 137 (7.30%) 11 | | |
| Dyspepsia subjects affected / exposed occurrences (all) | 12 / 137 (8.76%) 15 | | |
| Nausea subjects affected / exposed occurrences (all) | 85 / 137 (62.04%) 123 | | |
| Vomiting subjects affected / exposed occurrences (all) | 34 / 137 (24.82%) 43 | | |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia subjects affected / exposed occurrences (all) | 11 / 137 (8.03%) 11 | | |
| Pruritus subjects affected / exposed occurrences (all) | 9 / 137 (6.57%) 9 | | |
| Rash subjects affected / exposed occurrences (all) | 12 / 137 (8.76%) 21 | | |
| Renal and urinary disorders | | | |

| | | | |
|--|-------------------------|--|--|
| Acute kidney injury subjects affected / exposed occurrences (all) | 11 / 137 (8.03%) 12 | | |
| Pollakiuria subjects affected / exposed occurrences (all) | 7 / 137 (5.11%) 9 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia subjects affected / exposed occurrences (all) | 32 / 137 (23.36%) 48 | | |
| Back pain subjects affected / exposed occurrences (all) | 29 / 137 (21.17%) 36 | | |
| Bone pain subjects affected / exposed occurrences (all) | 18 / 137 (13.14%) 23 | | |
| Muscle spasms subjects affected / exposed occurrences (all) | 9 / 137 (6.57%) 13 | | |
| Musculoskeletal chest pain subjects affected / exposed occurrences (all) | 11 / 137 (8.03%) 26 | | |
| Myalgia subjects affected / exposed occurrences (all) | 8 / 137 (5.84%) 10 | | |
| Pain in extremity subjects affected / exposed occurrences (all) | 12 / 137 (8.76%) 15 | | |
| Infections and infestations | | | |
| Influenza subjects affected / exposed occurrences (all) | 9 / 137 (6.57%) 11 | | |
| Candida infection subjects affected / exposed occurrences (all) | 8 / 137 (5.84%) 9 | | |
| Nasopharyngitis | | | |

| | | | |
|------------------------------------|-------------------|--|--|
| subjects affected / exposed | 10 / 137 (7.30%) | | |
| occurrences (all) | 12 | | |
| Pneumonia | | | |
| subjects affected / exposed | 9 / 137 (6.57%) | | |
| occurrences (all) | 9 | | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 8 / 137 (5.84%) | | |
| occurrences (all) | 10 | | |
| Sinusitis | | | |
| subjects affected / exposed | 7 / 137 (5.11%) | | |
| occurrences (all) | 9 | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 21 / 137 (15.33%) | | |
| occurrences (all) | 37 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 8 / 137 (5.84%) | | |
| occurrences (all) | 8 | | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 41 / 137 (29.93%) | | |
| occurrences (all) | 58 | | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 12 / 137 (8.76%) | | |
| occurrences (all) | 19 | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 15 / 137 (10.95%) | | |
| occurrences (all) | 49 | | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 7 / 137 (5.11%) | | |
| occurrences (all) | 7 | | |
| Hyperuricaemia | | | |
| subjects affected / exposed | 13 / 137 (9.49%) | | |
| occurrences (all) | 16 | | |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 26 / 137 (18.98%) | | |
| occurrences (all) | 60 | | |

| | | | |
|-----------------------------|-------------------|--|--|
| Hypocalcaemia | | | |
| subjects affected / exposed | 37 / 137 (27.01%) | | |
| occurrences (all) | 118 | | |
| Hypokalaemia | | | |
| subjects affected / exposed | 56 / 137 (40.88%) | | |
| occurrences (all) | 93 | | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 35 / 137 (25.55%) | | |
| occurrences (all) | 59 | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 30 / 137 (21.90%) | | |
| occurrences (all) | 72 | | |
| Hypophosphataemia | | | |
| subjects affected / exposed | 46 / 137 (33.58%) | | |
| occurrences (all) | 106 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|--------------|--|
| 18 June 2019 | <ul style="list-style-type: none">• Moved minimal residual disease (MRD) assessment by EuroFlow to Exploratory Objectives and Exploratory Endpoints. Updated the term "vector copy number" (VCN).• Separated the secondary objective of characterization of the expansion of CAR+ T cells in the peripheral blood and bone marrow into two objectives. Evaluation of CAR+ T cells in the peripheral blood will remain as a secondary objective while evaluation in the bone marrow will be an exploratory objective. Evaluation in the bone marrow was also added as an exploratory endpoint.• Removed the secondary objective and secondary endpoint, "Evaluate cytokine induction in the blood of subjects after infusion of bb2121", and removed cytokines as a key safety assessment.• Moved the secondary objective and secondary endpoint, "Evaluate the percentage of B-cell maturation antigen (BCMA)-expressing (BCMA+) cells and levels of BCMA expression in bone marrow, and the level of circulating soluble BCMA" to exploratory objectives and exploratory endpoints.• Clarified the definition of "cellular kinetics". |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported