**Modul 4 Anhang 4-G**

# Dossier zur Nutzenbewertung gemäß § 35a SGB V

*Idecabtagen vicleucel (Abecma)*

Bristol-Myers Squibb GmbH & Co. KGaA

## Modul 4 – Anhang 4-G

## Ergänzende Analysen

Stand: 28.12.2021

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# I. Studie KarMMa

# 1. Gesamtüberleben

## 1.1 Datenschnitt vom 16.10.2019

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Protocol: BB2121-MM-001

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Cut-off date: 16OCT2019

Table 1.2.1a
Summary of Overall Survival
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=136) |
|---|---|---|
| Overall Survival (OS) | N | 136 |
| Censored | n (%) | 96 ( 70.6%) |
| Died | n (%) | 40 ( 29.4%) |
| Overall Survival Time (months) [a] | 25th Percentile (95% CI) | 12.42 ( 7.56,16.59) |
| | Median (95% CI) | NE (17.94, NE ) |
| | 75th Percentile (95% CI) | NE ( NE , NE ) |
| 3 Months Event-Free | % (SE) | 94.8 ( 1.92) |
| 6 Months Event-Free | % (SE) | 87.1 ( 2.93) |
| 9 Months Event-Free | % (SE) | 80.7 ( 3.47) |
| 12 Months Event-Free | % (SE) | 75.6 ( 3.83) |
| 15 Months Event-Free | % (SE) | 66.8 ( 4.86) |
| 18 Months Event-Free | % (SE) | 60.6 ( 6.17) |
| 21 Months Event-Free | % (SE) | NE ( NE ) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

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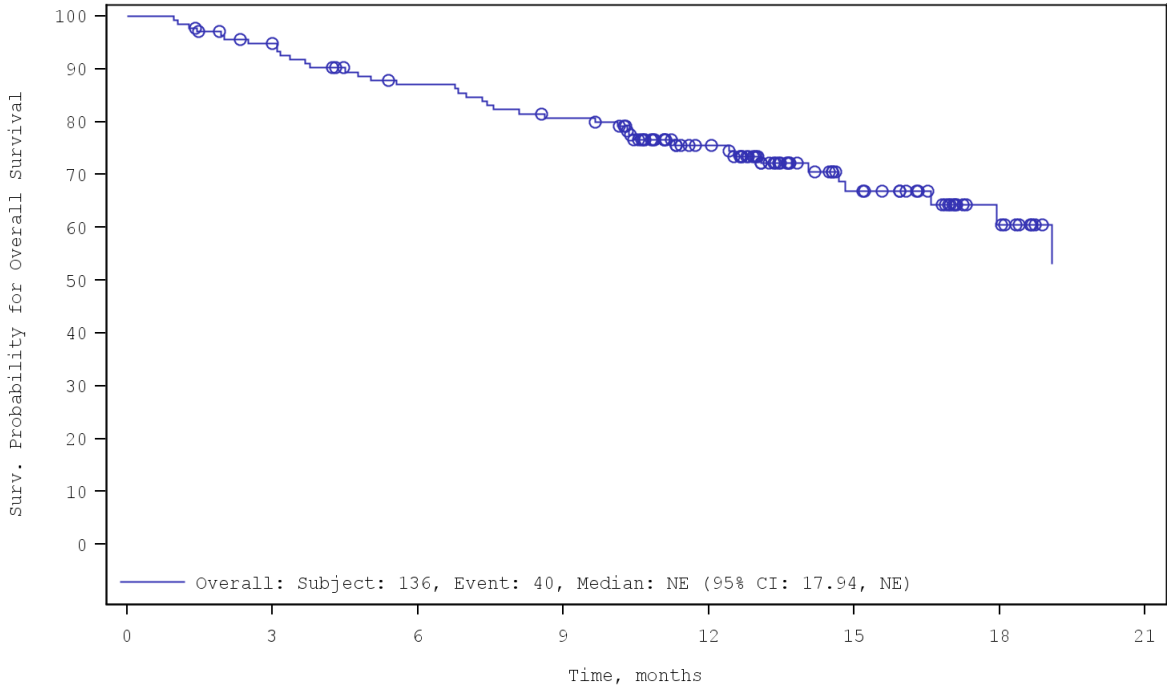
Figure 1.2.1a
Kaplan-Meier Curve of Overall Survival
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells




No. of Subjects at Risk

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Overall: | 136 | 124 | 110 | 101 | 72 | 36 | 16 | 0 |

NE=Not Estimable. Source Table: Table 1.2.1a.
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Protocol: BB2121-MM-001

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Cut-off date: 16OCT2019

Table 1.1a
Summary of Overall Survival by Ide-cel Target Dose Level
bb2121-Treated Population

| | Statistics | 150x10^6 cells (N=4) | 300x10^6 cells (N=70) | 450x10^6 cells (N=54) |
|---|---|---|---|---|
| Overall Survival (OS) | N | 4 | 70 | 54 |
| Censored | n (%) | 2 ( 50.0) | 50 ( 71.4) | 42 ( 77.8) |
| Died | n (%) | 2 ( 50.0) | 20 ( 28.6) | 12 ( 22.2) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | NE* | 13.40 (10.02, NE) | NE ( 7.23, NE) |
| | Median (95% CI) | NE* | NE (17.97, NE) | NE ( NE , NE) |
| | 75th Pcnt. (95% CI) | NE* | NE ( NE , NE) | NE ( NE , NE) |
| 3 Months Event-Free | % (SE) | NE* | 95.7 ( 2.44) | 92.6 ( 3.56) |
| 6 Months Event-Free | % (SE) | NE* | 89.6 ( 3.71) | 86.9 ( 4.61) |
| 9 Months Event-Free | % (SE) | NE* | 86.6 ( 4.16) | 79.1 ( 5.62) |
| 12 Months Event-Free | % (SE) | NE* | 78.6 ( 5.09) | 76.8 ( 5.92) |
| 15 Months Event-Free | % (SE) | NE* | 72.7 ( 5.73) | NE ( NE ) |
| 18 Months Event-Free | % (SE) | NE* | 52.4 (13.04) | NE ( NE ) |
| 21 Months Event-Free | % (SE) | NE* | NE ( NE ) | NE ( NE ) |

Note: CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

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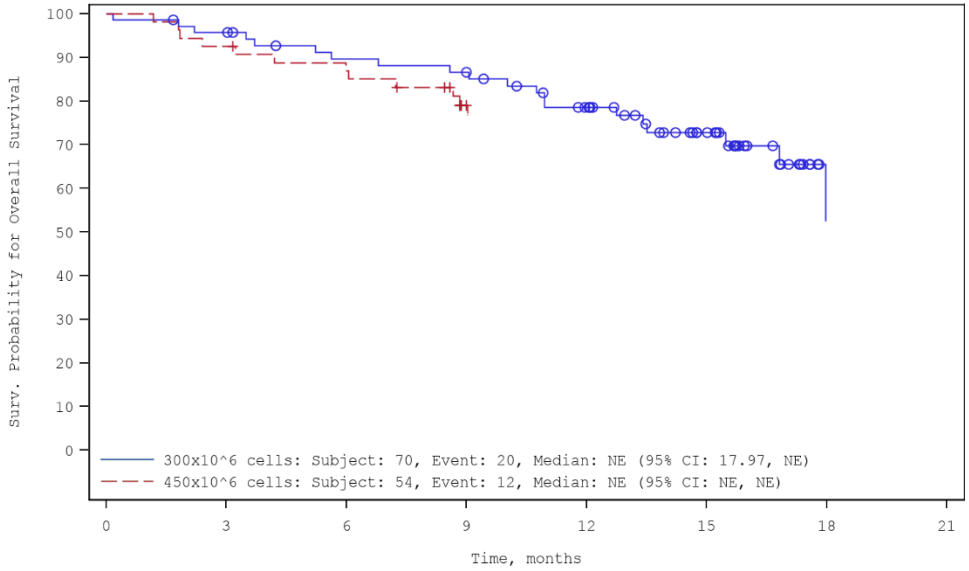
Protocol: BB2121-MM-001 Cut-off date: 16OCT2019

Figure 1.1a
Kaplan-Meier Curve of Overall Survival by Ide-cel Target Dose Level
bb2121-Treated Population




No. of Subjects at Risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 150x10^6 cells: | Fewer than 10 subjects for this subgroup level | | | | | | |
| 300x10^6 cells: 70 | 66 | 59 | 57 | 46 | 29 | 4 | 0 |
| 450x10^6 cells: 54 | 50 | 46 | 35 | 5 | 0 | 0 | 0 |

NE=Not Estimable. Missing categories are not presented. Source Table: Table 1.1a.

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# 1.3 Studie KarMMa – Datenschnitt vom 14.01.2020

# 1.2 Datenschnitt vom 14.01.2020

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Protocol: BB2121-MM-001

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Cut-off date: 14JAN2020

Table 1.2.1b
Summary of Overall Survival
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=136) |
|---|---|---|
| Overall Survival (OS) | N | 136 |
| Censored | n (%) | 86 ( 63.2%) |
| Died | n (%) | 50 ( 36.8%) |
| Overall Survival Time (months) [a] | 25th Percentile (95% CI) | 12.42 ( 7.56,14.82) |
| | Median (95% CI) | 20.76 (19.09, NE ) |
| | 75th Percentile (95% CI) | NE (21.36, NE ) |
| 3 Months Event-Free | % (SE) | 94.8 ( 1.92) |
| 6 Months Event-Free | % (SE) | 87.1 ( 2.93) |
| 9 Months Event-Free | % (SE) | 80.7 ( 3.48) |
| 12 Months Event-Free | % (SE) | 75.8 ( 3.79) |
| 15 Months Event-Free | % (SE) | 67.0 ( 4.36) |
| 18 Months Event-Free | % (SE) | 62.2 ( 4.89) |
| 21 Months Event-Free | % (SE) | 46.2 ( 7.33) |
| 24 Months Event-Free | % (SE) | NE ( NE ) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

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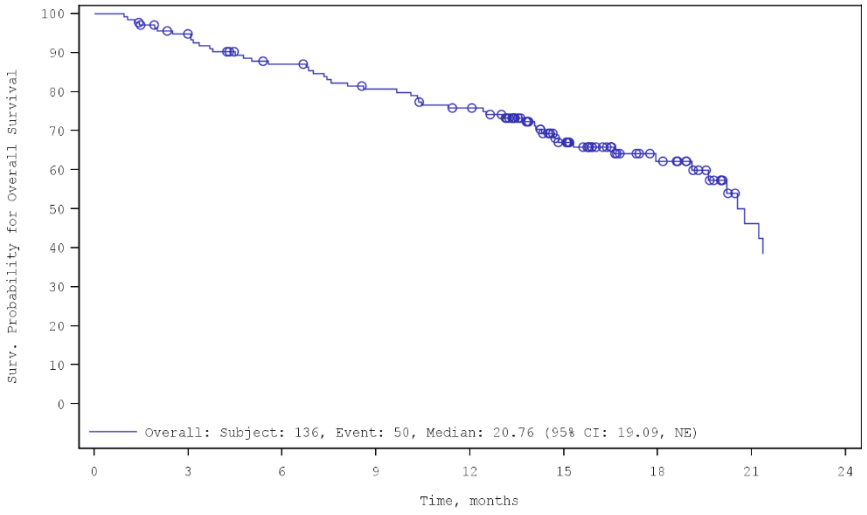
Protocol: BB2121-MM-001 Cut-off date: 14JAN2020

Figure 1.2.1b
Kaplan-Meier Curve of Overall Survival
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Overall: | 136 | 124 | 110 | 100 | 92 | 58 | 32 | 12 | 0 |

NE=Not Estimable. Source Table: Table 1.2.1b.
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Table 1.1b
Summary of Overall Survival by Ide-cel Target Dose Level
bb2121-Treated Population

| | Statistics | 150x10^6 cells (N=4) | 300x10^6 cells (N=70) | 450x10^6 cells (N=54) |
|---|---|---|---|---|
| Overall Survival (OS) | N | 4 | 70 | 54 |
| Censored | n (%) | 2 ( 50.0) | 43 ( 61.4) | 39 ( 72.2) |
| Died | n (%) | 2 ( 50.0) | 27 ( 38.6) | 15 ( 27.8) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | NE* | 13.44 (10.02,18.86) | 12.32 ( 7.23, NE ) |
| | Median (95% CI) | NE* | 19.94 (18.04, NE ) | NE ( NE , NE ) |
| | 75th Pcnt. (95% CI) | NE* | NE (20.24, NE ) | NE ( NE , NE ) |
| 3 Months Event-Free | % (SE) | NE* | 95.7 ( 2.44) | 92.6 ( 3.56) |
| 6 Months Event-Free | % (SE) | NE* | 89.6 ( 3.72) | 86.9 ( 4.61) |
| 9 Months Event-Free | % (SE) | NE* | 86.5 ( 4.18) | 79.3 ( 5.57) |
| 12 Months Event-Free | % (SE) | NE* | 78.5 ( 5.11) | 77.3 ( 5.76) |
| 15 Months Event-Free | % (SE) | NE* | 71.7 ( 5.69) | 68.6 ( 6.98) |
| 18 Months Event-Free | % (SE) | NE* | 65.1 ( 6.35) | NE ( NE ) |
| 21 Months Event-Free | % (SE) | NE* | 41.5 ( 8.85) | NE ( NE ) |
| 24 Months Event-Free | % (SE) | NE* | NE ( NE ) | NE ( NE ) |

Note: CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

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Protocol: BB2121-MM-001

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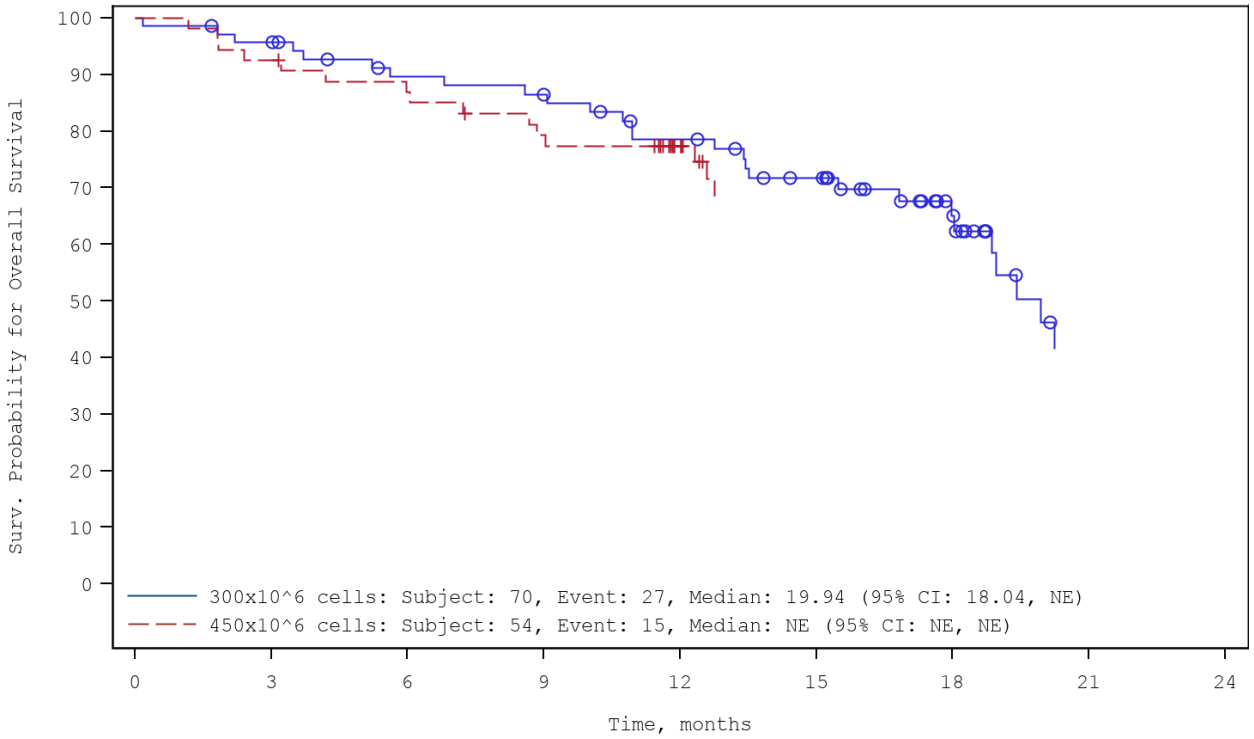
Cut-off date: 14JAN2020

Figure 1.1b
Kaplan-Meier Curve of Overall Survival by Ide-cel Target Dose Level
bb2121-Treated Population




No. of Subjects at Risk

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 150x10^6 cells: | Fewer than 10 subjects for this subgroup level | | | | | | | |
| 300x10^6 cells: 70 | 66 | 58 | 56 | 48 | 40 | 25 | 4 | 0 |
| 450x10^6 cells: 54 | 50 | 46 | 41 | 31 | 3 | 0 | 0 | 0 |

NE=Not Estimable. Missing categories are not presented. Source Table: Table 1.1b.
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# 1.3 Studie KarMMa – Datenschnitt vom 21.12.2020

## 1.3 Datenschnitt vom 21.12.2020

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Protocol: BB2121-MM-001

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Cut-off date: 21DEC2020

Table 1.1.1d
Summary of Overall Survival
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=124) |
|---|---|---|
| Overall Survival (OS) | N | 124 |
| Censored | n (%) | 63 ( 50.8%) |
| Died | n (%) | 61 ( 49.2%) |
| Overall Survival Time (months) [a] | 25th Percentile (95% CI) | 12.75 ( 9.03,17.08) |
| | Median (95% CI) | 24.80 (19.94,31.24) |
| | 75th Percentile (95% CI) | NE (31.24, NE ) |
| 3 Months Event-Free | % (SE) | 94.3 ( 2.08) |
| 6 Months Event-Free | % (SE) | 88.4 ( 2.91) |
| 9 Months Event-Free | % (SE) | 83.3 ( 3.41) |
| 12 Months Event-Free | % (SE) | 78.1 ( 3.81) |
| 15 Months Event-Free | % (SE) | 70.9 ( 4.22) |
| 18 Months Event-Free | % (SE) | 65.3 ( 4.47) |
| 21 Months Event-Free | % (SE) | 55.9 ( 4.71) |
| 24 Months Event-Free | % (SE) | 51.9 ( 4.78) |
| 27 Months Event-Free | % (SE) | 46.4 ( 5.01) |
| 30 Months Event-Free | % (SE) | 44.2 ( 5.23) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

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Analysis Plan: 12MAY2021 Confidential

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Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 1.1.1d
Summary of Overall Survival
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=124) |
|---|---|---|
| 33 Months Event-Free | % (SE) | NE ( NE ) |
| 36 Months Event-Free | % (SE) | NE ( NE ) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

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Date/time of run: 17JUN2021 10:37
Analysis Plan: 12MAY2021 Confidential

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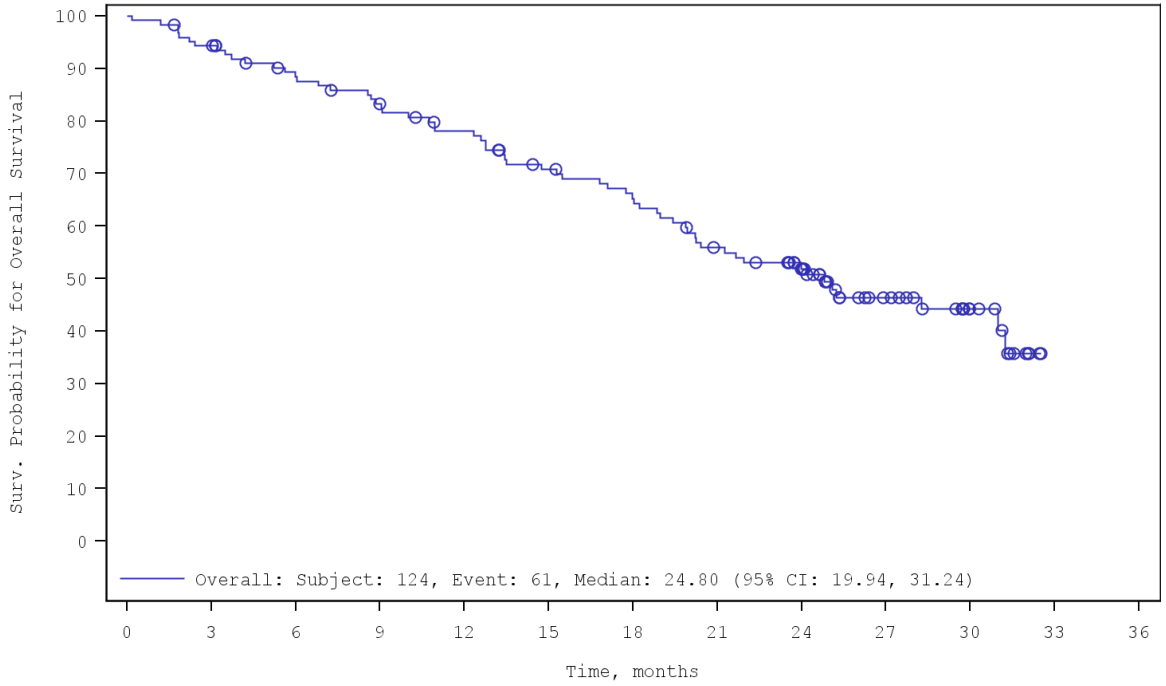
Protocol: BB2121-MM-001 Cut-off date: 21DEC2020

Figure 1.1.1d
Kaplan-Meier Curve of Overall Survival
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells




No. of Subjects at Risk

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Overall: | 124 | 116 | 104 | 97 | 88 | 77 | 70 | 58 | 47 | 25 | 13 | 0 | 0 |

Source Table: Table 1.1.1d.
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Date/time of run: 18JUN2021 13:31
Analysis Plan: 12MAY2021 Confidential

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Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 13.1d
Summary of Best Overall Response based on IMWG criteria - IRC Review, Overall and by Target Dose Level
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells

| | 300x10^6 cells (N=70) | 450x10^6 cells (N=54) | Total (N=124) |
|---|---|---|---|
| Best Overall Response - n (%) | | | |
| Stringent Complete Response (sCR) | 19 ( 27.1) | 21 ( 38.9) | 40 ( 32.3) |
| Complete Response (CR) | 1 ( 1.4) | 0 | 1 ( 0.8) |
| Very Good Partial Response (VGPR) | 11 ( 15.7) | 14 ( 25.9) | 25 ( 20.2) |
| Partial Response (PR) | 17 ( 24.3) | 9 ( 16.7) | 26 ( 21.0) |
| Minimal Response (MR) | 2 ( 2.9) | 0 | 2 ( 1.6) |
| Stable Disease (SD) | 14 ( 20.0) | 7 ( 13.0) | 21 ( 16.9) |
| Progressive Disease (PD) | 6 ( 8.6) | 2 ( 3.7) | 8 ( 6.5) |
| Not Evaluable or Not Done (NE) [a] | 0 | 1 ( 1.9) | 1 ( 0.8) |
| Overall Response Rate - n (%) [b] | 48 ( 68.6) | 44 ( 81.5) | 92 ( 74.2) |
| 95% CI [c] | 56.4, 79.1 | 68.6, 90.7 | 66.5, 81.9 |
| p-value [d] | - | - | <.0001 |

IMWG = International Myeloma Working Group; IRC = Independent Response Committee; CI = Confidence Interval.
[a] Including subjects who did not have any response assessment data, or whose only assessment was response not evaluable.
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR);
Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR).
The denominator used for rate calculation is the number of subjects in the designated study population.
[c] For 'Total': Wald CI; for individual target doses: Clopper-Pearson exact CI.
[d] One-sided p-value from one-sample binomial test (normal approximation).

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# 2. Ansprechen (Datenschnitt vom 21.12.2020)

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Protocol: BB2121-MM-001 Cut-off date: 21DEC2020

Table 13.1d
Summary of Best Overall Response based on IMWG criteria - IRC Review, Overall and by Target Dose Level
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells

| | 300x10^6 cells (N=70) | 450x10^6 cells (N=54) | Total (N=124) |
|---|---|---|---|
| Complete Response Rate - n (%) [b] | 20 ( 28.6) | 21 ( 38.9) | 41 ( 33.1) |
| 95% CI [c] | 18.4, 40.6 | 25.9, 53.1 | 24.8, 41.3 |
| p-value [d] | - | - | <.0001 |
| Response Rate of VGPR or better (sCR or CR or VGPR) - n (%) | 31 ( 44.3) | 35 ( 64.8) | 66 ( 53.2) |
| 95% CI [c] | 32.4, 56.7 | 50.6, 77.3 | 44.4, 62.0 |

IMWG = International Myeloma Working Group; IRC = Independent Response Committee; CI = Confidence Interval.
[a] Including subjects who did not have any response assessment data, or whose only assessment was response not evaluable.
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR);
Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR).
The denominator used for rate calculation is the number of subjects in the designated study population.
[c] For 'Total': Wald CI; for individual target doses: Clopper-Pearson exact CI.
[d] One-sided p-value from one-sample binomial test (normal approximation).

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Analysis Plan: 12MAY2021 Confidential

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Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 17.2.1d
Time to Response and Duration of Response for Subjects with Best Overall Response at Least Partial Response
Using IMWG Criteria - IRC Review
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, FDA Censoring Rules, Responders Only

| | Statistics | Total (N=92) |
|---|---|---|
| Time to Response (months) [a] | n | 92 |
| | Mean | 1.2 |
| | SD | 0.89 |
| | Median | 1.0 |
| | Min, Max | 0.5, 8.8 |

Note: CI=Confidence interval. NE=Not Estimable.
[a] Time to response and DOR analyses are based on responders only hence the results are the same for bb2121-Treated Population, Enrolled Population, and Efficacy Evaluable Population.
[b] For summary of time to response categories, 3 days window is added to each month for Month 1 to Month 8; and 14 days window is added to Month 9 and onwards.
[c] Only subjects with a response of sCR, CR, VGPR or PR are included in the analysis.
[d] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_17_1_1.SAS
Date/time of run: 14JUL2021 13:53
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 17.2.1d
Time to Response and Duration of Response for Subjects with Best Overall Response at Least Partial Response
Using IMWG Criteria - IRC Review
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, FDA Censoring Rules, Responders Only

| | Statistics | Total (N=92) |
|---|---|---|
| Time to Response (months) [a] [b] | | |
| <=1 | n (%) | 77 ( 83.7%) |
| 1 - <=2 | n (%) | 12 ( 13.0%) |
| 2 - <=3 | n (%) | 2 ( 2.2%) |
| 3 - <=4 | n (%) | 0 |
| 4 - <=5 | n (%) | 0 |
| 5 - <=6 | n (%) | 0 |
| 6 - <=7 | n (%) | 0 |
| 7 - <=8 | n (%) | 0 |
| 8 - <=9 | n (%) | 1 ( 1.1%) |
| 9 - <=10 | n (%) | 0 |
| 10 - <=11 | n (%) | 0 |
| 11 - <=12 | n (%) | 0 |
| 12 - <=13 | n (%) | 0 |
| 13 - <=14 | n (%) | 0 |
| 14 - <=15 | n (%) | 0 |
| 15 - <=16 | n (%) | 0 |

Note: CI=Confidence interval. NE=Not Estimable.
[a] Time to response and DOR analyses are based on responders only hence the results are the same for bb2121-Treated Population, Enrolled Population, and Efficacy Evaluable Population.
[b] For summary of time to response categories, 3 days window is added to each month for Month 1 to Month 8; and 14 days window is added to Month 9 and onwards.
[c] Only subjects with a response of sCR, CR, VGPR or PR are included in the analysis.
[d] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_17_1_1.SAS
Date/time of run: 14JUL2021 13:53
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 17.2.1d
Time to Response and Duration of Response for Subjects with Best Overall Response at Least Partial Response
Using IMWG Criteria - IRC Review
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, FDA Censoring Rules, Responders Only

| | Statistics | Total (N=92) |
|---|---|---|
| Duration of Response (DOR) [a] [c] | N | 92 |
| Censored | n (%) | 22 ( 23.9%) |
| Progressed/Died | n (%) | 70 ( 76.1%) |
| Progressed | n (%) | 67 ( 72.8%) |
| Died | n (%) | 3 ( 3.3%) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] Time to response and DOR analyses are based on responders only hence the results are the same for bb2121-Treated Population, Enrolled Population, and Efficacy Evaluable Population.
[b] For summary of time to response categories, 3 days window is added to each month for Month 1 to Month 8; and 14 days window is added to Month 9 and onwards.
[c] Only subjects with a response of sCR, CR, VGPR or PR are included in the analysis.
[d] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_17_1_1.SAS
Date/time of run: 14JUL2021 13:53
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 17.2.1d
Time to Response and Duration of Response for Subjects with Best Overall Response at Least Partial Response
Using IMWG Criteria - IRC Review
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, FDA Censoring Rules, Responders Only

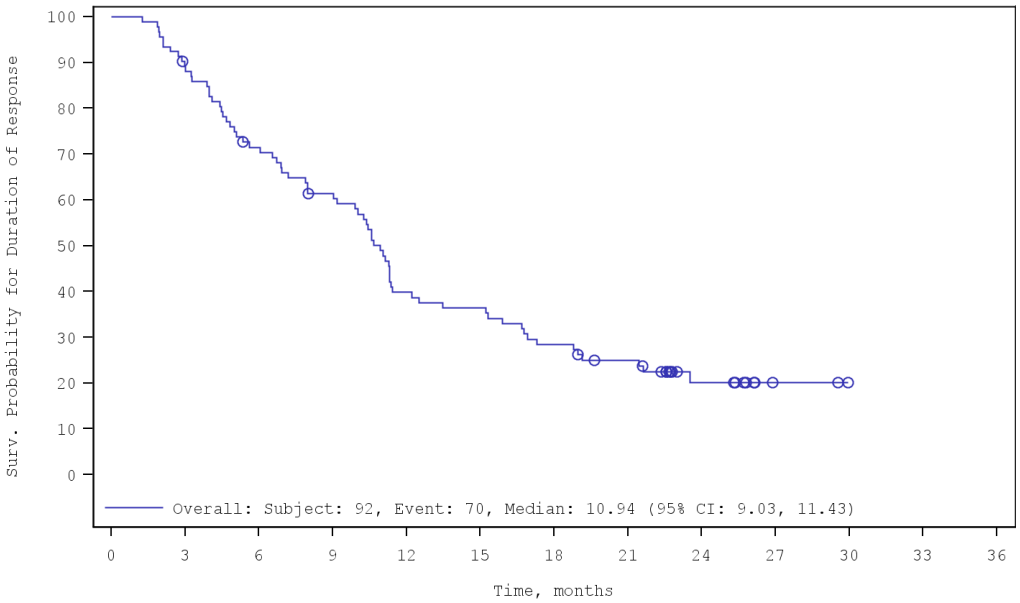
| | Statistics | Total (N=92) |
|---|---|---|
| Duration of Response (months) [a] [c] [d] | 25th Percentile (95% CI) | 4.99 ( 3.98, 6.93) |
| | Median (95% CI) | 10.94 ( 9.03,11.43) |
| | 75th Percentile (95% CI) | 19.15 (15.31, NE ) |
| 3 Months Event-Free | % (SE) | 89.1 ( 3.25) |
| 6 Months Event-Free | % (SE) | 71.5 ( 4.73) |
| 9 Months Event-Free | % (SE) | 61.4 ( 5.12) |
| 12 Months Event-Free | % (SE) | 39.8 ( 5.19) |
| 15 Months Event-Free | % (SE) | 36.4 ( 5.11) |
| 18 Months Event-Free | % (SE) | 28.4 ( 4.79) |
| 21 Months Event-Free | % (SE) | 25.0 ( 4.61) |
| 24 Months Event-Free | % (SE) | 20.2 ( 4.56) |
| 27 Months Event-Free | % (SE) | 20.2 ( 4.56) |
| 30 Months Event-Free | % (SE) | NE ( NE ) |
| 33 Months Event-Free | % (SE) | NE ( NE ) |
| 36 Months Event-Free | % (SE) | NE ( NE ) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] Time to response and DOR analyses are based on responders only hence the results are the same for bb2121-Treated Population, Enrolled Population, and Efficacy Evaluable Population.
[b] For summary of time to response categories, 3 days window is added to each month for Month 1 to Month 8; and 14 days window is added to Month 9 and onwards.
[c] Only subjects with a response of sCR, CR, VGPR or PR are included in the analysis.
[d] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_17_1_1.SAS
Date/time of run: 14JUL2021 13:53
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Figure 11.2.1d
Kaplan-Meier Curve of Duration of Response for Subjects with Best Overall Response at Least Partial Response
Using IMWG Criteria - IRC Review
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, FDA Censoring Rules, Responders Only




No. of Subjects at Risk

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Overall: | 92 | 81 | 64 | 54 | 35 | 32 | 25 | 20 | 9 | 2 | 0 | 0 | 0 |

Source Table: Table 17.2.1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_11_1_1.SAS
Date/time of run: 16JUL2021 12:14
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 17.1.1d
Time to Complete Response and Duration of Response for Subjects with Best Overall Response at Least Complete Response
Using IMWG Criteria - IRC Review
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, FDA Censoring Rules, Responders Only

| | Statistics | Total (N=41) |
|---|---|---|
| Time to Complete Response or Better (months) [a] | n | 41 |
| | Mean | 3.7 |
| | SD | 3.65 |
| | Median | 2.9 |
| | Min, Max | 1.0, 15.8 |

Note: CI=Confidence interval. NE=Not Estimable.
[a] Time to response and DOR analyses are based on responders only hence the results are the same for bb2121-Treated Population, Enrolled Population, and Efficacy Evaluable Population.
[b] For summary of time to response categories, 3 days window is added to each month for Month 1 to Month 8; and 14 days window is added to Month 9 and onwards.
[c] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_17_1_1.SAS
Date/time of run: 14JUL2021 13:53
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 17.1.1d
Time to Complete Response and Duration of Response for Subjects with Best Overall Response at Least Complete Response
Using IMWG Criteria - IRC Review
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, FDA Censoring Rules, Responders Only

| | Statistics | Total (N=41) |
|---|---|---|
| Time to Complete Response or Better (months) [a] [b] | | |
| <=1 | n (%) | 13 ( 31.7%) |
| 1 - <=2 | n (%) | 6 ( 14.6%) |
| 2 - <=3 | n (%) | 8 ( 19.5%) |
| 3 - <=4 | n (%) | 6 ( 14.6%) |
| 4 - <=5 | n (%) | 0 |
| 5 - <=6 | n (%) | 1 ( 2.4%) |
| 6 - <=7 | n (%) | 0 |
| 7 - <=8 | n (%) | 1 ( 2.4%) |
| 8 - <=9 | n (%) | 2 ( 4.9%) |
| 9 - <=10 | n (%) | 0 |
| 10 - <=11 | n (%) | 0 |
| 11 - <=12 | n (%) | 3 ( 7.3%) |
| 12 - <=13 | n (%) | 0 |
| 13 - <=14 | n (%) | 0 |
| 14 - <=15 | n (%) | 0 |
| 15 - <=16 | n (%) | 1 ( 2.4%) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] Time to response and DOR analyses are based on responders only hence the results are the same for bb2121-Treated Population, Enrolled Population, and Efficacy Evaluable Population.
[b] For summary of time to response categories, 3 days window is added to each month for Month 1 to Month 8; and 14 days window is added to Month 9 and onwards.
[c] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_17_1_1.SAS
Date/time of run: 14JUL2021 13:53
Analysis Plan: 12MAY2021 Confidential

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Protocol: BB2121-MM-001 Cut-off date: 21DEC2020

Table 17.1.1d
Time to Complete Response and Duration of Response for Subjects with Best Overall Response at Least Complete Response
Using IMWG Criteria - IRC Review
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, FDA Censoring Rules, Responders Only

| | Statistics | Total (N=41) |
|---|---|---|
| Duration of Response (DOR) [a] | N | 41 |
| Censored | n (%) | 19 ( 46.3%) |
| Progressed/Died | n (%) | 22 ( 53.7%) |
| Progressed | n (%) | 20 ( 48.8%) |
| Died | n (%) | 2 ( 4.9%) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] Time to response and DOR analyses are based on responders only hence the results are the same for bb2121-Treated Population, Enrolled Population, and Efficacy Evaluable Population.
[b] For summary of time to response categories, 3 days window is added to each month for Month 1 to Month 8; and 14 days window is added to Month 9 and onwards.
[c] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_17_1_1.SAS
Date/time of run: 14JUL2021 13:53
Analysis Plan: 12MAY2021 Confidential

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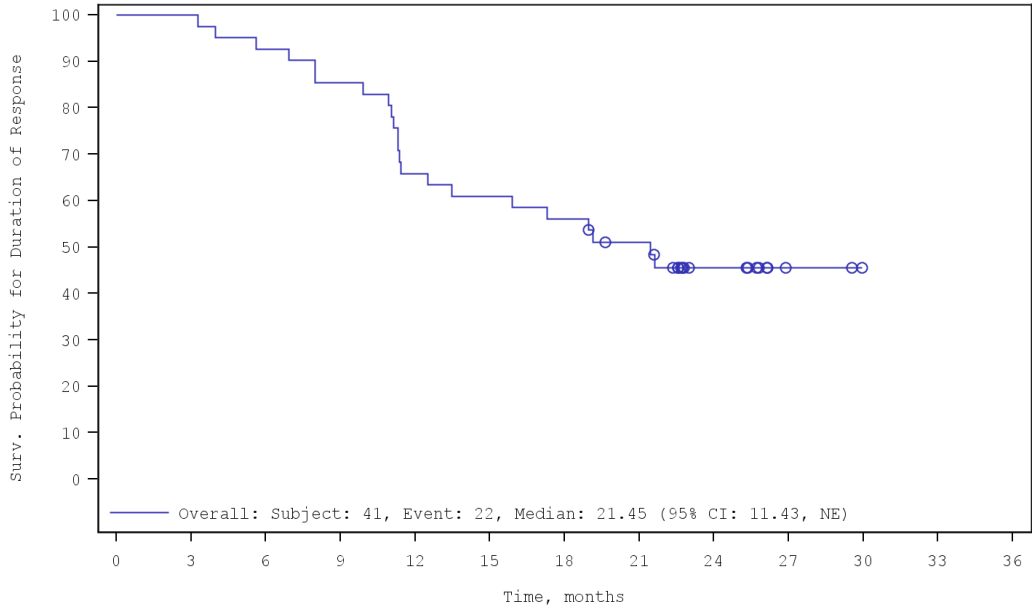
Table 17.1.1d
Time to Complete Response and Duration of Response for Subjects with Best Overall Response at Least Complete Response
Using IMWG Criteria - IRC Review
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, FDA Censoring Rules, Responders Only

| | Statistics | Total (N=41) |
|---|---|---|
| Duration of Response (months) [a] [c] | 25th Percentile (95% CI) | 11.30 ( 7.98,13.47) |
| | Median (95% CI) | 21.45 (11.43, NE ) |
| | 75th Percentile (95% CI) | NE ( NE , NE ) |
| 3 Months Event-Free | % (SE) | 100.0 ( 0.00) |
| 6 Months Event-Free | % (SE) | 92.7 ( 4.07) |
| 9 Months Event-Free | % (SE) | 85.4 ( 5.52) |
| 12 Months Event-Free | % (SE) | 65.9 ( 7.41) |
| 15 Months Event-Free | % (SE) | 61.0 ( 7.62) |
| 18 Months Event-Free | % (SE) | 56.1 ( 7.75) |
| 21 Months Event-Free | % (SE) | 51.1 ( 7.82) |
| 24 Months Event-Free | % (SE) | 45.6 ( 7.90) |
| 27 Months Event-Free | % (SE) | 45.6 ( 7.90) |
| 30 Months Event-Free | % (SE) | NE ( NE ) |
| 33 Months Event-Free | % (SE) | NE ( NE ) |
| 36 Months Event-Free | % (SE) | NE ( NE ) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] Time to response and DOR analyses are based on responders only hence the results are the same for bb2121-Treated Population, Enrolled Population, and Efficacy Evaluable Population.
[b] For summary of time to response categories, 3 days window is added to each month for Month 1 to Month 8; and 14 days window is added to Month 9 and onwards.
[c] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_17_1_1.SAS
Date/time of run: 14JUL2021 13:53
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001 Cut-off date: 21DEC2020

Figure 11.1.1d
Kaplan-Meier Curve of Duration of Response for Subjects with Best Overall Response at Least Complete Response
Using IMWG Criteria - IRC Review
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, FDA Censoring Rules, Responders Only




No. of Subjects at Risk

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Overall: | 41 | 41 | 38 | 35 | 27 | 25 | 23 | 19 | 9 | 2 | 0 | 0 | 0 |

NE=Not Estimable. Source Table: Table 17.1.1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_11_1_1.SAS
Date/time of run: 16JUL2021 12:14
Analysis Plan: 12MAY2021 Confidential

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Protocol: BB2121-MM-001 Cut-off date: 21DEC2020

Table 18.1d
Proportion of Subjects Who Achieved >= CR and MRD Negative Status at Any Time Point from within 3 Months prior to Achieving CR or above to until Time of Progression/Death (Exclusive)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Method= Next Generation Sequencing

| | 10^(-4) Sensitivity N=124 | 10^(-5) Sensitivity N=124 | 10^(-6) Sensitivity N=124 |
|---|---|---|---|
| MRD Negativity Rate - n (%) [a] | 31 ( 25.0) | 31 ( 25.0) | 20 ( 16.1) |
| 95% CI [b] | ( 17.7 , 33.6) | ( 17.7 , 33.6) | ( 10.1 , 23.8) |
| p-value [c] | <0.0001 | <0.0001 | 0.0219 |

[a] The negative MRD value post bb2121 infusion is considered. MRD negativity is determined by at least one negative MRD value from within 3 months prior to achieving CR or above to until time of progression/death (exclusive). bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells is used as a denominator.
The primary analysis for MRD negative response uses the sensitivity of 10^(-5).
[b] Clopper-Pearson exact confidence interval (CI).
[c] One-sided p-value from one-sample exact binomial test against a null hypothesis of 10% negative MRD.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_18_1.SAS
Date/time of run: 14JUL2021 11:21
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 18.3d
Proportion of Subjects Who Achieved >= CR and MRD Negative Status by Visit and Target Dose Level - Sensitivity Level at 10^-6
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Method= Next Generation Sequencing

| Visit | | 300x10^6 N=70 | 450x10^6 N=54 | Total N=124 |
|---|---|---|---|---|
| Overall | MRD Negativity Rate - n (%) [a] | 10 ( 14.3) | 10 ( 18.5) | 20 ( 16.1) |
| | 95% CI [b] | ( 7.1 , 24.7) | ( 9.3 , 31.4) | ( 10.1 , 23.8) |
| Month 1 | MRD Negativity Rate - n (%) [a] | 4 ( 5.7) | 4 ( 7.4) | 8 ( 6.5) |
| | 95% CI [b] | ( 1.6 , 14.0) | ( 2.1 , 17.9) | ( 2.8 , 12.3) |
| Month 3 | MRD Negativity Rate - n (%) [a] | 4 ( 5.7) | 5 ( 9.3) | 9 ( 7.3) |
| | 95% CI [b] | ( 1.6 , 14.0) | ( 3.1 , 20.3) | ( 3.4 , 13.3) |
| Month 6 | MRD Negativity Rate - n (%) [a] | 4 ( 5.7) | 5 ( 9.3) | 9 ( 7.3) |
| | 95% CI [b] | ( 1.6 , 14.0) | ( 3.1 , 20.3) | ( 3.4 , 13.3) |
| Month 12 | MRD Negativity Rate - n (%) [a] | 4 ( 5.7) | 3 ( 5.6) | 7 ( 5.6) |
| | 95% CI [b] | ( 1.6 , 14.0) | ( 1.2 , 15.4) | ( 2.3 , 11.3) |
| Month 18 | MRD Negativity Rate - n (%) [a] | 3 ( 4.3) | 3 ( 5.6) | 6 ( 4.8) |
| | 95% CI [b] | ( 0.9 , 12.0) | ( 1.2 , 15.4) | ( 1.8 , 10.2) |

[a] The negative MRD value post bb2121 infusion is considered. Only negative MRD value within 3 months prior to achieving CR or above until time of progression/death (exclusive) is considered. bb2121-Treated population is used as a denominator.
[b] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_18_2.SAS
Date/time of run: 16JUL2021 12:02
Analysis Plan: 12MAY2021 Confidential

# 3. Progressionsfreies Überleben (Datenschnitt vom 21.12.2020)

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 2.2.1d
Summary of Progression-free Survival Based on IMWG Criteria - IRC Review
Censoring Rules According to FDA
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=136) |
|---|---|---|
| Progression-free Survival (PFS) | N | 136 |
| Censored | n (%) | 33 ( 24.3%) |
| Progressed/Died | n (%) | 103 ( 75.7%) |
| Progressed | n (%) | 94 ( 69.1%) |
| Died | n (%) | 9 ( 6.6%) |
| Progression-free Survival Time (months) [a] | 25th Percentile (95% CI) | 4.27 ( 3.22, 5.49) |
| | Median (95% CI) | 9.95 ( 6.93,12.68) |
| | 75th Percentile (95% CI) | 18.07 (13.67,23.69) |
| 3 Months Event-Free | % (SE) | 88.9 ( 2.79) |
| 6 Months Event-Free | % (SE) | 65.7 ( 4.24) |
| 9 Months Event-Free | % (SE) | 53.6 ( 4.47) |
| 12 Months Event-Free | % (SE) | 43.6 ( 4.47) |
| 15 Months Event-Free | % (SE) | 28.5 ( 4.10) |
| 18 Months Event-Free | % (SE) | 26.0 ( 3.99) |
| 21 Months Event-Free | % (SE) | 21.0 ( 3.71) |
| 24 Months Event-Free | % (SE) | 16.5 ( 3.41) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_1_1_1.SAS
Date/time of run: 17JUN2021 10:37
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 2.2.1d
Summary of Progression-free Survival Based on IMWG Criteria - IRC Review
Censoring Rules According to FDA
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=136) |
|---|---|---|
| 27 Months Event-Free | % (SE) | 14.9 ( 3.45) |
| 30 Months Event-Free | % (SE) | 14.9 ( 3.45) |
| 33 Months Event-Free | % (SE) | NE ( NE ) |
| 36 Months Event-Free | % (SE) | NE ( NE ) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_1_1_1.SAS
Date/time of run: 17JUN2021 10:37
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001

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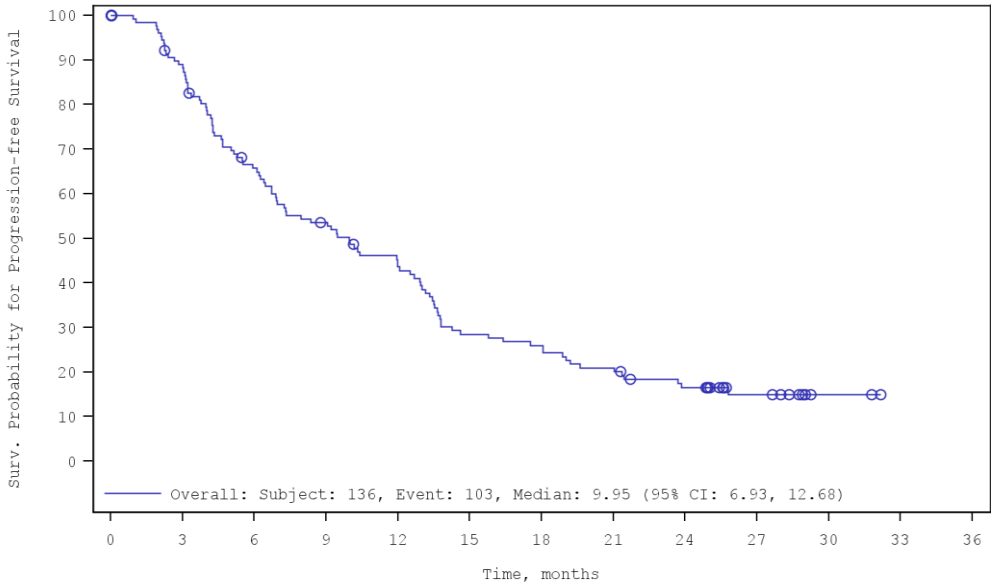
Cut-off date: 21DEC2020

Figure 2.2.1d
Kaplan-Meier Curve of Progression-free Survival Based on IMWG Criteria - IRC Review
Censoring Rules According to FDA
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells




No. of Subjects at Risk

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Overall: | 136 | 112 | 81 | 65 | 52 | 34 | 31 | 25 | 18 | 9 | 2 | 0 | 0 |

Source Table: Table 2.2.1d.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_1_1_1.SAS
Date/time of run: 18JUN2021 13:31
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 3.2.1d
Summary of Progression-free Survival Based on IMWG Criteria - IRC Review
Censoring Rules According to EMA Guideline
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=136) |
|---|---|---|
| Progression-free Survival (PFS) | N | 136 |
| Censored | n (%) | 25 ( 18.4%) |
| Progressed/Died | n (%) | 111 ( 81.6%) |
| Progressed | n (%) | 96 ( 70.6%) |
| Died | n (%) | 15 ( 11.0%) |
| Progression-free Survival Time (months) [a] | 25th Percentile (95% CI) | 4.24 ( 3.22, 5.29) |
| | Median (95% CI) | 9.07 ( 6.74,11.99) |
| | 75th Percentile (95% CI) | 16.39 (13.50,21.36) |
| 3 Months Event-Free | % (SE) | 87.1 ( 2.92) |
| 6 Months Event-Free | % (SE) | 64.2 ( 4.19) |
| 9 Months Event-Free | % (SE) | 50.4 ( 4.37) |
| 12 Months Event-Free | % (SE) | 40.4 ( 4.29) |
| 15 Months Event-Free | % (SE) | 26.4 ( 3.87) |
| 18 Months Event-Free | % (SE) | 24.1 ( 3.76) |
| 21 Months Event-Free | % (SE) | 19.4 ( 3.48) |
| 24 Months Event-Free | % (SE) | 15.3 ( 3.19) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_1_1_1.SAS
Date/time of run: 17JUN2021 10:37
Analysis Plan: 12MAY2021 Confidential

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Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 3.2.1d
Summary of Progression-free Survival Based on IMWG Criteria - IRC Review
Censoring Rules According to EMA Guideline
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=136) |
|---|---|---|
| 27 Months Event-Free | % (SE) | 13.8 ( 3.22) |
| 30 Months Event-Free | % (SE) | 13.8 ( 3.22) |
| 33 Months Event-Free | % (SE) | NE ( NE ) |
| 36 Months Event-Free | % (SE) | NE ( NE ) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_1_1_1.SAS
Date/time of run: 17JUN2021 10:37
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001

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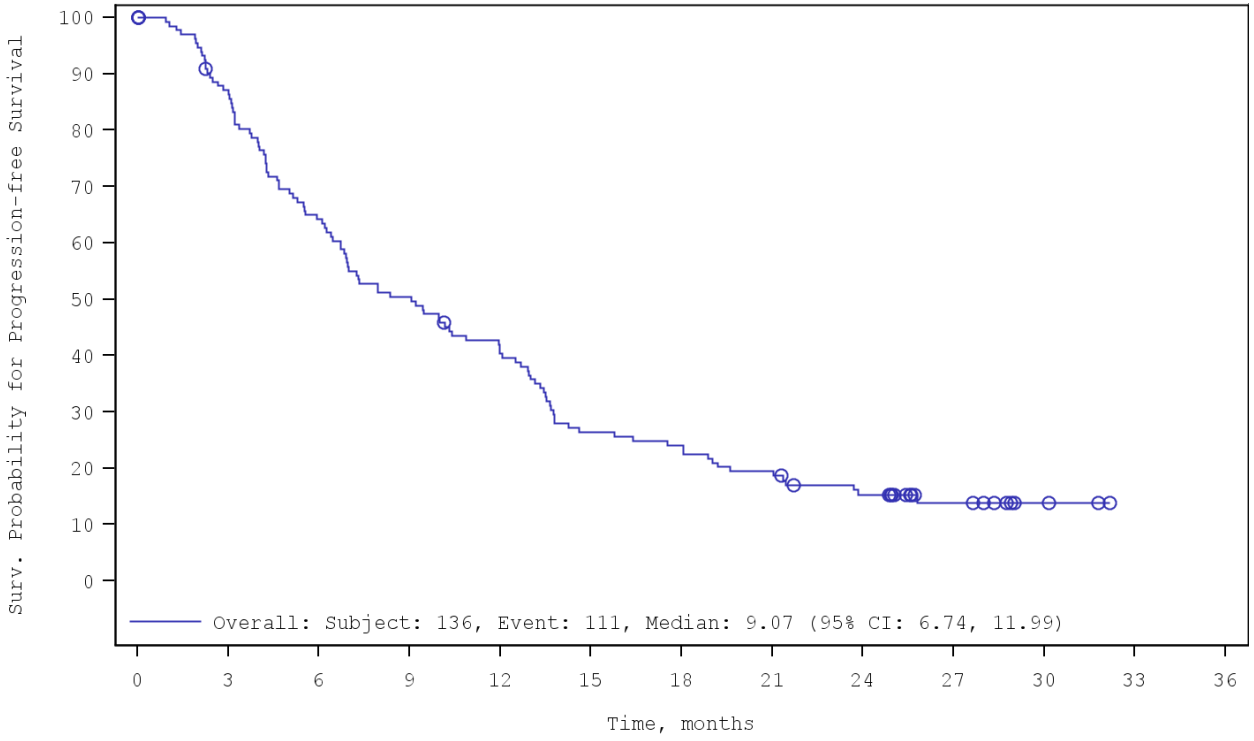
Cut-off date: 21DEC2020

Figure 3.2.1d
Kaplan-Meier Curve of Progression-free Survival Based on IMWG Criteria - IRC Review
Censoring Rules According to EMA Guideline
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells




No. of Subjects at Risk

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Overall: | 136 | 114 | 84 | 66 | 52 | 34 | 31 | 25 | 18 | 9 | 3 | 0 | 0 |

Source Table: Table 3.2.1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_1_1_1.SAS
Date/time of run: 18JUN2021 13:31
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 14.1.1d
Summary of Time to Progression Based on IMWG Criteria - IRC Review
Censoring Rules According to FDA Guideline
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=124) |
|---|---|---|
| Time to Progression (TTP) | N | 124 |
| Censored | n (%) | 30 ( 24.2) |
| Progressed | n (%) | 94 ( 75.8) |
| Time to Progression (months) [a] | 25th Percentile (95% CI) | 3.15 ( 2.86, 4.90) |
| | Median (95% CI) | 8.90 ( 6.08,11.86) |
| | 75th Percentile (95% CI) | 17.61 (12.35, NE ) |
| 3 Months Event-Free | % (SE) | 77.5 ( 3.81) |
| 6 Months Event-Free | % (SE) | 60.4 ( 4.50) |
| 9 Months Event-Free | % (SE) | 49.0 ( 4.63) |
| 12 Months Event-Free | % (SE) | 40.1 ( 4.56) |
| 15 Months Event-Free | % (SE) | 28.5 ( 4.23) |
| 18 Months Event-Free | % (SE) | 23.0 ( 3.97) |
| 21 Months Event-Free | % (SE) | 21.0 ( 3.86) |
| 24 Months Event-Free | % (SE) | 18.9 ( 3.75) |
| 27 Months Event-Free | % (SE) | 17.0 ( 3.83) |
| 30 Months Event-Free | % (SE) | 17.0 ( 3.83) |
| 33 Months Event-Free | % (SE) | NE ( NE ) |
| 36 Months Event-Free | % (SE) | NE ( NE ) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_14_1_1.SAS
Date/time of run: 14JUL2021 12:12
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001

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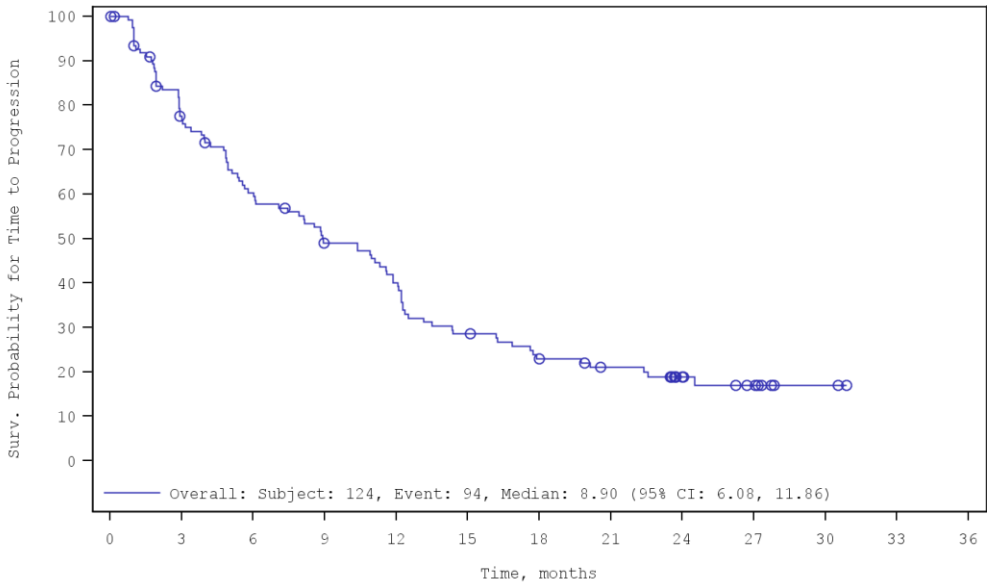
Cut-off date: 21DEC2020

Figure 8.1.1d
Kaplan-Meier Curve of Time to Progression Based on IMWG Criteria - IRC Review
Censoring Rules According to FDA Guideline
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells




No. of Subjects at Risk

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Overall: | 124 | 91 | 70 | 55 | 45 | 32 | 25 | 20 | 11 | 7 | 2 | 0 | 0 |

Source Table: Table 14.1.1d.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_8_1_1.SAS
Date/time of run: 14JUL2021 12:28
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Cut-off date: 21DEC2020

Table 3.1.1d
Summary of Progression-free Survival Based on IMWG Criteria - IRC Review
Censoring Rules According to EMA Guideline
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=124) |
|---|---|---|
| Progression-free Survival (PFS) | N | 124 |
| Censored | n (%) | 21 ( 16.9%) |
| Progressed/Died | n (%) | 103 ( 83.1%) |
| Progressed | n (%) | 96 ( 77.4%) |
| Died | n (%) | 7 ( 5.6%) |
| Progression-free Survival Time (months) [a] | 25th Percentile (95% CI) | 3.02 ( 1.94, 4.76) |
| | Median (95% CI) | 8.57 ( 5.65,11.10) |
| | 75th Percentile (95% CI) | 16.26 (12.22,22.37) |
| 3 Months Event-Free | % (SE) | 75.7 ( 3.87) |
| 6 Months Event-Free | % (SE) | 57.8 ( 4.45) |
| 9 Months Event-Free | % (SE) | 46.4 ( 4.50) |
| 12 Months Event-Free | % (SE) | 37.3 ( 4.37) |
| 15 Months Event-Free | % (SE) | 26.5 ( 4.00) |
| 18 Months Event-Free | % (SE) | 21.5 ( 3.73) |
| 21 Months Event-Free | % (SE) | 18.1 ( 3.51) |
| 24 Months Event-Free | % (SE) | 16.3 ( 3.38) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_1_1_1.SAS
Date/time of run: 17JUN2021 10:37
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 3.1.1d
Summary of Progression-free Survival Based on IMWG Criteria - IRC Review
Censoring Rules According to EMA Guideline
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Total (N=124) |
|---|---|---|
| 27 Months Event-Free | % (SE) | 14.7 ( 3.42) |
| 30 Months Event-Free | % (SE) | 14.7 ( 3.42) |
| 33 Months Event-Free | % (SE) | NE ( NE ) |
| 36 Months Event-Free | % (SE) | NE ( NE ) |

Note: CI=Confidence interval. NE=Not Estimable.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_1_1_1.SAS
Date/time of run: 17JUN2021 10:37
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001

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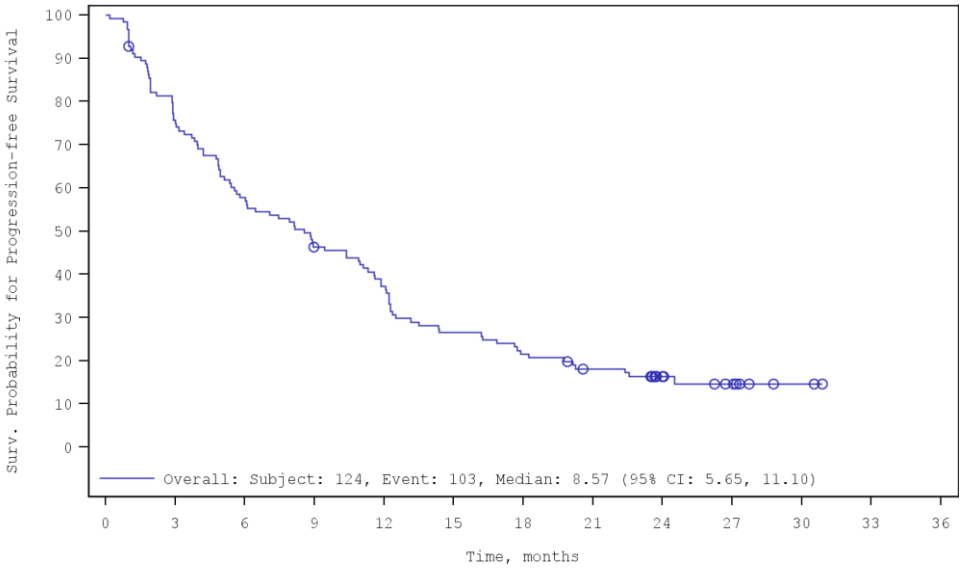
Cut-off date: 21DEC2020

Figure 3.1.1d
Kaplan-Meier Curve of Progression-free Survival Based on IMWG Criteria - IRC Review
Censoring Rules According to EMA Guideline
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells




No. of Subjects at Risk

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Overall: | 124 | 93 | 71 | 56 | 45 | 32 | 26 | 20 | 11 | 7 | 2 | 0 | 0 |

Source Table: Table 3.1.1d.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_1_1_1.SAS
Date/time of run: 18JUN2021 13:31
Analysis Plan: 12MAY2021 Confidential

# 4. Symptomatik

## 4.1 Symptomatik gemessen anhand der Symptomskalen des EORTC QLQ-C30 (Datenschnitt vom 21.12.2020)

- Exploratory Responder Definition MCID = 15
- Responder definition MCID = 30
- Exploratory Responder Definition MCID = 10 (with baseline defined as the screening visit)
- Exploratory Responder Definition MCID = 15 (with baseline defined as the screening visit)
- Responder definition MCID = 30 (with baseline defined as the screening visit)
- Scores by timepoint
- Change of scores from baseline (with baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy)
- Change of scores from baseline (with baseline as the screening visit)

*Anmerkung:* Ergebnisse zu den Symptomskalen Schmerz und Fatigue sind in Abschnitt 6.1 dargestellt.

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Cut-off date: 21DEC2020

Table 4.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 7 ( 6.4) | 23 ( 20.9) | 22 ( 20.0) | 7 ( 6.4) | 9 ( 8.2) | 16 ( 14.5) |
| | No Change - n(%) | 40 ( 36.4) | 78 ( 70.9) | 72 ( 65.5) | 47 ( 42.7) | 60 ( 54.5) | 76 ( 69.1) |
| | Deterioration - n(%) | 63 ( 57.3) | 9 ( 8.2) | 16 ( 14.5) | 56 ( 50.9) | 41 ( 37.3) | 18 ( 16.4) |
| | Missing | 12 | 12 | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 26 ( 24.3) | 27 ( 25.2) | 34 ( 31.8) | 22 ( 20.6) | 18 ( 16.8) | 19 ( 17.8) |
| | No Change - n(%) | 63 ( 58.9) | 58 ( 54.2) | 56 ( 52.3) | 50 ( 46.7) | 75 ( 70.1) | 71 ( 66.4) |
| | Deterioration - n(%) | 18 ( 16.8) | 22 ( 20.6) | 17 ( 15.9) | 35 ( 32.7) | 14 ( 13.1) | 17 ( 15.9) |
| | Missing | 15 | 15 | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 23 ( 23.7) | 26 ( 26.8) | 30 ( 30.9) | 22 ( 22.7) | 17 ( 17.5) | 16 ( 16.5) |
| | No Change - n(%) | 63 ( 64.9) | 47 ( 48.5) | 50 ( 51.5) | 55 ( 56.7) | 71 ( 73.2) | 59 ( 60.8) |
| | Deterioration - n(%) | 11 ( 11.3) | 24 ( 24.7) | 17 ( 17.5) | 20 ( 20.6) | 9 ( 9.3) | 22 ( 22.7) |
| | Missing | 25 | 25 | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 20 ( 23.8) | 22 ( 26.2) | 30 ( 35.7) | 18 ( 21.4) | 22 ( 26.2) | 16 ( 19.0) |
| | No Change - n(%) | 54 ( 64.3) | 54 ( 64.3) | 39 ( 46.4) | 49 ( 58.3) | 56 ( 66.7) | 52 ( 61.9) |
| | Deterioration - n(%) | 10 ( 11.9) | 8 ( 9.5) | 15 ( 17.9) | 17 ( 20.2) | 6 ( 7.1) | 16 ( 19.0) |
| | Missing | 38 | 38 | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 22 ( 28.2) | 20 ( 25.6) | 27 ( 34.6) | 18 ( 23.1) | 17 ( 21.8) | 16 ( 20.5) |
| | No Change - n(%) | 43 ( 55.1) | 47 ( 60.3) | 40 ( 51.3) | 49 ( 62.8) | 57 ( 73.1) | 50 ( 64.1) |
| | Deterioration - n(%) | 13 ( 16.7) | 11 ( 14.1) | 11 ( 14.1) | 11 ( 14.1) | 4 ( 5.1) | 12 ( 15.4) |
| | Missing | 44 | 44 | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 22 ( 28.9) | 27 ( 35.5) | 26 ( 34.2) | 22 ( 28.9) | 16 ( 21.1) | 18 ( 23.7) |
| | No Change - n(%) | 48 ( 63.2) | 41 ( 53.9) | 45 ( 59.2) | 45 ( 59.2) | 56 ( 73.7) | 45 ( 59.2) |
| | Deterioration - n(%) | 6 ( 7.9) | 8 ( 10.5) | 5 ( 6.6) | 9 ( 11.8) | 4 ( 5.3) | 13 ( 17.1) |
| | Missing | 46 | 46 | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 20 ( 26.7) | 23 ( 30.7) | 28 ( 37.3) | 22 ( 29.3) | 17 ( 22.7) | 18 ( 24.0) |
| | No Change - n(%) | 47 ( 62.7) | 43 ( 57.3) | 41 ( 54.7) | 41 ( 54.7) | 54 ( 72.0) | 45 ( 60.0) |
| | Deterioration - n(%) | 8 ( 10.7) | 9 ( 12.0) | 6 ( 8.0) | 12 ( 16.0) | 4 ( 5.3) | 12 ( 16.0) |
| | Missing | 47 | 47 | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 15 ( 25.9) | 17 ( 29.3) | 24 ( 41.4) | 18 ( 31.0) | 11 ( 19.0) | 13 ( 22.4) |
| | No Change - n(%) | 37 ( 63.8) | 36 ( 62.1) | 28 ( 48.3) | 34 ( 58.6) | 44 ( 75.9) | 44 ( 75.9) |
| | Deterioration - n(%) | 6 ( 10.3) | 5 ( 8.6) | 6 ( 10.3) | 6 ( 10.3) | 3 ( 5.2) | 1 ( 1.7) |
| | Missing | 64 | 64 | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 15 ( 27.8) | 17 ( 31.5) | 20 ( 37.0) | 17 ( 31.5) | 13 ( 24.1) | 16 ( 29.6) |
| | No Change - n(%) | 32 ( 59.3) | 34 ( 63.0) | 27 ( 50.0) | 32 ( 59.3) | 40 ( 74.1) | 33 ( 61.1) |
| | Deterioration - n(%) | 7 ( 13.0) | 3 ( 5.6) | 7 ( 13.0) | 5 ( 9.3) | 1 ( 1.9) | 5 ( 9.3) |
| | Missing | 68 | 68 | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 6 ( 19.4) | 11 ( 35.5) | 13 ( 41.9) | 8 ( 25.8) | 7 ( 22.6) | 10 ( 32.3) |
| | No Change - n(%) | 22 ( 71.0) | 16 ( 51.6) | 13 ( 41.9) | 18 ( 58.1) | 22 ( 71.0) | 20 ( 64.5) |
| | Deterioration - n(%) | 3 ( 9.7) | 4 ( 12.9) | 5 ( 16.1) | 5 ( 16.1) | 2 ( 6.5) | 1 ( 3.2) |
| | Missing | 91 | 91 | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 6 ( 24.0) | 10 ( 40.0) | 11 ( 44.0) | 9 ( 36.0) | 6 ( 24.0) | 6 ( 24.0) |
| | No Change - n(%) | 13 ( 52.0) | 14 ( 56.0) | 8 ( 32.0) | 10 ( 40.0) | 16 ( 64.0) | 15 ( 60.0) |
| | Deterioration - n(%) | 6 ( 24.0) | 1 ( 4.0) | 6 ( 24.0) | 6 ( 24.0) | 3 ( 12.0) | 4 ( 16.0) |
| | Missing | 97 | 97 | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 5 ( 19.2) | 9 ( 34.6) | 12 ( 46.2) | 7 ( 26.9) | 8 ( 30.8) | 5 ( 19.2) |
| | No Change - n(%) | 15 ( 57.7) | 13 ( 50.0) | 10 ( 38.5) | 16 ( 61.5) | 17 ( 65.4) | 17 ( 65.4) |
| | Deterioration - n(%) | 6 ( 23.1) | 4 ( 15.4) | 4 ( 15.4) | 3 ( 11.5) | 1 ( 3.8) | 4 ( 15.4) |
| | Missing | 96 | 96 | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 4.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 2 ( 15.4) | 2 ( 15.4) | 4 ( 30.8) | 3 ( 23.1) | 2 ( 15.4) | 6 ( 46.2) |
| | No Change - n(%) | 8 ( 61.5) | 11 ( 84.6) | 6 ( 46.2) | 8 ( 61.5) | 10 ( 76.9) | 5 ( 38.5) |
| | Deterioration - n(%) | 3 ( 23.1) | 0 | 3 ( 23.1) | 2 ( 15.4) | 1 ( 7.7) | 2 ( 15.4) |
| | Missing | 109 | 109 | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 0 | 0 | 0 | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 1 (100.0) | 0 | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 | 1 (100.0) | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| PD | n | 29 | 29 | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 7 ( 24.1) | 9 ( 31.0) | 8 ( 27.6) | 7 ( 24.1) | 6 ( 20.7) | 8 ( 27.6) |
| | No Change - n(%) | 13 ( 44.8) | 13 ( 44.8) | 17 ( 58.6) | 13 ( 44.8) | 18 ( 62.1) | 17 ( 58.6) |
| | Deterioration - n(%) | 9 ( 31.0) | 7 ( 24.1) | 4 ( 13.8) | 9 ( 31.0) | 5 ( 17.2) | 4 ( 13.8) |
| | Missing | 93 | 93 | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 0 | 1 (100.0) | 0 | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 1 (100.0) | 0 | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

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Table 4.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| End of Study | n | 9 | 9 | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 2 ( 22.2) | 1 ( 11.1) | 3 ( 33.3) | 4 ( 44.4) | 3 ( 33.3) | 2 ( 22.2) |
| | No Change - n(%) | 6 ( 66.7) | 6 ( 66.7) | 3 ( 33.3) | 4 ( 44.4) | 6 ( 66.7) | 7 ( 77.8) |
| | Deterioration - n(%) | 1 ( 11.1) | 2 ( 22.2) | 3 ( 33.3) | 1 ( 11.1) | 0 | 0 |
| | Missing | 113 | 113 | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

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Table 4.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 23 ( 20.9) | 22 ( 20.0) | 7 ( 6.4) | 9 ( 8.2) | 16 ( 14.5) |
| | No Change - n(%) | 78 ( 70.9) | 72 ( 65.5) | 47 ( 42.7) | 60 ( 54.5) | 76 ( 69.1) |
| | Deterioration - n(%) | 9 ( 8.2) | 16 ( 14.5) | 56 ( 50.9) | 41 ( 37.3) | 18 ( 16.4) |
| | Missing | 12 | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 27 ( 25.2) | 34 ( 31.8) | 22 ( 20.6) | 18 ( 16.8) | 19 ( 17.8) |
| | No Change - n(%) | 58 ( 54.2) | 56 ( 52.3) | 50 ( 46.7) | 75 ( 70.1) | 71 ( 66.4) |
| | Deterioration - n(%) | 22 ( 20.6) | 17 ( 15.9) | 35 ( 32.7) | 14 ( 13.1) | 17 ( 15.9) |
| | Missing | 15 | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.

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Table 4.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 26 ( 26.8) | 30 ( 30.9) | 22 ( 22.7) | 17 ( 17.5) | 16 ( 16.5) |
| | No Change - n(%) | 47 ( 48.5) | 50 ( 51.5) | 55 ( 56.7) | 71 ( 73.2) | 59 ( 60.8) |
| | Deterioration - n(%) | 24 ( 24.7) | 17 ( 17.5) | 20 ( 20.6) | 9 ( 9.3) | 22 ( 22.7) |
| | Missing | 25 | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 22 ( 26.2) | 30 ( 35.7) | 18 ( 21.4) | 22 ( 26.2) | 16 ( 19.0) |
| | No Change - n(%) | 54 ( 64.3) | 39 ( 46.4) | 49 ( 58.3) | 56 ( 66.7) | 52 ( 61.9) |
| | Deterioration - n(%) | 8 ( 9.5) | 15 ( 17.9) | 17 ( 20.2) | 6 ( 7.1) | 16 ( 19.0) |
| | Missing | 38 | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 20 ( 25.6) | 27 ( 34.6) | 18 ( 23.1) | 17 ( 21.8) | 16 ( 20.5) |
| | No Change - n(%) | 47 ( 60.3) | 40 ( 51.3) | 49 ( 62.8) | 57 ( 73.1) | 50 ( 64.1) |
| | Deterioration - n(%) | 11 ( 14.1) | 11 ( 14.1) | 11 ( 14.1) | 4 ( 5.1) | 12 ( 15.4) |
| | Missing | 44 | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 27 ( 35.5) | 26 ( 34.2) | 22 ( 28.9) | 16 ( 21.1) | 18 ( 23.7) |
| | No Change - n(%) | 41 ( 53.9) | 45 ( 59.2) | 45 ( 59.2) | 56 ( 73.7) | 45 ( 59.2) |
| | Deterioration - n(%) | 8 ( 10.5) | 5 ( 6.6) | 9 ( 11.8) | 4 ( 5.3) | 13 ( 17.1) |
| | Missing | 46 | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.

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Table 4.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 23 ( 30.7) | 28 ( 37.3) | 22 ( 29.3) | 17 ( 22.7) | 18 ( 24.0) |
| | No Change - n(%) | 43 ( 57.3) | 41 ( 54.7) | 41 ( 54.7) | 54 ( 72.0) | 45 ( 60.0) |
| | Deterioration - n(%) | 9 ( 12.0) | 6 ( 8.0) | 12 ( 16.0) | 4 ( 5.3) | 12 ( 16.0) |
| | Missing | 47 | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 17 ( 29.3) | 24 ( 41.4) | 18 ( 31.0) | 11 ( 19.0) | 13 ( 22.4) |
| | No Change - n(%) | 36 ( 62.1) | 28 ( 48.3) | 34 ( 58.6) | 44 ( 75.9) | 44 ( 75.9) |
| | Deterioration - n(%) | 5 ( 8.6) | 6 ( 10.3) | 6 ( 10.3) | 3 ( 5.2) | 1 ( 1.7) |
| | Missing | 64 | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.

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Table 4.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 17 ( 31.5) | 20 ( 37.0) | 17 ( 31.5) | 13 ( 24.1) | 16 ( 29.6) |
| | No Change - n(%) | 34 ( 63.0) | 27 ( 50.0) | 32 ( 59.3) | 40 ( 74.1) | 33 ( 61.1) |
| | Deterioration - n(%) | 3 ( 5.6) | 7 ( 13.0) | 5 ( 9.3) | 1 ( 1.9) | 5 ( 9.3) |
| | Missing | 68 | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 11 ( 35.5) | 13 ( 41.9) | 8 ( 25.8) | 7 ( 22.6) | 10 ( 32.3) |
| | No Change - n(%) | 16 ( 51.6) | 13 ( 41.9) | 18 ( 58.1) | 22 ( 71.0) | 20 ( 64.5) |
| | Deterioration - n(%) | 4 ( 12.9) | 5 ( 16.1) | 5 ( 16.1) | 2 ( 6.5) | 1 ( 3.2) |
| | Missing | 91 | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.

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Table 4.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 10 ( 40.0) | 11 ( 44.0) | 9 ( 36.0) | 6 ( 24.0) | 6 ( 24.0) |
| | No Change - n(%) | 14 ( 56.0) | 8 ( 32.0) | 10 ( 40.0) | 16 ( 64.0) | 15 ( 60.0) |
| | Deterioration - n(%) | 1 ( 4.0) | 6 ( 24.0) | 6 ( 24.0) | 3 ( 12.0) | 4 ( 16.0) |
| | Missing | 97 | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 9 ( 34.6) | 12 ( 46.2) | 7 ( 26.9) | 8 ( 30.8) | 5 ( 19.2) |
| | No Change - n(%) | 13 ( 50.0) | 10 ( 38.5) | 16 ( 61.5) | 17 ( 65.4) | 17 ( 65.4) |
| | Deterioration - n(%) | 4 ( 15.4) | 4 ( 15.4) | 3 ( 11.5) | 1 ( 3.8) | 4 ( 15.4) |
| | Missing | 96 | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.

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Table 4.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 2 ( 15.4) | 4 ( 30.8) | 3 ( 23.1) | 2 ( 15.4) | 6 ( 46.2) |
| | No Change - n(%) | 11 ( 84.6) | 6 ( 46.2) | 8 ( 61.5) | 10 ( 76.9) | 5 ( 38.5) |
| | Deterioration - n(%) | 0 | 3 ( 23.1) | 2 ( 15.4) | 1 ( 7.7) | 2 ( 15.4) |
| | Missing | 109 | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 0 | 0 | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 0 | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 1 (100.0) | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.

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Table 4.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| PD | n | 29 | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 9 ( 31.0) | 8 ( 27.6) | 7 ( 24.1) | 6 ( 20.7) | 8 ( 27.6) |
| | No Change - n(%) | 13 ( 44.8) | 17 ( 58.6) | 13 ( 44.8) | 18 ( 62.1) | 17 ( 58.6) |
| | Deterioration - n(%) | 7 ( 24.1) | 4 ( 13.8) | 9 ( 31.0) | 5 ( 17.2) | 4 ( 13.8) |
| | Missing | 93 | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 1 (100.0) | 0 | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 0 | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| End of Study | n | 9 | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 1 ( 11.1) | 3 ( 33.3) | 4 ( 44.4) | 3 ( 33.3) | 2 ( 22.2) |
| | No Change - n(%) | 6 ( 66.7) | 3 ( 33.3) | 4 ( 44.4) | 6 ( 66.7) | 7 ( 77.8) |
| | Deterioration - n(%) | 2 ( 22.2) | 3 ( 33.3) | 1 ( 11.1) | 0 | 0 |
| | Missing | 113 | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.

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Table 4.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 5 ( 4.5) | 18 ( 16.4) | 22 ( 20.0) | 7 ( 6.4) | 11 ( 10.0) | 25 ( 22.7) |
| | No Change - n(%) | 38 ( 34.5) | 73 ( 66.4) | 60 ( 54.5) | 39 ( 35.5) | 56 ( 50.9) | 63 ( 57.3) |
| | Deterioration - n(%) | 67 ( 60.9) | 19 ( 17.3) | 28 ( 25.5) | 64 ( 58.2) | 43 ( 39.1) | 22 ( 20.0) |
| | Missing | 12 | 12 | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 20 ( 18.7) | 21 ( 19.6) | 31 ( 29.0) | 12 ( 11.2) | 18 ( 16.8) | 23 ( 21.5) |
| | No Change - n(%) | 70 ( 65.4) | 62 ( 57.9) | 53 ( 49.5) | 58 ( 54.2) | 72 ( 67.3) | 68 ( 63.6) |
| | Deterioration - n(%) | 17 ( 15.9) | 24 ( 22.4) | 23 ( 21.5) | 37 ( 34.6) | 17 ( 15.9) | 16 ( 15.0) |
| | Missing | 15 | 15 | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 15 ( 15.5) | 18 ( 18.6) | 23 ( 23.7) | 11 ( 11.3) | 14 ( 14.4) | 17 ( 17.5) |
| | No Change - n(%) | 72 ( 74.2) | 57 ( 58.8) | 54 ( 55.7) | 62 ( 63.9) | 72 ( 74.2) | 61 ( 62.9) |
| | Deterioration - n(%) | 10 ( 10.3) | 22 ( 22.7) | 20 ( 20.6) | 24 ( 24.7) | 11 ( 11.3) | 19 ( 19.6) |
| | Missing | 25 | 25 | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 12 ( 14.3) | 16 ( 19.0) | 22 ( 26.2) | 14 ( 16.7) | 18 ( 21.4) | 13 ( 15.5) |
| | No Change - n(%) | 63 ( 75.0) | 59 ( 70.2) | 47 ( 56.0) | 49 ( 58.3) | 57 ( 67.9) | 57 ( 67.9) |
| | Deterioration - n(%) | 9 ( 10.7) | 9 ( 10.7) | 15 ( 17.9) | 21 ( 25.0) | 9 ( 10.7) | 14 ( 16.7) |
| | Missing | 38 | 38 | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 14 ( 17.9) | 15 ( 19.2) | 19 ( 24.4) | 8 ( 10.3) | 15 ( 19.2) | 14 ( 17.9) |
| | No Change - n(%) | 52 ( 66.7) | 50 ( 64.1) | 51 ( 65.4) | 59 ( 75.6) | 55 ( 70.5) | 51 ( 65.4) |
| | Deterioration - n(%) | 12 ( 15.4) | 13 ( 16.7) | 8 ( 10.3) | 11 ( 14.1) | 8 ( 10.3) | 13 ( 16.7) |
| | Missing | 44 | 44 | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 13 ( 17.1) | 15 ( 19.7) | 21 ( 27.6) | 9 ( 11.8) | 15 ( 19.7) | 19 ( 25.0) |
| | No Change - n(%) | 57 ( 75.0) | 51 ( 67.1) | 45 ( 59.2) | 58 ( 76.3) | 53 ( 69.7) | 42 ( 55.3) |
| | Deterioration - n(%) | 6 ( 7.9) | 10 ( 13.2) | 10 ( 13.2) | 9 ( 11.8) | 8 ( 10.5) | 15 ( 19.7) |
| | Missing | 46 | 46 | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 11 ( 14.7) | 11 ( 14.7) | 26 ( 34.7) | 7 ( 9.3) | 17 ( 22.7) | 20 ( 26.7) |
| | No Change - n(%) | 58 ( 77.3) | 53 ( 70.7) | 42 ( 56.0) | 56 ( 74.7) | 50 ( 66.7) | 41 ( 54.7) |
| | Deterioration - n(%) | 6 ( 8.0) | 11 ( 14.7) | 7 ( 9.3) | 12 ( 16.0) | 8 ( 10.7) | 14 ( 18.7) |
| | Missing | 47 | 47 | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 11 ( 19.0) | 11 ( 19.0) | 21 ( 36.2) | 6 ( 10.3) | 10 ( 17.2) | 12 ( 20.7) |
| | No Change - n(%) | 41 ( 70.7) | 42 ( 72.4) | 34 ( 58.6) | 47 ( 81.0) | 43 ( 74.1) | 43 ( 74.1) |
| | Deterioration - n(%) | 6 ( 10.3) | 5 ( 8.6) | 3 ( 5.2) | 5 ( 8.6) | 5 ( 8.6) | 3 ( 5.2) |
| | Missing | 64 | 64 | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 11 ( 20.4) | 9 ( 16.7) | 17 ( 31.5) | 8 ( 14.8) | 11 ( 20.4) | 12 ( 22.2) |
| | No Change - n(%) | 38 ( 70.4) | 41 ( 75.9) | 29 ( 53.7) | 40 ( 74.1) | 40 ( 74.1) | 36 ( 66.7) |
| | Deterioration - n(%) | 5 ( 9.3) | 4 ( 7.4) | 8 ( 14.8) | 6 ( 11.1) | 3 ( 5.6) | 6 ( 11.1) |
| | Missing | 68 | 68 | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 5 ( 16.1) | 6 ( 19.4) | 8 ( 25.8) | 4 ( 12.9) | 5 ( 16.1) | 6 ( 19.4) |
| | No Change - n(%) | 22 ( 71.0) | 21 ( 67.7) | 20 ( 64.5) | 20 ( 64.5) | 22 ( 71.0) | 23 ( 74.2) |
| | Deterioration - n(%) | 4 ( 12.9) | 4 ( 12.9) | 3 ( 9.7) | 7 ( 22.6) | 4 ( 12.9) | 2 ( 6.5) |
| | Missing | 91 | 91 | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 30JUL2021 15:19
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Table 4.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 6 ( 24.0) | 4 ( 16.0) | 7 ( 28.0) | 4 ( 16.0) | 4 ( 16.0) | 3 ( 12.0) |
| | No Change - n(%) | 15 ( 60.0) | 17 ( 68.0) | 16 ( 64.0) | 17 ( 68.0) | 19 ( 76.0) | 19 ( 76.0) |
| | Deterioration - n(%) | 4 ( 16.0) | 4 ( 16.0) | 2 ( 8.0) | 4 ( 16.0) | 2 ( 8.0) | 3 ( 12.0) |
| | Missing | 97 | 97 | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 3 ( 11.5) | 5 ( 19.2) | 9 ( 34.6) | 3 ( 11.5) | 7 ( 26.9) | 6 ( 23.1) |
| | No Change - n(%) | 19 ( 73.1) | 15 ( 57.7) | 15 ( 57.7) | 20 ( 76.9) | 18 ( 69.2) | 15 ( 57.7) |
| | Deterioration - n(%) | 4 ( 15.4) | 6 ( 23.1) | 2 ( 7.7) | 3 ( 11.5) | 1 ( 3.8) | 5 ( 19.2) |
| | Missing | 96 | 96 | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 4 ( 30.8) | 3 ( 23.1) | 2 ( 15.4) | 4 ( 30.8) | 3 ( 23.1) | 5 ( 38.5) |
| | No Change - n(%) | 7 ( 53.8) | 9 ( 69.2) | 8 ( 61.5) | 7 ( 53.8) | 10 ( 76.9) | 7 ( 53.8) |
| | Deterioration - n(%) | 2 ( 15.4) | 1 ( 7.7) | 3 ( 23.1) | 2 ( 15.4) | 0 | 1 ( 7.7) |
| | Missing | 109 | 109 | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) | 0 | 1 (100.0) | 0 | 1 (100.0) |
| | No Change - n(%) | 0 | 0 | 1 (100.0) | 0 | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 4.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| PD | n | 29 | 29 | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 3 ( 10.3) | 8 ( 27.6) | 10 ( 34.5) | 3 ( 10.3) | 4 ( 13.8) | 7 ( 24.1) |
| | No Change - n(%) | 17 ( 58.6) | 14 ( 48.3) | 12 ( 41.4) | 17 ( 58.6) | 20 ( 69.0) | 18 ( 62.1) |
| | Deterioration - n(%) | 9 ( 31.0) | 7 ( 24.1) | 7 ( 24.1) | 9 ( 31.0) | 5 ( 17.2) | 4 ( 13.8) |
| | Missing | 93 | 93 | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 0 | 1 (100.0) | 0 | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 0 | 0 | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 1 (100.0) | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 4.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| End of Study | n | 9 | 9 | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 0 | 0 | 3 ( 33.3) | 1 ( 11.1) | 1 ( 11.1) | 1 ( 11.1) |
| | No Change - n(%) | 7 ( 77.8) | 5 ( 55.6) | 3 ( 33.3) | 7 ( 77.8) | 8 ( 88.9) | 7 ( 77.8) |
| | Deterioration - n(%) | 2 ( 22.2) | 4 ( 44.4) | 3 ( 33.3) | 1 ( 11.1) | 0 | 1 ( 11.1) |
| | Missing | 113 | 113 | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 5 ( 4.5) | 18 ( 16.4) | 22 ( 20.0) | 7 ( 6.4) | 11 ( 10.0) | 25 ( 22.7) |
| | No Change - n(%) | 38 ( 34.5) | 73 ( 66.4) | 60 ( 54.5) | 39 ( 35.5) | 56 ( 50.9) | 63 ( 57.3) |
| | Deterioration - n(%) | 67 ( 60.9) | 19 ( 17.3) | 28 ( 25.5) | 64 ( 58.2) | 43 ( 39.1) | 22 ( 20.0) |
| | Missing | 12 | 12 | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 20 ( 18.7) | 21 ( 19.6) | 31 ( 29.0) | 12 ( 11.2) | 18 ( 16.8) | 23 ( 21.5) |
| | No Change - n(%) | 70 ( 65.4) | 62 ( 57.9) | 53 ( 49.5) | 58 ( 54.2) | 72 ( 67.3) | 68 ( 63.6) |
| | Deterioration - n(%) | 17 ( 15.9) | 24 ( 22.4) | 23 ( 21.5) | 37 ( 34.6) | 17 ( 15.9) | 16 ( 15.0) |
| | Missing | 15 | 15 | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 15 ( 15.5) | 18 ( 18.6) | 23 ( 23.7) | 11 ( 11.3) | 14 ( 14.4) | 17 ( 17.5) |
| | No Change - n(%) | 72 ( 74.2) | 57 ( 58.8) | 54 ( 55.7) | 62 ( 63.9) | 72 ( 74.2) | 61 ( 62.9) |
| | Deterioration - n(%) | 10 ( 10.3) | 22 ( 22.7) | 20 ( 20.6) | 24 ( 24.7) | 11 ( 11.3) | 19 ( 19.6) |
| | Missing | 25 | 25 | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 12 ( 14.3) | 16 ( 19.0) | 22 ( 26.2) | 14 ( 16.7) | 18 ( 21.4) | 13 ( 15.5) |
| | No Change - n(%) | 63 ( 75.0) | 59 ( 70.2) | 47 ( 56.0) | 49 ( 58.3) | 57 ( 67.9) | 57 ( 67.9) |
| | Deterioration - n(%) | 9 ( 10.7) | 9 ( 10.7) | 15 ( 17.9) | 21 ( 25.0) | 9 ( 10.7) | 14 ( 16.7) |
| | Missing | 38 | 38 | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 14 ( 17.9) | 15 ( 19.2) | 19 ( 24.4) | 8 ( 10.3) | 15 ( 19.2) | 14 ( 17.9) |
| | No Change - n(%) | 52 ( 66.7) | 50 ( 64.1) | 51 ( 65.4) | 59 ( 75.6) | 55 ( 70.5) | 51 ( 65.4) |
| | Deterioration - n(%) | 12 ( 15.4) | 13 ( 16.7) | 8 ( 10.3) | 11 ( 14.1) | 8 ( 10.3) | 13 ( 16.7) |
| | Missing | 44 | 44 | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 13 ( 17.1) | 15 ( 19.7) | 21 ( 27.6) | 9 ( 11.8) | 15 ( 19.7) | 19 ( 25.0) |
| | No Change - n(%) | 57 ( 75.0) | 51 ( 67.1) | 45 ( 59.2) | 58 ( 76.3) | 53 ( 69.7) | 42 ( 55.3) |
| | Deterioration - n(%) | 6 ( 7.9) | 10 ( 13.2) | 10 ( 13.2) | 9 ( 11.8) | 8 ( 10.5) | 15 ( 19.7) |
| | Missing | 46 | 46 | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 11 ( 14.7) | 11 ( 14.7) | 26 ( 34.7) | 7 ( 9.3) | 17 ( 22.7) | 20 ( 26.7) |
| | No Change - n(%) | 58 ( 77.3) | 53 ( 70.7) | 42 ( 56.0) | 56 ( 74.7) | 50 ( 66.7) | 41 ( 54.7) |
| | Deterioration - n(%) | 6 ( 8.0) | 11 ( 14.7) | 7 ( 9.3) | 12 ( 16.0) | 8 ( 10.7) | 14 ( 18.7) |
| | Missing | 47 | 47 | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 11 ( 19.0) | 11 ( 19.0) | 21 ( 36.2) | 6 ( 10.3) | 10 ( 17.2) | 12 ( 20.7) |
| | No Change - n(%) | 41 ( 70.7) | 42 ( 72.4) | 34 ( 58.6) | 47 ( 81.0) | 43 ( 74.1) | 43 ( 74.1) |
| | Deterioration - n(%) | 6 ( 10.3) | 5 ( 8.6) | 3 ( 5.2) | 5 ( 8.6) | 5 ( 8.6) | 3 ( 5.2) |
| | Missing | 64 | 64 | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 30JUL2021 15:19
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 4.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 11 ( 20.4) | 9 ( 16.7) | 17 ( 31.5) | 8 ( 14.8) | 11 ( 20.4) | 12 ( 22.2) |
| | No Change - n(%) | 38 ( 70.4) | 41 ( 75.9) | 29 ( 53.7) | 40 ( 74.1) | 40 ( 74.1) | 36 ( 66.7) |
| | Deterioration - n(%) | 5 ( 9.3) | 4 ( 7.4) | 8 ( 14.8) | 6 ( 11.1) | 3 ( 5.6) | 6 ( 11.1) |
| | Missing | 68 | 68 | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 5 ( 16.1) | 6 ( 19.4) | 8 ( 25.8) | 4 ( 12.9) | 5 ( 16.1) | 6 ( 19.4) |
| | No Change - n(%) | 22 ( 71.0) | 21 ( 67.7) | 20 ( 64.5) | 20 ( 64.5) | 22 ( 71.0) | 23 ( 74.2) |
| | Deterioration - n(%) | 4 ( 12.9) | 4 ( 12.9) | 3 ( 9.7) | 7 ( 22.6) | 4 ( 12.9) | 2 ( 6.5) |
| | Missing | 91 | 91 | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 30JUL2021 15:19
Analysis Plan: 12MAY2021 Confidential

Table 4.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 6 ( 24.0) | 4 ( 16.0) | 7 ( 28.0) | 4 ( 16.0) | 4 ( 16.0) | 3 ( 12.0) |
| | No Change - n(%) | 15 ( 60.0) | 17 ( 68.0) | 16 ( 64.0) | 17 ( 68.0) | 19 ( 76.0) | 19 ( 76.0) |
| | Deterioration - n(%) | 4 ( 16.0) | 4 ( 16.0) | 2 ( 8.0) | 4 ( 16.0) | 2 ( 8.0) | 3 ( 12.0) |
| | Missing | 97 | 97 | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 3 ( 11.5) | 5 ( 19.2) | 9 ( 34.6) | 3 ( 11.5) | 7 ( 26.9) | 6 ( 23.1) |
| | No Change - n(%) | 19 ( 73.1) | 15 ( 57.7) | 15 ( 57.7) | 20 ( 76.9) | 18 ( 69.2) | 15 ( 57.7) |
| | Deterioration - n(%) | 4 ( 15.4) | 6 ( 23.1) | 2 ( 7.7) | 3 ( 11.5) | 1 ( 3.8) | 5 ( 19.2) |
| | Missing | 96 | 96 | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 4 ( 30.8) | 3 ( 23.1) | 2 ( 15.4) | 4 ( 30.8) | 3 ( 23.1) | 5 ( 38.5) |
| | No Change - n(%) | 7 ( 53.8) | 9 ( 69.2) | 8 ( 61.5) | 7 ( 53.8) | 10 ( 76.9) | 7 ( 53.8) |
| | Deterioration - n(%) | 2 ( 15.4) | 1 ( 7.7) | 3 ( 23.1) | 2 ( 15.4) | 0 | 1 ( 7.7) |
| | Missing | 109 | 109 | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) | 0 | 1 (100.0) | 0 | 1 (100.0) |
| | No Change - n(%) | 0 | 0 | 1 (100.0) | 0 | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Celgene Corporation
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Cut-off date: 21DEC2020

Table 4.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| PD | n | 29 | 29 | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 3 ( 10.3) | 8 ( 27.6) | 10 ( 34.5) | 3 ( 10.3) | 4 ( 13.8) | 7 ( 24.1) |
| | No Change - n(%) | 17 ( 58.6) | 14 ( 48.3) | 12 ( 41.4) | 17 ( 58.6) | 20 ( 69.0) | 18 ( 62.1) |
| | Deterioration - n(%) | 9 ( 31.0) | 7 ( 24.1) | 7 ( 24.1) | 9 ( 31.0) | 5 ( 17.2) | 4 ( 13.8) |
| | Missing | 93 | 93 | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 0 | 1 (100.0) | 0 | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 0 | 0 | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 1 (100.0) | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| End of Study | n | 9 | 9 | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 0 | 0 | 3 ( 33.3) | 1 ( 11.1) | 1 ( 11.1) | 1 ( 11.1) |
| | No Change - n(%) | 7 ( 77.8) | 5 ( 55.6) | 3 ( 33.3) | 7 ( 77.8) | 8 ( 88.9) | 7 ( 77.8) |
| | Deterioration - n(%) | 2 ( 22.2) | 4 ( 44.4) | 3 ( 33.3) | 1 ( 11.1) | 0 | 1 ( 11.1) |
| | Missing | 113 | 113 | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 18 ( 16.4) | 22 ( 20.0) | 7 ( 6.4) | 11 ( 10.0) | 25 ( 22.7) |
| | No Change - n(%) | 73 ( 66.4) | 60 ( 54.5) | 39 ( 35.5) | 56 ( 50.9) | 63 ( 57.3) |
| | Deterioration - n(%) | 19 ( 17.3) | 28 ( 25.5) | 64 ( 58.2) | 43 ( 39.1) | 22 ( 20.0) |
| | Missing | 12 | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 21 ( 19.6) | 31 ( 29.0) | 12 ( 11.2) | 18 ( 16.8) | 23 ( 21.5) |
| | No Change - n(%) | 62 ( 57.9) | 53 ( 49.5) | 58 ( 54.2) | 72 ( 67.3) | 68 ( 63.6) |
| | Deterioration - n(%) | 24 ( 22.4) | 23 ( 21.5) | 37 ( 34.6) | 17 ( 15.9) | 16 ( 15.0) |
| | Missing | 15 | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 18 ( 18.6) | 23 ( 23.7) | 11 ( 11.3) | 14 ( 14.4) | 17 ( 17.5) |
| | No Change - n(%) | 57 ( 58.8) | 54 ( 55.7) | 62 ( 63.9) | 72 ( 74.2) | 61 ( 62.9) |
| | Deterioration - n(%) | 22 ( 22.7) | 20 ( 20.6) | 24 ( 24.7) | 11 ( 11.3) | 19 ( 19.6) |
| | Missing | 25 | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 16 ( 19.0) | 22 ( 26.2) | 14 ( 16.7) | 18 ( 21.4) | 13 ( 15.5) |
| | No Change - n(%) | 59 ( 70.2) | 47 ( 56.0) | 49 ( 58.3) | 57 ( 67.9) | 57 ( 67.9) |
| | Deterioration - n(%) | 9 ( 10.7) | 15 ( 17.9) | 21 ( 25.0) | 9 ( 10.7) | 14 ( 16.7) |
| | Missing | 38 | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 15 ( 19.2) | 19 ( 24.4) | 8 ( 10.3) | 15 ( 19.2) | 14 ( 17.9) |
| | No Change - n(%) | 50 ( 64.1) | 51 ( 65.4) | 59 ( 75.6) | 55 ( 70.5) | 51 ( 65.4) |
| | Deterioration - n(%) | 13 ( 16.7) | 8 ( 10.3) | 11 ( 14.1) | 8 ( 10.3) | 13 ( 16.7) |
| | Missing | 44 | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 15 ( 19.7) | 21 ( 27.6) | 9 ( 11.8) | 15 ( 19.7) | 19 ( 25.0) |
| | No Change - n(%) | 51 ( 67.1) | 45 ( 59.2) | 58 ( 76.3) | 53 ( 69.7) | 42 ( 55.3) |
| | Deterioration - n(%) | 10 ( 13.2) | 10 ( 13.2) | 9 ( 11.8) | 8 ( 10.5) | 15 ( 19.7) |
| | Missing | 46 | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 11 ( 14.7) | 26 ( 34.7) | 7 ( 9.3) | 17 ( 22.7) | 20 ( 26.7) |
| | No Change - n(%) | 53 ( 70.7) | 42 ( 56.0) | 56 ( 74.7) | 50 ( 66.7) | 41 ( 54.7) |
| | Deterioration - n(%) | 11 ( 14.7) | 7 ( 9.3) | 12 ( 16.0) | 8 ( 10.7) | 14 ( 18.7) |
| | Missing | 47 | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 11 ( 19.0) | 21 ( 36.2) | 6 ( 10.3) | 10 ( 17.2) | 12 ( 20.7) |
| | No Change - n(%) | 42 ( 72.4) | 34 ( 58.6) | 47 ( 81.0) | 43 ( 74.1) | 43 ( 74.1) |
| | Deterioration - n(%) | 5 ( 8.6) | 3 ( 5.2) | 5 ( 8.6) | 5 ( 8.6) | 3 ( 5.2) |
| | Missing | 64 | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 9 ( 16.7) | 17 ( 31.5) | 8 ( 14.8) | 11 ( 20.4) | 12 ( 22.2) |
| | No Change - n(%) | 41 ( 75.9) | 29 ( 53.7) | 40 ( 74.1) | 40 ( 74.1) | 36 ( 66.7) |
| | Deterioration - n(%) | 4 ( 7.4) | 8 ( 14.8) | 6 ( 11.1) | 3 ( 5.6) | 6 ( 11.1) |
| | Missing | 68 | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 6 ( 19.4) | 8 ( 25.8) | 4 ( 12.9) | 5 ( 16.1) | 6 ( 19.4) |
| | No Change - n(%) | 21 ( 67.7) | 20 ( 64.5) | 20 ( 64.5) | 22 ( 71.0) | 23 ( 74.2) |
| | Deterioration - n(%) | 4 ( 12.9) | 3 ( 9.7) | 7 ( 22.6) | 4 ( 12.9) | 2 ( 6.5) |
| | Missing | 91 | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 4 ( 16.0) | 7 ( 28.0) | 4 ( 16.0) | 4 ( 16.0) | 3 ( 12.0) |
| | No Change - n(%) | 17 ( 68.0) | 16 ( 64.0) | 17 ( 68.0) | 19 ( 76.0) | 19 ( 76.0) |
| | Deterioration - n(%) | 4 ( 16.0) | 2 ( 8.0) | 4 ( 16.0) | 2 ( 8.0) | 3 ( 12.0) |
| | Missing | 97 | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 5 ( 19.2) | 9 ( 34.6) | 3 ( 11.5) | 7 ( 26.9) | 6 ( 23.1) |
| | No Change - n(%) | 15 ( 57.7) | 15 ( 57.7) | 20 ( 76.9) | 18 ( 69.2) | 15 ( 57.7) |
| | Deterioration - n(%) | 6 ( 23.1) | 2 ( 7.7) | 3 ( 11.5) | 1 ( 3.8) | 5 ( 19.2) |
| | Missing | 96 | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 3 ( 23.1) | 2 ( 15.4) | 4 ( 30.8) | 3 ( 23.1) | 5 ( 38.5) |
| | No Change - n(%) | 9 ( 69.2) | 8 ( 61.5) | 7 ( 53.8) | 10 ( 76.9) | 7 ( 53.8) |
| | Deterioration - n(%) | 1 ( 7.7) | 3 ( 23.1) | 2 ( 15.4) | 0 | 1 ( 7.7) |
| | Missing | 109 | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 0 | 1 (100.0) | 0 | 1 (100.0) |
| | No Change - n(%) | 0 | 1 (100.0) | 0 | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Date/time of run: 30JUL2021 15:19
Analysis Plan: 12MAY2021 Confidential

Table 4.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| PD | n | 29 | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 8 ( 27.6) | 10 ( 34.5) | 3 ( 10.3) | 4 ( 13.8) | 7 ( 24.1) |
| | No Change - n(%) | 14 ( 48.3) | 12 ( 41.4) | 17 ( 58.6) | 20 ( 69.0) | 18 ( 62.1) |
| | Deterioration - n(%) | 7 ( 24.1) | 7 ( 24.1) | 9 ( 31.0) | 5 ( 17.2) | 4 ( 13.8) |
| | Missing | 93 | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 1 (100.0) | 0 | 0 | 0 |
| | No Change - n(%) | 0 | 0 | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 1 (100.0) | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| End of Study | n | 9 | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 0 | 3 ( 33.3) | 1 ( 11.1) | 1 ( 11.1) | 1 ( 11.1) |
| | No Change - n(%) | 5 ( 55.6) | 3 ( 33.3) | 7 ( 77.8) | 8 ( 88.9) | 7 ( 77.8) |
| | Deterioration - n(%) | 4 ( 44.4) | 3 ( 33.3) | 1 ( 11.1) | 0 | 1 ( 11.1) |
| | Missing | 113 | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-30 for improvement and >=+30 for worsening on Dyspnoea, Insomnia, Appetite Loss, Constipation and Diarrhoea.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.1d
Scores on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Screening | n | 117 | 117 | 117 | 117 | 117 | 117 |
| | Mean | 5.6 | 15.7 | 27.1 | 13.4 | 12.5 | 13.4 |
| | SD | 10.94 | 22.98 | 26.96 | 24.39 | 22.63 | 20.09 |
| | Median | 0.0 | 0.0 | 33.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 |
| | Min, Max | 0, 67 | 0,100 | 0,100 | 0,100 | 0,100 | 0, 67 |
| Baseline Evaluations | n | 122 | 122 | 122 | 122 | 122 | 122 |
| | Mean | 8.2 | 20.8 | 31.7 | 18.6 | 13.1 | 13.7 |
| | SD | 14.41 | 23.99 | 29.33 | 26.08 | 21.67 | 20.44 |
| | Median | 0.0 | 0.0 | 33.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 |
| | Min, Max | 0, 83 | 0,100 | 0,100 | 0,100 | 0,100 | 0, 67 |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 | 110 |
| | Mean | 21.8 | 16.1 | 30.3 | 37.9 | 26.7 | 14.8 |
| | SD | 20.29 | 25.03 | 27.30 | 28.01 | 29.88 | 24.14 |
| | Median | 16.7 | 0.0 | 33.3 | 33.3 | 33.3 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 33.3, 66.7 | 0.0, 33.3 | 0.0, 33.3 |
| | Min, Max | 0,100 | 0,100 | 0,100 | 0,100 | 0,100 | 0,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.1d
Scores on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 | 107 |
| | Mean | 6.9 | 19.3 | 23.4 | 25.9 | 13.1 | 14.0 |
| | SD | 15.00 | 24.67 | 25.58 | 30.48 | 22.32 | 24.67 |
| | Median | 0.0 | 0.0 | 33.3 | 33.3 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 |
| | Min, Max | 0, 67 | 0,100 | 0,100 | 0,100 | 0,100 | 0,100 |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 | 97 |
| | Mean | 5.3 | 17.9 | 26.5 | 17.9 | 9.6 | 16.2 |
| | SD | 12.63 | 22.60 | 29.63 | 25.03 | 17.98 | 23.63 |
| | Median | 0.0 | 0.0 | 33.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | 0, 67 | 0, 67 | 0,100 | 0,100 | 0, 67 | 0,100 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 | 84 |
| | Mean | 6.0 | 11.9 | 22.2 | 15.9 | 7.1 | 15.5 |
| | SD | 14.55 | 18.40 | 25.52 | 25.07 | 15.58 | 23.96 |
| | Median | 0.0 | 0.0 | 33.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | 0, 83 | 0, 67 | 0,100 | 0,100 | 0, 67 | 0,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.1d
Scores on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 | 78 |
| | Mean | 6.4 | 12.4 | 21.4 | 14.5 | 6.4 | 14.1 |
| | SD | 15.48 | 17.08 | 27.38 | 25.53 | 14.27 | 25.49 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 0, 67 | 0,100 | 0,100 | 0, 67 | 0,100 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 | 76 |
| | Mean | 3.5 | 8.8 | 19.7 | 10.5 | 7.5 | 11.8 |
| | SD | 8.74 | 16.66 | 25.05 | 22.58 | 16.86 | 20.87 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | 0, 33 | 0, 67 | 0,100 | 0,100 | 0, 67 | 0,100 |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 | 75 |
| | Mean | 4.9 | 11.6 | 18.2 | 12.9 | 8.4 | 11.1 |
| | SD | 11.22 | 19.37 | 23.44 | 21.15 | 19.06 | 19.25 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | 0, 50 | 0, 67 | 0,100 | 0, 67 | 0,100 | 0,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.1d
Scores on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 | 58 |
| | Mean | 4.9 | 8.0 | 17.2 | 6.9 | 8.6 | 9.2 |
| | SD | 12.09 | 15.68 | 23.56 | 16.23 | 17.17 | 16.27 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | 0, 50 | 0, 67 | 0, 67 | 0, 67 | 0, 67 | 0, 67 |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 | 54 |
| | Mean | 5.9 | 9.3 | 21.0 | 8.6 | 5.6 | 9.9 |
| | SD | 14.17 | 16.40 | 29.17 | 19.62 | 14.11 | 17.89 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | 0, 67 | 0, 67 | 0,100 | 0, 67 | 0, 67 | 0, 67 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 | 31 |
| | Mean | 5.4 | 12.9 | 21.5 | 17.2 | 10.8 | 6.5 |
| | SD | 10.88 | 23.85 | 27.95 | 29.65 | 21.75 | 15.91 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | 0, 33 | 0,100 | 0,100 | 0,100 | 0,100 | 0, 67 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.1d
Scores on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 | 25 |
| | Mean | 6.0 | 10.7 | 17.3 | 12.0 | 6.7 | 16.0 |
| | SD | 9.48 | 18.56 | 21.77 | 21.26 | 13.61 | 27.42 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | 0, 33 | 0, 67 | 0, 67 | 0, 67 | 0, 33 | 0,100 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 | 26 |
| | Mean | 9.6 | 15.4 | 16.7 | 14.1 | 3.8 | 16.7 |
| | SD | 20.10 | 25.35 | 25.39 | 31.51 | 10.86 | 27.08 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | 0, 67 | 0,100 | 0,100 | 0,100 | 0, 33 | 0,100 |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 | 13 |
| | Mean | 3.8 | 10.3 | 23.1 | 10.3 | 5.1 | 7.7 |
| | SD | 7.31 | 16.01 | 25.04 | 21.01 | 12.52 | 14.62 |
| | Median | 0.0 | 0.0 | 33.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | 0, 17 | 0, 33 | 0, 67 | 0, 67 | 0, 33 | 0, 33 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.1d
Scores on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Mean | 0.0 | 0.0 | 66.7 | 0.0 | 0.0 | 33.3 |
| | SD | | | | | | |
| | Median | 0.0 | 0.0 | 66.7 | 0.0 | 0.0 | 33.3 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | 66.7, 66.7 | 0.0, 0.0 | 0.0, 0.0 | 33.3, 33.3 |
| | Min, Max | 0, 0 | 0, 0 | 67, 67 | 0, 0 | 0, 0 | 33, 33 |
| PD | n | 29 | 29 | 29 | 29 | 29 | 29 |
| | Mean | 8.6 | 16.1 | 24.1 | 18.4 | 10.3 | 12.6 |
| | SD | 15.18 | 29.03 | 25.03 | 26.10 | 22.01 | 27.33 |
| | Median | 0.0 | 0.0 | 33.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | 0, 67 | 0,100 | 0,100 | 0,100 | 0,100 | 0,100 |
| CR | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Mean | 0.0 | 33.3 | 0.0 | 0.0 | 0.0 | 0.0 |
| | SD | | | | | | |
| | Median | 0.0 | 33.3 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 33.3, 33.3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | 0, 0 | 33, 33 | 0, 0 | 0, 0 | 0, 0 | 0, 0 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.1d
Scores on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| End of Study | n | 9 | 9 | 9 | 9 | 9 | 9 |
| | Mean | 9.3 | 18.5 | 29.6 | 3.7 | 3.7 | 11.1 |
| | SD | 18.84 | 17.57 | 30.93 | 11.11 | 11.11 | 23.57 |
| | Median | 0.0 | 33.3 | 33.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 66.7 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | 0, 50 | 0, 33 | 0, 67 | 0, 33 | 0, 33 | 0, 67 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 | 110 |
| | Mean | 13.0 | -5.2 | -1.8 | 19.1 | 13.3 | 1.2 |
| | SD | 20.37 | 20.29 | 25.48 | 28.72 | 28.63 | 23.43 |
| | Median | 16.7 | 0.0 | 0.0 | 33.3 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -50,100 | -100, 33 | -100, 67 | -67,100 | -67,100 | -67,100 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.016 | 0.307 | <0.001 | <0.001 | 0.558 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 | 107 |
| | Mean | -1.6 | -1.6 | -6.9 | 7.2 | -1.2 | -0.3 |
| | SD | 18.39 | 29.45 | 29.22 | 32.06 | 21.44 | 24.44 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -83, 67 | -100,100 | -100, 67 | -67,100 | -67, 67 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.520 | 0.678 | 0.021 | 0.018 | 0.597 | 0.753 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 | 97 |
| | Mean | -1.7 | -3.1 | -4.1 | -0.3 | -3.1 | 2.1 |
| | SD | 14.92 | 30.08 | 28.97 | 25.68 | 19.89 | 24.44 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -50, 67 | -100, 67 | -67, 67 | -67, 67 | -67, 67 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.303 | 0.316 | 0.162 | 0.984 | 0.129 | 0.410 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 | 84 |
| | Mean | -2.2 | -7.9 | -7.5 | -1.2 | -6.7 | 0.4 |
| | SD | 15.69 | 26.19 | 28.03 | 25.05 | 21.20 | 27.13 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 |
| | Min, Max | -67, 67 | -100, 67 | -67, 67 | -67, 67 | -67, 67 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.147 | 0.006 | 0.012 | 0.647 | 0.003 | 0.953 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUN2021 13:37
Analysis Plan: 12MAY2021 Confidential

Table 4.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 | 78 |
| | Mean | -1.3 | -6.4 | -8.1 | -1.3 | -6.8 | 0.0 |
| | SD | 17.77 | 26.35 | 26.42 | 27.10 | 19.64 | 31.32 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -33,100 | -100, 33 | -67, 67 | -67,100 | -67, 33 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.226 | 0.033 | 0.006 | 0.439 | 0.001 | 0.982 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 | 76 |
| | Mean | -4.2 | -10.1 | -11.4 | -6.1 | -6.1 | -3.9 |
| | SD | 12.80 | 26.12 | 25.27 | 27.06 | 18.63 | 28.79 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 0.0 | -33.3, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -67, 33 | -67, 67 | -67, 67 | -67, 67 | -67, 33 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.003 | <0.001 | <0.001 | 0.065 | 0.006 | 0.167 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUN2021 13:37
Analysis Plan: 12MAY2021 Confidential

Table 4.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 | 75 |
| | Mean | -3.1 | -7.6 | -12.4 | -3.6 | -5.8 | -3.6 |
| | SD | 14.16 | 25.45 | 24.98 | 26.04 | 19.28 | 27.17 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 0.0 | -33.3, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -50, 50 | -67, 67 | -67, 33 | -67, 67 | -67, 67 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.045 | 0.011 | <0.001 | 0.234 | 0.009 | 0.192 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 | 58 |
| | Mean | -2.3 | -9.2 | -13.8 | -8.0 | -4.6 | -7.5 |
| | SD | 15.75 | 27.07 | 27.95 | 22.78 | 15.86 | 19.79 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 0.0 | -33.3, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -50, 50 | -100, 67 | -100, 33 | -67, 33 | -33, 33 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.325 | 0.011 | <0.001 | 0.006 | 0.048 | 0.009 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 | 54 |
| | Mean | -2.2 | -11.7 | -9.3 | -8.0 | -8.0 | -7.4 |
| | SD | 14.13 | 25.21 | 27.79 | 24.17 | 17.05 | 23.94 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 0.0 | -33.3, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 | -33.3, 0.0 |
| | Min, Max | -33, 50 | -100, 33 | -100, 67 | -67, 67 | -67, 33 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.205 | 0.001 | 0.031 | 0.015 | 0.002 | 0.026 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 | 31 |
| | Mean | -1.1 | -9.7 | -10.8 | -1.1 | -3.2 | -9.7 |
| | SD | 10.48 | 26.10 | 32.65 | 26.50 | 24.88 | 23.08 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 | -33.3, 0.0 |
| | Min, Max | -17, 33 | -67, 33 | -100, 67 | -33, 67 | -33,100 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.781 | 0.125 | 0.089 | 0.897 | 0.398 | 0.047 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUN2021 13:37
Analysis Plan: 12MAY2021 Confidential

Table 4.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 | 25 |
| | Mean | 0.0 | -13.3 | -9.3 | -4.0 | -4.0 | -5.3 |
| | SD | 11.79 | 21.52 | 31.21 | 26.03 | 20.00 | 26.67 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -17, 17 | -67, 33 | -67, 33 | -33, 33 | -33, 33 | -67, 33 |
| | p-value for Comparison to Zero [b] | 1.000 | 0.011 | 0.190 | 0.607 | 0.508 | 0.479 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 | 26 |
| | Mean | 2.6 | -9.0 | -15.4 | -2.6 | -10.3 | 0.0 |
| | SD | 18.07 | 27.58 | 42.41 | 26.54 | 20.59 | 29.81 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 | -33.3, 0.0 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 |
| | Min, Max | -33, 50 | -67, 33 | -100,100 | -33, 67 | -67, 33 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.510 | 0.227 | 0.054 | 0.809 | 0.035 | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUN2021 13:37
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Table 4.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 | 13 |
| | Mean | 1.3 | -7.7 | -5.1 | -2.6 | -2.6 | -12.8 |
| | SD | 10.68 | 19.97 | 29.96 | 21.35 | 16.45 | 28.99 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 |
| | Min, Max | -17, 17 | -67, 0 | -67, 33 | -33, 33 | -33, 33 | -67, 33 |
| | p-value for Comparison to Zero [b] | 1.000 | 0.500 | 0.766 | 1.000 | 1.000 | 0.234 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Mean | 0.0 | 0.0 | 33.3 | 0.0 | 0.0 | 0.0 |
| | SD | | | | | | |
| | Median | 0.0 | 0.0 | 33.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | 33.3, 33.3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | 0, 0 | 0, 0 | 33, 33 | 0, 0 | 0, 0 | 0, 0 |
| | p-value for Comparison to Zero [b] | N/A | N/A | 1.000 | N/A | N/A | N/A |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUN2021 13:37
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Table 4.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| PD | n | 29 | 29 | 29 | 29 | 29 | 29 |
| | Mean | 2.9 | -3.4 | -5.7 | 5.7 | 0.0 | -2.3 |
| | SD | 17.86 | 31.30 | 29.64 | 32.21 | 23.57 | 36.66 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 33.3 | 0.0, 0.0 | -33.3, 0.0 |
| | Min, Max | -33, 50 | -67, 67 | -100, 67 | -33,100 | -33, 67 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.450 | 0.879 | 0.472 | 0.456 | 1.000 | 0.607 |
| CR | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Mean | 0.0 | 0.0 | -33.3 | 0.0 | 0.0 | 0.0 |
| | SD | | | | | | |
| | Median | 0.0 | 0.0 | -33.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3,-33.3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | 0, 0 | 0, 0 | -33,-33 | 0, 0 | 0, 0 | 0, 0 |
| | p-value for Comparison to Zero [b] | N/A | N/A | 1.000 | N/A | N/A | N/A |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Cut-off date: 21DEC2020

Table 4.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| End of Study | n | 9 | 9 | 9 | 9 | 9 | 9 |
| | Mean | -1.9 | 3.7 | -7.4 | -11.1 | -11.1 | -11.1 |
| | SD | 10.02 | 20.03 | 43.39 | 23.57 | 16.67 | 23.57 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 33.3 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 0.0 |
| | Min, Max | -17, 17 | -33, 33 | -100, 33 | -33, 33 | -33, 0 | -67, 0 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 | 1.000 | 0.375 | 0.250 | 0.500 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Cut-off date: 21DEC2020

Table 4.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 | 110 |
| | Mean | 15.2 | 0.3 | 2.7 | 23.6 | 13.3 | -0.6 |
| | SD | 18.83 | 23.68 | 26.76 | 31.07 | 31.35 | 28.55 |
| | Median | 16.7 | 0.0 | 0.0 | 33.3 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -33,100 | -67, 67 | -67, 67 | -67,100 | -67,100 | -67, 67 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.925 | 0.432 | <0.001 | <0.001 | 0.925 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 | 107 |
| | Mean | -0.0 | 2.8 | -3.7 | 10.6 | -0.3 | -0.6 |
| | SD | 18.88 | 29.72 | 29.79 | 30.23 | 26.50 | 27.08 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -83, 67 | -67,100 | -100, 67 | -67,100 | -67,100 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.819 | 0.397 | 0.215 | 0.001 | 0.873 | 0.827 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUL2021 14:20
Analysis Plan: 12MAY2021 Confidential

Table 4.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 | 97 |
| | Mean | -0.5 | 1.4 | -1.4 | 4.5 | -1.7 | 1.0 |
| | SD | 13.91 | 24.49 | 27.18 | 24.83 | 21.18 | 25.66 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -67, 67 | -67, 67 | -67, 67 | -100, 67 | -100, 67 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.848 | 0.697 | 0.644 | 0.098 | 0.492 | 0.656 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 | 84 |
| | Mean | 0.2 | -4.4 | -3.2 | 3.2 | -5.2 | 0.8 |
| | SD | 12.27 | 23.59 | 26.19 | 27.68 | 26.13 | 25.86 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 16.7 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -33, 67 | -67, 67 | -67, 67 | -67,100 | -100, 67 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.929 | 0.083 | 0.270 | 0.545 | 0.083 | 0.768 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 | 78 |
| | Mean | 0.4 | -2.1 | -6.0 | 1.7 | -6.0 | 0.4 |
| | SD | 16.77 | 23.01 | 22.63 | 25.71 | 25.62 | 26.04 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -33,100 | -67, 33 | -100, 33 | -100,100 | -100, 33 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.702 | 0.326 | 0.016 | 0.766 | 0.042 | 0.731 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 | 76 |
| | Mean | -1.1 | -3.9 | -7.0 | 0.0 | -5.3 | -2.2 |
| | SD | 10.66 | 25.51 | 25.71 | 21.08 | 25.56 | 28.98 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 | -16.7, 0.0 |
| | Min, Max | -33, 33 | -100, 67 | -100, 33 | -67, 67 | -100, 67 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.478 | 0.193 | 0.014 | 0.950 | 0.078 | 0.427 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 | 75 |
| | Mean | -1.3 | -0.9 | -10.7 | 2.2 | -5.8 | -4.0 |
| | SD | 13.07 | 25.10 | 25.21 | 19.25 | 27.60 | 28.98 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 |
| | Min, Max | -67, 50 | -100, 67 | -100, 33 | -67, 67 | -100,100 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.400 | 0.803 | <0.001 | 0.557 | 0.051 | 0.172 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 | 58 |
| | Mean | 0.0 | -5.7 | -13.2 | -1.7 | -4.0 | -6.3 |
| | SD | 13.25 | 22.63 | 24.13 | 18.12 | 22.58 | 19.20 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -17, 50 | -67, 33 | -67, 33 | -67, 33 | -67, 67 | -67, 33 |
| | p-value for Comparison to Zero [b] | 0.847 | 0.058 | <0.001 | 0.464 | 0.212 | 0.023 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 | 54 |
| | Mean | 0.0 | -6.2 | -5.6 | -1.9 | -6.8 | -4.9 |
| | SD | 14.84 | 24.29 | 24.87 | 18.79 | 20.86 | 24.58 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -17, 67 | -100, 33 | -67, 67 | -67, 33 | -67, 33 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.695 | 0.058 | 0.092 | 0.441 | 0.029 | 0.186 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 | 31 |
| | Mean | -0.5 | -3.2 | -5.4 | 7.5 | 0.0 | -4.3 |
| | SD | 9.11 | 30.25 | 19.43 | 28.17 | 27.22 | 22.35 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -17, 17 | -67, 67 | -33, 33 | -33, 67 | -67,100 | -67, 67 |
| | p-value for Comparison to Zero [b] | 1.000 | 0.666 | 0.183 | 0.177 | 1.000 | 0.438 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 | 25 |
| | Mean | -2.0 | -1.3 | -6.7 | 1.3 | -2.7 | 0.0 |
| | SD | 15.46 | 22.53 | 19.25 | 22.53 | 16.44 | 23.57 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -50, 33 | -67, 33 | -33, 33 | -33, 67 | -33, 33 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.684 | 1.000 | 0.180 | 1.000 | 0.688 | 1.000 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 | 26 |
| | Mean | 1.9 | 0.0 | -11.5 | 3.8 | -9.0 | -3.8 |
| | SD | 23.25 | 29.81 | 26.57 | 33.10 | 20.13 | 27.21 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 |
| | Min, Max | -67, 50 | -67, 67 | -100, 33 | -67,100 | -67, 33 | -67, 33 |
| | p-value for Comparison to Zero [b] | 0.703 | 0.945 | 0.109 | 0.781 | 0.063 | 0.608 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 | 13 |
| | Mean | -2.6 | -7.7 | 2.6 | -5.1 | -10.3 | -10.3 |
| | SD | 11.48 | 24.17 | 21.35 | 22.96 | 21.01 | 21.01 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 0.0 | 0.0, 0.0 | 0.0, 0.0 | -33.3, 0.0 | 0.0, 0.0 | -33.3, 0.0 |
| | Min, Max | -17, 17 | -67, 33 | -33, 33 | -33, 33 | -67, 0 | -33, 33 |
| | p-value for Comparison to Zero [b] | 0.688 | 0.500 | 1.000 | 0.531 | 0.250 | 0.219 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Mean | -16.7 | -33.3 | 0.0 | -33.3 | 0.0 | -33.3 |
| | SD | | | | | | |
| | Median | -16.7 | -33.3 | 0.0 | -33.3 | 0.0 | -33.3 |
| | Q1, Q3 | -16.7,-16.7 | -33.3,-33.3 | 0.0, 0.0 | -33.3,-33.3 | 0.0, 0.0 | -33.3,-33.3 |
| | Min, Max | -17,-17 | -33,-33 | 0, 0 | -33,-33 | 0, 0 | -33,-33 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 | N/A | 1.000 | N/A | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| PD | n | 29 | 29 | 29 | 29 | 29 | 29 |
| | Mean | 5.7 | 0.0 | -2.3 | 6.9 | 1.1 | -2.3 |
| | SD | 14.96 | 39.84 | 32.04 | 39.22 | 24.37 | 29.45 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 33.3 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | -17, 50 | -100,100 | -67, 67 | -100,100 | -67, 67 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.065 | 0.974 | 0.711 | 0.449 | 0.973 | 0.800 |
| CR | n | 1 | 1 | 1 | 1 | 1 | 1 |
| | Mean | 0.0 | 33.3 | -33.3 | 0.0 | 0.0 | 0.0 |
| | SD | | | | | | |
| | Median | 0.0 | 33.3 | -33.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 33.3, 33.3 | -33.3,-33.3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | 0, 0 | 33, 33 | -33,-33 | 0, 0 | 0, 0 | 0, 0 |
| | p-value for Comparison to Zero [b] | N/A | 1.000 | 1.000 | N/A | N/A | N/A |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Symptom Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | | |
|---|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Nausea/Vomiting | Dyspnoea | Insomnia | Appetite Loss | Constipation | Diarrhoea |
| End of Study | n | 9 | 9 | 9 | 9 | 9 | 9 |
| | Mean | 9.3 | 14.8 | 0.0 | 0.0 | -3.7 | 0.0 |
| | SD | 18.84 | 17.57 | 28.87 | 16.67 | 11.11 | 16.67 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 | -33.3, 33.3 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | 0, 50 | 0, 33 | -33, 33 | -33, 33 | -33, 0 | -33, 33 |
| | p-value for Comparison to Zero [b] | 0.500 | 0.125 | 1.000 | 1.000 | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.

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## 4.2 Symptomatik gemessen anhand der Symptomskalen des EORTC QLQ-MY20 (Datenschnitt vom 21.12.2020)

- Exploratory Responder Definition MCID = 15
- Responder definition (RD) MCID = + 11 / -16 (disease symptoms) and MCID = +9 / - 6 (body image)
- Exploratory Responder Definition MCID = 10 (with baseline defined as the screening visit)
- Exploratory Responder Definition MCID = 15 (with baseline defined as the screening visit)
- Responder definition (RD) MCID = + 11 / -16 (disease symptoms) and MCID = +9 / - 6 (body image) (with baseline defined as the screening visit)
- Scores by timepoint
- Change of scores from baseline (with baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy)
- Change of scores from baseline (with baseline defined as screening visit)

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Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint

Table 6.6.3d
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Disease Symptoms | Side Effects |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 15 ( 13.6) | 2 ( 1.8) |
| | No Change - n(%) | 85 ( 77.3) | 100 ( 90.9) |
| | Deterioration - n(%) | 10 ( 9.1) | 8 ( 7.3) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 37 ( 34.6) | 10 ( 9.3) |
| | No Change - n(%) | 60 ( 56.1) | 87 ( 81.3) |
| | Deterioration - n(%) | 10 ( 9.3) | 10 ( 9.3) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

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Table 6.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 2 | n | 96 | 96 |
| | Improvement - n(%) | 30 ( 31.3) | 8 ( 8.3) |
| | No Change - n(%) | 57 ( 59.4) | 84 ( 87.5) |
| | Deterioration - n(%) | 9 ( 9.4) | 4 ( 4.2) |
| | Missing | 26 | 26 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 34 ( 40.5) | 8 ( 9.5) |
| | No Change - n(%) | 45 ( 53.6) | 71 ( 84.5) |
| | Deterioration - n(%) | 5 ( 6.0) | 5 ( 6.0) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

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Table 6.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Disease Symptoms | Side Effects |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 31 ( 39.7) | 14 ( 17.9) |
| | No Change - n(%) | 45 ( 57.7) | 61 ( 78.2) |
| | Deterioration - n(%) | 2 ( 2.6) | 3 ( 3.8) |
| | Missing | 44 | 44 |
| Month 5 | n | 75 | 75 |
| | Improvement - n(%) | 29 ( 38.7) | 8 ( 10.7) |
| | No Change - n(%) | 42 ( 56.0) | 66 ( 88.0) |
| | Deterioration - n(%) | 4 ( 5.3) | 1 ( 1.3) |
| | Missing | 47 | 47 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

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Table 6.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Disease Symptoms | Side Effects |
| Month 6 | n | 74 | 74 |
| | Improvement - n(%) | 24 ( 32.4) | 10 ( 13.5) |
| | No Change - n(%) | 47 ( 63.5) | 63 ( 85.1) |
| | Deterioration - n(%) | 3 ( 4.1) | 1 ( 1.4) |
| | Missing | 48 | 48 |
| Month 9 | n | 57 | 57 |
| | Improvement - n(%) | 26 ( 45.6) | 8 ( 14.0) |
| | No Change - n(%) | 27 ( 47.4) | 49 ( 86.0) |
| | Deterioration - n(%) | 4 ( 7.0) | 0 |
| | Missing | 65 | 65 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

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Table 6.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Disease Symptoms | Side Effects |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 28 ( 51.9) | 8 ( 14.8) |
| | No Change - n(%) | 21 ( 38.9) | 44 ( 81.5) |
| | Deterioration - n(%) | 5 ( 9.3) | 2 ( 3.7) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 15 ( 48.4) | 3 ( 9.7) |
| | No Change - n(%) | 14 ( 45.2) | 27 ( 87.1) |
| | Deterioration - n(%) | 2 ( 6.5) | 1 ( 3.2) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

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Table 6.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 9 ( 36.0) | 4 ( 16.0) |
| | No Change - n(%) | 14 ( 56.0) | 20 ( 80.0) |
| | Deterioration - n(%) | 2 ( 8.0) | 1 ( 4.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 8 ( 30.8) | 2 ( 7.7) |
| | No Change - n(%) | 16 ( 61.5) | 22 ( 84.6) |
| | Deterioration - n(%) | 2 ( 7.7) | 2 ( 7.7) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

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Table 6.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 4 ( 30.8) | 1 ( 7.7) |
| | No Change - n(%) | 8 ( 61.5) | 12 ( 92.3) |
| | Deterioration - n(%) | 1 ( 7.7) | 0 |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 0 | 1 (100.0) |
| | No Change - n(%) | 0 | 0 |
| | Deterioration - n(%) | 1 (100.0) | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Analysis Plan: 12MAY2021 Confidential

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Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 6.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 9 ( 31.0) | 3 ( 10.3) |
| | No Change - n(%) | 16 ( 55.2) | 24 ( 82.8) |
| | Deterioration - n(%) | 4 ( 13.8) | 2 ( 6.9) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 0 |
| | No Change - n(%) | 0 | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

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Date/time of run: 12JUL2021 16:20
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Cut-off date: 21DEC2020

Table 6.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 7 ( 77.8) | 9 (100.0) |
| | Deterioration - n(%) | 2 ( 22.2) | 0 |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.

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Cut-off date: 21DEC2020

Table 6.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 15 ( 13.6) | 15 ( 13.6) |
| | No Change - n(%) | 73 ( 66.4) | 69 ( 62.7) |
| | Deterioration - n(%) | 22 ( 20.0) | 26 ( 23.6) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 37 ( 34.6) | 28 ( 26.2) |
| | No Change - n(%) | 57 ( 53.3) | 63 ( 58.9) |
| | Deterioration - n(%) | 13 ( 12.1) | 16 ( 15.0) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.

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Table 6.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 2 | n | 96 | 96 |
| | Improvement - n(%) | 30 ( 31.3) | 32 ( 33.3) |
| | No Change - n(%) | 51 ( 53.1) | 53 ( 55.2) |
| | Deterioration - n(%) | 15 ( 15.6) | 11 ( 11.5) |
| | Missing | 26 | 26 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 34 ( 40.5) | 29 ( 34.5) |
| | No Change - n(%) | 41 ( 48.8) | 42 ( 50.0) |
| | Deterioration - n(%) | 9 ( 10.7) | 13 ( 15.5) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.

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Table 6.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 31 ( 39.7) | 27 ( 34.6) |
| | No Change - n(%) | 40 ( 51.3) | 41 ( 52.6) |
| | Deterioration - n(%) | 7 ( 9.0) | 10 ( 12.8) |
| | Missing | 44 | 44 |
| Month 5 | n | 75 | 75 |
| | Improvement - n(%) | 29 ( 38.7) | 25 ( 33.3) |
| | No Change - n(%) | 40 ( 53.3) | 48 ( 64.0) |
| | Deterioration - n(%) | 6 ( 8.0) | 2 ( 2.7) |
| | Missing | 47 | 47 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.

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Table 6.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 6 | n | 74 | 74 |
| | Improvement - n(%) | 24 ( 32.4) | 28 ( 37.8) |
| | No Change - n(%) | 43 ( 58.1) | 43 ( 58.1) |
| | Deterioration - n(%) | 7 ( 9.5) | 3 ( 4.1) |
| | Missing | 48 | 48 |
| Month 9 | n | 57 | 57 |
| | Improvement - n(%) | 26 ( 45.6) | 23 ( 40.4) |
| | No Change - n(%) | 27 ( 47.4) | 33 ( 57.9) |
| | Deterioration - n(%) | 4 ( 7.0) | 1 ( 1.8) |
| | Missing | 65 | 65 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.

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Table 6.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 28 ( 51.9) | 23 ( 42.6) |
| | No Change - n(%) | 20 ( 37.0) | 27 ( 50.0) |
| | Deterioration - n(%) | 6 ( 11.1) | 4 ( 7.4) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 15 ( 48.4) | 13 ( 41.9) |
| | No Change - n(%) | 11 ( 35.5) | 16 ( 51.6) |
| | Deterioration - n(%) | 5 ( 16.1) | 2 ( 6.5) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.

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Table 6.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 9 ( 36.0) | 9 ( 36.0) |
| | No Change - n(%) | 13 ( 52.0) | 13 ( 52.0) |
| | Deterioration - n(%) | 3 ( 12.0) | 3 ( 12.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 8 ( 30.8) | 10 ( 38.5) |
| | No Change - n(%) | 14 ( 53.8) | 14 ( 53.8) |
| | Deterioration - n(%) | 4 ( 15.4) | 2 ( 7.7) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.

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Table 6.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 4 ( 30.8) | 5 ( 38.5) |
| | No Change - n(%) | 8 ( 61.5) | 7 ( 53.8) |
| | Deterioration - n(%) | 1 ( 7.7) | 1 ( 7.7) |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 0 | 1 (100.0) |
| | No Change - n(%) | 0 | 0 |
| | Deterioration - n(%) | 1 (100.0) | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.

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Table 6.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 9 ( 31.0) | 10 ( 34.5) |
| | No Change - n(%) | 14 ( 48.3) | 13 ( 44.8) |
| | Deterioration - n(%) | 6 ( 20.7) | 6 ( 20.7) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 0 |
| | No Change - n(%) | 0 | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.

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Table 6.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 6 ( 66.7) | 8 ( 88.9) |
| | Deterioration - n(%) | 3 ( 33.3) | 1 ( 11.1) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.

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Table 6.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 21 ( 19.1) | 12 ( 10.9) |
| | No Change - n(%) | 48 ( 43.6) | 71 ( 64.5) |
| | Deterioration - n(%) | 41 ( 37.3) | 27 ( 24.5) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 34 ( 31.8) | 14 ( 13.1) |
| | No Change - n(%) | 50 ( 46.7) | 73 ( 68.2) |
| | Deterioration - n(%) | 23 ( 21.5) | 20 ( 18.7) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 30JUL2021 15:19
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Table 6.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 2 | n | 96 | 96 |
| | Improvement - n(%) | 29 ( 30.2) | 15 ( 15.6) |
| | No Change - n(%) | 42 ( 43.8) | 72 ( 75.0) |
| | Deterioration - n(%) | 25 ( 26.0) | 9 ( 9.4) |
| | Missing | 26 | 26 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 32 ( 38.1) | 12 ( 14.3) |
| | No Change - n(%) | 37 ( 44.0) | 61 ( 72.6) |
| | Deterioration - n(%) | 15 ( 17.9) | 11 ( 13.1) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Date/time of run: 30JUL2021 15:19
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Table 6.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 35 ( 44.9) | 16 ( 20.5) |
| | No Change - n(%) | 32 ( 41.0) | 55 ( 70.5) |
| | Deterioration - n(%) | 11 ( 14.1) | 7 ( 9.0) |
| | Missing | 44 | 44 |
| Month 5 | n | 75 | 75 |
| | Improvement - n(%) | 37 ( 49.3) | 18 ( 24.0) |
| | No Change - n(%) | 26 ( 34.7) | 55 ( 73.3) |
| | Deterioration - n(%) | 12 ( 16.0) | 2 ( 2.7) |
| | Missing | 47 | 47 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 6 | n | 74 | 74 |
| | Improvement - n(%) | 28 ( 37.8) | 18 ( 24.3) |
| | No Change - n(%) | 34 ( 45.9) | 52 ( 70.3) |
| | Deterioration - n(%) | 12 ( 16.2) | 4 ( 5.4) |
| | Missing | 48 | 48 |
| Month 9 | n | 57 | 57 |
| | Improvement - n(%) | 28 ( 49.1) | 16 ( 28.1) |
| | No Change - n(%) | 23 ( 40.4) | 39 ( 68.4) |
| | Deterioration - n(%) | 6 ( 10.5) | 2 ( 3.5) |
| | Missing | 65 | 65 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 23 ( 42.6) | 12 ( 22.2) |
| | No Change - n(%) | 23 ( 42.6) | 37 ( 68.5) |
| | Deterioration - n(%) | 8 ( 14.8) | 5 ( 9.3) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 16 ( 51.6) | 8 ( 25.8) |
| | No Change - n(%) | 11 ( 35.5) | 20 ( 64.5) |
| | Deterioration - n(%) | 4 ( 12.9) | 3 ( 9.7) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 12 ( 48.0) | 6 ( 24.0) |
| | No Change - n(%) | 11 ( 44.0) | 16 ( 64.0) |
| | Deterioration - n(%) | 2 ( 8.0) | 3 ( 12.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 10 ( 38.5) | 6 ( 23.1) |
| | No Change - n(%) | 9 ( 34.6) | 18 ( 69.2) |
| | Deterioration - n(%) | 7 ( 26.9) | 2 ( 7.7) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 6 ( 46.2) | 3 ( 23.1) |
| | No Change - n(%) | 6 ( 46.2) | 10 ( 76.9) |
| | Deterioration - n(%) | 1 ( 7.7) | 0 |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 10 ( 34.5) | 2 ( 6.9) |
| | No Change - n(%) | 10 ( 34.5) | 20 ( 69.0) |
| | Deterioration - n(%) | 9 ( 31.0) | 7 ( 24.1) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 1 (100.0) |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Protocol: BB2121-MM-001


Cut-off date: 21DEC2020

Table 6.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 3 ( 33.3) | 1 ( 11.1) |
| | No Change - n(%) | 3 ( 33.3) | 6 ( 66.7) |
| | Deterioration - n(%) | 3 ( 33.3) | 2 ( 22.2) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS

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Cut-off date: 21DEC2020

Table 6.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 13 ( 11.8) | 5 ( 4.5) |
| | No Change - n(%) | 63 ( 57.3) | 89 ( 80.9) |
| | Deterioration - n(%) | 34 ( 30.9) | 16 ( 14.5) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 29 ( 27.1) | 8 ( 7.5) |
| | No Change - n(%) | 62 ( 57.9) | 87 ( 81.3) |
| | Deterioration - n(%) | 16 ( 15.0) | 12 ( 11.2) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 6.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Disease Symptoms | Side Effects |
| Month 2 | n | 96 | 96 |
| | Improvement - n(%) | 20 ( 20.8) | 7 ( 7.3) |
| | No Change - n(%) | 60 ( 62.5) | 80 ( 83.3) |
| | Deterioration - n(%) | 16 ( 16.7) | 9 ( 9.4) |
| | Missing | 26 | 26 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 22 ( 26.2) | 6 ( 7.1) |
| | No Change - n(%) | 54 ( 64.3) | 75 ( 89.3) |
| | Deterioration - n(%) | 8 ( 9.5) | 3 ( 3.6) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 22 ( 28.2) | 7 ( 9.0) |
| | No Change - n(%) | 50 ( 64.1) | 66 ( 84.6) |
| | Deterioration - n(%) | 6 ( 7.7) | 5 ( 6.4) |
| | Missing | 44 | 44 |
| Month 5 | n | 75 | 75 |
| | Improvement - n(%) | 23 ( 30.7) | 6 ( 8.0) |
| | No Change - n(%) | 46 ( 61.3) | 67 ( 89.3) |
| | Deterioration - n(%) | 6 ( 8.0) | 2 ( 2.7) |
| | Missing | 47 | 47 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 6 | n | 74 | 74 |
| | Improvement - n(%) | 20 ( 27.0) | 9 ( 12.2) |
| | No Change - n(%) | 47 ( 63.5) | 65 ( 87.8) |
| | Deterioration - n(%) | 7 ( 9.5) | 0 |
| | Missing | 48 | 48 |
| Month 9 | n | 57 | 57 |
| | Improvement - n(%) | 19 ( 33.3) | 7 ( 12.3) |
| | No Change - n(%) | 36 ( 63.2) | 50 ( 87.7) |
| | Deterioration - n(%) | 2 ( 3.5) | 0 |
| | Missing | 65 | 65 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 18 ( 33.3) | 6 ( 11.1) |
| | No Change - n(%) | 32 ( 59.3) | 45 ( 83.3) |
| | Deterioration - n(%) | 4 ( 7.4) | 3 ( 5.6) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 10 ( 32.3) | 2 ( 6.5) |
| | No Change - n(%) | 19 ( 61.3) | 28 ( 90.3) |
| | Deterioration - n(%) | 2 ( 6.5) | 1 ( 3.2) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 8 ( 32.0) | 3 ( 12.0) |
| | No Change - n(%) | 16 ( 64.0) | 20 ( 80.0) |
| | Deterioration - n(%) | 1 ( 4.0) | 2 ( 8.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 7 ( 26.9) | 3 ( 11.5) |
| | No Change - n(%) | 15 ( 57.7) | 21 ( 80.8) |
| | Deterioration - n(%) | 4 ( 15.4) | 2 ( 7.7) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 5 ( 38.5) | 0 |
| | No Change - n(%) | 7 ( 53.8) | 13 (100.0) |
| | Deterioration - n(%) | 1 ( 7.7) | 0 |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 7 ( 24.1) | 1 ( 3.4) |
| | No Change - n(%) | 17 ( 58.6) | 23 ( 79.3) |
| | Deterioration - n(%) | 5 ( 17.2) | 5 ( 17.2) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 2 ( 22.2) | 0 |
| | No Change - n(%) | 4 ( 44.4) | 8 ( 88.9) |
| | Deterioration - n(%) | 3 ( 33.3) | 1 ( 11.1) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 13 ( 11.8) | 25 ( 22.7) |
| | No Change - n(%) | 56 ( 50.9) | 55 ( 50.0) |
| | Deterioration - n(%) | 41 ( 37.3) | 30 ( 27.3) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 29 ( 27.1) | 24 ( 22.4) |
| | No Change - n(%) | 55 ( 51.4) | 63 ( 58.9) |
| | Deterioration - n(%) | 23 ( 21.5) | 20 ( 18.7) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 2 | n | 96 | 96 |
| | Improvement - n(%) | 20 ( 20.8) | 28 ( 29.2) |
| | No Change - n(%) | 51 ( 53.1) | 58 ( 60.4) |
| | Deterioration - n(%) | 25 ( 26.0) | 10 ( 10.4) |
| | Missing | 26 | 26 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 22 ( 26.2) | 21 ( 25.0) |
| | No Change - n(%) | 47 ( 56.0) | 52 ( 61.9) |
| | Deterioration - n(%) | 15 ( 17.9) | 11 ( 13.1) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 22 ( 28.2) | 24 ( 30.8) |
| | No Change - n(%) | 45 ( 57.7) | 46 ( 59.0) |
| | Deterioration - n(%) | 11 ( 14.1) | 8 ( 10.3) |
| | Missing | 44 | 44 |
| Month 5 | n | 75 | 75 |
| | Improvement - n(%) | 23 ( 30.7) | 27 ( 36.0) |
| | No Change - n(%) | 40 ( 53.3) | 44 ( 58.7) |
| | Deterioration - n(%) | 12 ( 16.0) | 4 ( 5.3) |
| | Missing | 47 | 47 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 6 | n | 74 | 74 |
| | Improvement - n(%) | 20 ( 27.0) | 32 ( 43.2) |
| | No Change - n(%) | 42 ( 56.8) | 38 ( 51.4) |
| | Deterioration - n(%) | 12 ( 16.2) | 4 ( 5.4) |
| | Missing | 48 | 48 |
| Month 9 | n | 57 | 57 |
| | Improvement - n(%) | 19 ( 33.3) | 28 ( 49.1) |
| | No Change - n(%) | 32 ( 56.1) | 27 ( 47.4) |
| | Deterioration - n(%) | 6 ( 10.5) | 2 ( 3.5) |
| | Missing | 65 | 65 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 18 ( 33.3) | 21 ( 38.9) |
| | No Change - n(%) | 28 ( 51.9) | 28 ( 51.9) |
| | Deterioration - n(%) | 8 ( 14.8) | 5 ( 9.3) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 10 ( 32.3) | 11 ( 35.5) |
| | No Change - n(%) | 17 ( 54.8) | 17 ( 54.8) |
| | Deterioration - n(%) | 4 ( 12.9) | 3 ( 9.7) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 8 ( 32.0) | 11 ( 44.0) |
| | No Change - n(%) | 15 ( 60.0) | 11 ( 44.0) |
| | Deterioration - n(%) | 2 ( 8.0) | 3 ( 12.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 7 ( 26.9) | 9 ( 34.6) |
| | No Change - n(%) | 12 ( 46.2) | 14 ( 53.8) |
| | Deterioration - n(%) | 7 ( 26.9) | 3 ( 11.5) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 5 ( 38.5) | 4 ( 30.8) |
| | No Change - n(%) | 7 ( 53.8) | 9 ( 69.2) |
| | Deterioration - n(%) | 1 ( 7.7) | 0 |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 0 | 1 (100.0) |
| | No Change - n(%) | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 7 ( 24.1) | 9 ( 31.0) |
| | No Change - n(%) | 13 ( 44.8) | 13 ( 44.8) |
| | Deterioration - n(%) | 9 ( 31.0) | 7 ( 24.1) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 1 (100.0) |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Disease Symptoms | Side Effects |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 2 ( 22.2) | 1 ( 11.1) |
| | No Change - n(%) | 4 ( 44.4) | 6 ( 66.7) |
| | Deterioration - n(%) | 3 ( 33.3) | 2 ( 22.2) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: <=-16 for improvement and >=+11 for worsening on Disease Symptoms; <=-6 for improvement and >=+9 for worsening on Side Effects.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Cut-off date: 21DEC2020

Table 6.4d
Scores on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Screening | n | 117 | 117 |
| | Mean | 27.6 | 17.4 |
| | SD | 21.67 | 13.25 |
| | Median | 27.8 | 14.8 |
| | Q1, Q3 | 11.1, 38.9 | 7.4, 25.9 |
| | Min, Max | 0,100 | 0, 59 |
| Baseline Evaluations | n | 122 | 122 |
| | Mean | 32.6 | 18.2 |
| | SD | 23.53 | 14.64 |
| | Median | 27.8 | 14.8 |
| | Q1, Q3 | 16.7, 50.0 | 7.4, 25.9 |
| | Min, Max | 0, 89 | 0, 67 |
| Day 1 | n | 110 | 110 |
| | Mean | 30.9 | 19.9 |
| | SD | 22.17 | 13.22 |
| | Median | 27.8 | 18.5 |
| | Q1, Q3 | 11.1, 50.0 | 11.1, 25.9 |
| | Min, Max | 0, 94 | 0, 63 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
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Table 6.4d
Scores on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 1 | n | 107 | 107 |
| | Mean | 23.3 | 18.3 |
| | SD | 18.93 | 16.82 |
| | Median | 16.7 | 14.8 |
| | Q1, Q3 | 11.1, 33.3 | 3.7, 25.9 |
| | Min, Max | 0, 78 | 0, 90 |
| Month 2 | n | 96 | 96 |
| | Mean | 23.7 | 15.3 |
| | SD | 19.60 | 14.45 |
| | Median | 22.2 | 11.1 |
| | Q1, Q3 | 11.1, 33.3 | 3.7, 20.0 |
| | Min, Max | 0, 83 | 0, 67 |
| Month 3 | n | 84 | 84 |
| | Mean | 20.6 | 14.0 |
| | SD | 16.74 | 12.64 |
| | Median | 19.4 | 11.1 |
| | Q1, Q3 | 5.6, 27.8 | 3.7, 19.3 |
| | Min, Max | 0, 67 | 0, 53 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
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Table 6.4d
Scores on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Disease Symptoms | Side Effects |
| Month 4 | n | 78 | 78 |
| | Mean | 19.7 | 14.0 |
| | SD | 15.63 | 14.01 |
| | Median | 22.2 | 10.6 |
| | Q1, Q3 | 5.6, 27.8 | 3.7, 22.2 |
| | Min, Max | 0, 61 | 0, 53 |
| Month 5 | n | 75 | 75 |
| | Mean | 18.8 | 12.0 |
| | SD | 14.78 | 12.99 |
| | Median | 16.7 | 7.4 |
| | Q1, Q3 | 11.1, 27.8 | 3.7, 14.8 |
| | Min, Max | 0, 61 | 0, 67 |
| Month 6 | n | 74 | 74 |
| | Mean | 20.7 | 11.7 |
| | SD | 17.14 | 10.78 |
| | Median | 19.4 | 7.4 |
| | Q1, Q3 | 5.6, 33.3 | 3.7, 14.8 |
| | Min, Max | 0, 67 | 0, 43 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
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Table 6.4d
Scores on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Disease Symptoms | Side Effects |
| Month 9 | n | 57 | 57 |
| | Mean | 18.0 | 8.6 |
| | SD | 16.07 | 9.28 |
| | Median | 16.7 | 7.4 |
| | Q1, Q3 | 5.6, 22.2 | 3.7, 11.1 |
| | Min, Max | 0, 61 | 0, 44 |
| Month 12 | n | 54 | 54 |
| | Mean | 20.3 | 12.3 |
| | SD | 18.79 | 12.92 |
| | Median | 16.7 | 7.4 |
| | Q1, Q3 | 5.6, 27.8 | 3.7, 18.5 |
| | Min, Max | 0, 78 | 0, 48 |
| Month 15 | n | 31 | 31 |
| | Mean | 21.1 | 13.2 |
| | SD | 19.85 | 15.07 |
| | Median | 22.2 | 7.4 |
| | Q1, Q3 | 5.6, 33.3 | 3.7, 18.5 |
| | Min, Max | 0, 89 | 0, 63 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
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Table 6.4d
Scores on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 18 | n | 25 | 25 |
| | Mean | 16.2 | 10.9 |
| | SD | 10.87 | 12.17 |
| | Median | 16.7 | 7.4 |
| | Q1, Q3 | 5.6, 22.2 | 3.7, 14.8 |
| | Min, Max | 0, 33 | 0, 47 |
| Month 21 | n | 26 | 26 |
| | Mean | 19.4 | 12.9 |
| | SD | 14.68 | 16.39 |
| | Median | 16.7 | 7.4 |
| | Q1, Q3 | 5.6, 27.8 | 3.7, 11.1 |
| | Min, Max | 0, 50 | 0, 63 |
| Month 24 | n | 13 | 13 |
| | Mean | 11.1 | 10.9 |
| | SD | 15.55 | 10.88 |
| | Median | 5.6 | 7.4 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 18.5 |
| | Min, Max | 0, 56 | 0, 30 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
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Table 6.4d
Scores on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 30 | n | 1 | 1 |
| | Mean | 16.7 | 11.1 |
| | SD | | |
| | Median | 16.7 | 11.1 |
| | Q1, Q3 | 16.7, 16.7 | 11.1, 11.1 |
| | Min, Max | 17, 17 | 11, 11 |
| PD | n | 29 | 29 |
| | Mean | 25.5 | 17.6 |
| | SD | 17.73 | 12.95 |
| | Median | 22.2 | 18.5 |
| | Q1, Q3 | 16.7, 38.9 | 7.4, 25.9 |
| | Min, Max | 0, 61 | 0, 52 |
| CR | n | 1 | 1 |
| | Mean | 22.2 | 22.2 |
| | SD | | |
| | Median | 22.2 | 22.2 |
| | Q1, Q3 | 22.2, 22.2 | 22.2, 22.2 |
| | Min, Max | 22, 22 | 22, 22 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
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Table 6.4d
Scores on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| End of Study | n | 9 | 9 |
| | Mean | 24.7 | 12.0 |
| | SD | 18.03 | 7.56 |
| | Median | 22.2 | 11.1 |
| | Q1, Q3 | 11.1, 33.3 | 7.4, 14.8 |
| | Min, Max | 0, 56 | 0, 26 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 6.5d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Day 1 | n | 110 | 110 |
| | Mean | -1.1 | 2.3 |
| | SD | 13.68 | 9.20 |
| | Median | 0.0 | 0.9 |
| | Q1, Q3 | -5.6, 5.6 | -3.7, 7.4 |
| | Min, Max | -50, 39 | -26, 22 |
| | p-value for Comparison to Zero [b] | 0.478 | 0.010 |
| Month 1 | n | 107 | 107 |
| | Mean | -10.5 | -0.0 |
| | SD | 18.50 | 12.06 |
| | Median | -11.1 | 0.0 |
| | Q1, Q3 | -27.8, 0.0 | -7.4, 4.8 |
| | Min, Max | -78, 28 | -37, 34 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.775 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 6.5d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 2 | n | 96 | 96 |
| | Mean | -7.5 | -2.1 |
| | SD | 19.41 | 10.33 |
| | Median | -5.6 | -2.6 |
| | Q1, Q3 | -16.7, 5.6 | -8.1, 3.5 |
| | Min, Max | -67, 56 | -30, 29 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.013 |
| Month 3 | n | 84 | 84 |
| | Mean | -11.4 | -2.8 |
| | SD | 20.08 | 11.51 |
| | Median | -5.6 | -3.7 |
| | Q1, Q3 | -16.7, 0.0 | -9.3, 3.7 |
| | Min, Max | -78, 39 | -37, 26 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.020 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 4 | n | 78 | 78 |
| | Mean | -12.8 | -3.4 |
| | SD | 18.98 | 12.04 |
| | Median | -11.1 | -2.2 |
| | Q1, Q3 | -22.2, 0.0 | -11.1, 3.7 |
| | Min, Max | -78, 17 | -37, 26 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.014 |
| Month 5 | n | 75 | 75 |
| | Mean | -14.1 | -4.7 |
| | SD | 20.31 | 9.81 |
| | Median | -5.6 | -3.7 |
| | Q1, Q3 | -27.8, 0.0 | -7.4, 0.0 |
| | Min, Max | -67, 28 | -41, 19 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 6 | n | 74 | 74 |
| | Mean | -12.8 | -4.7 |
| | SD | 20.90 | 10.22 |
| | Median | -5.6 | -3.7 |
| | Q1, Q3 | -22.2, 0.0 | -11.1, 0.0 |
| | Min, Max | -78, 28 | -44, 19 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 |
| Month 9 | n | 57 | 57 |
| | Mean | -14.7 | -6.7 |
| | SD | 20.29 | 10.34 |
| | Median | -11.1 | -3.7 |
| | Q1, Q3 | -22.2, 0.0 | -12.2, 0.0 |
| | Min, Max | -78, 17 | -48, 15 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 6.5d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 12 | n | 54 | 54 |
| | Mean | -15.9 | -4.1 |
| | SD | 23.40 | 11.97 |
| | Median | -16.7 | -2.4 |
| | Q1, Q3 | -27.8, 0.0 | -11.1, 3.3 |
| | Min, Max | -72, 33 | -33, 30 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.007 |
| Month 15 | n | 31 | 31 |
| | Mean | -17.0 | -4.4 |
| | SD | 24.26 | 9.49 |
| | Median | -11.1 | -3.7 |
| | Q1, Q3 | -33.3, -5.6 | -11.1, 0.0 |
| | Min, Max | -67, 50 | -22, 22 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.004 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 18 | n | 25 | 25 |
| | Mean | -12.4 | -3.6 |
| | SD | 20.74 | 10.14 |
| | Median | -5.6 | -3.7 |
| | Q1, Q3 | -22.2, 0.0 | -7.4, 0.0 |
| | Min, Max | -67, 17 | -25, 17 |
| | p-value for Comparison to Zero [b] | 0.004 | 0.072 |
| Month 21 | n | 26 | 26 |
| | Mean | -8.8 | -1.9 |
| | SD | 21.61 | 10.78 |
| | Median | -5.6 | -3.7 |
| | Q1, Q3 | -16.7, 5.6 | -7.4, 3.7 |
| | Min, Max | -72, 28 | -22, 30 |
| | p-value for Comparison to Zero [b] | 0.046 | 0.114 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 24 | n | 13 | 13 |
| | Mean | -14.1 | -3.4 |
| | SD | 19.46 | 8.25 |
| | Median | -11.1 | -3.7 |
| | Q1, Q3 | -16.7, 0.0 | -7.4, 0.0 |
| | Min, Max | -44, 17 | -21, 11 |
| | p-value for Comparison to Zero [b] | 0.025 | 0.188 |
| Month 30 | n | 1 | 1 |
| | Mean | 16.7 | -28.9 |
| | SD | | |
| | Median | 16.7 | -28.9 |
| | Q1, Q3 | 16.7, 16.7 | -28.9,-28.9 |
| | Min, Max | 17, 17 | -29,-29 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| PD | n | 29 | 29 |
| | Mean | -5.7 | -2.0 |
| | SD | 19.78 | 14.02 |
| | Median | -11.1 | 0.0 |
| | Q1, Q3 | -16.7, 5.6 | -7.4, 4.1 |
| | Min, Max | -44, 33 | -44, 26 |
| | p-value for Comparison to Zero [b] | 0.070 | 0.657 |
| CR | n | 1 | 1 |
| | Mean | -33.3 | 7.4 |
| | SD | | |
| | Median | -33.3 | 7.4 |
| | Q1, Q3 | -33.3,-33.3 | 7.4, 7.4 |
| | Min, Max | -33,-33 | 7, 7 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| End of Study | n | 9 | 9 |
| | Mean | 4.9 | 1.4 |
| | SD | 13.45 | 5.80 |
| | Median | 0.0 | -1.1 |
| | Q1, Q3 | 0.0, 11.1 | -3.7, 3.7 |
| | Min, Max | -11, 28 | -4, 13 |
| | p-value for Comparison to Zero [b] | 0.469 | 0.727 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5.1d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Day 1 | n | 110 | 110 |
| | Mean | 4.7 | 2.5 |
| | SD | 17.52 | 11.64 |
| | Median | 5.6 | 0.0 |
| | Q1, Q3 | -5.6, 16.7 | -3.7, 10.0 |
| | Min, Max | -44, 39 | -30, 30 |
| | p-value for Comparison to Zero [b] | 0.002 | 0.017 |
| Month 1 | n | 107 | 107 |
| | Mean | -4.7 | 1.2 |
| | SD | 18.63 | 14.33 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 5.6 | -3.7, 7.4 |
| | Min, Max | -72, 39 | -44, 47 |
| | p-value for Comparison to Zero [b] | 0.010 | 0.300 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5.1d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| | | Disease Symptoms | Side Effects |
| Month 2 | n | 96 | 96 |
| | Mean | -2.4 | -1.2 |
| | SD | 17.84 | 11.91 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | -11.1, 11.1 | -7.4, 3.7 |
| | Min, Max | -78, 33 | -48, 29 |
| | p-value for Comparison to Zero [b] | 0.357 | 0.258 |
| Month 3 | n | 84 | 84 |
| | Mean | -6.3 | -1.5 |
| | SD | 16.99 | 10.64 |
| | Median | -5.6 | 0.0 |
| | Q1, Q3 | -16.7, 0.0 | -5.9, 3.7 |
| | Min, Max | -78, 28 | -44, 19 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.421 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5.1d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| | | Disease Symptoms | Side Effects |
| Month 4 | n | 78 | 78 |
| | Mean | -7.3 | -2.7 |
| | SD | 17.56 | 12.11 |
| | Median | -5.6 | -1.9 |
| | Q1, Q3 | -16.7, 0.0 | -7.4, 3.0 |
| | Min, Max | -94, 28 | -52, 26 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.070 |
| Month 5 | n | 75 | 75 |
| | Mean | -7.0 | -4.0 |
| | SD | 17.62 | 10.51 |
| | Median | -5.6 | -3.7 |
| | Q1, Q3 | -16.7, 0.0 | -8.1, 3.0 |
| | Min, Max | -78, 44 | -48, 26 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5.1d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 6 | n | 74 | 74 |
| | Mean | -6.6 | -4.7 |
| | SD | 19.06 | 9.80 |
| | Median | -5.6 | -3.7 |
| | Q1, Q3 | -16.7, 5.6 | -8.1, 0.0 |
| | Min, Max | -78, 22 | -48, 15 |
| | p-value for Comparison to Zero [b] | 0.020 | <0.001 |
| Month 9 | n | 57 | 57 |
| | Mean | -9.3 | -5.8 |
| | SD | 14.56 | 9.87 |
| | Median | -5.6 | -4.8 |
| | Q1, Q3 | -16.7, 0.0 | -11.1, 0.0 |
| | Min, Max | -50, 22 | -48, 15 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5.1d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 12 | n | 54 | 54 |
| | Mean | -7.6 | -2.9 |
| | SD | 16.45 | 9.80 |
| | Median | -5.6 | -3.7 |
| | Q1, Q3 | -16.7, 5.6 | -7.4, 2.6 |
| | Min, Max | -44, 28 | -20, 26 |
| | p-value for Comparison to Zero [b] | 0.001 | 0.010 |
| Month 15 | n | 31 | 31 |
| | Mean | -7.9 | -2.9 |
| | SD | 17.14 | 9.71 |
| | Median | -11.1 | -3.7 |
| | Q1, Q3 | -16.7, 5.6 | -11.1, 3.7 |
| | Min, Max | -50, 33 | -26, 23 |
| | p-value for Comparison to Zero [b] | 0.008 | 0.093 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5.1d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 18 | n | 25 | 25 |
| | Mean | -9.8 | -3.2 |
| | SD | 16.30 | 12.04 |
| | Median | -5.6 | -3.7 |
| | Q1, Q3 | -16.7, 0.0 | -7.4, 0.0 |
| | Min, Max | -50, 17 | -22, 28 |
| | p-value for Comparison to Zero [b] | 0.003 | 0.062 |
| Month 21 | n | 26 | 26 |
| | Mean | -2.4 | -1.8 |
| | SD | 15.41 | 13.78 |
| | Median | -2.8 | -3.5 |
| | Q1, Q3 | -16.7, 11.1 | -7.4, 3.0 |
| | Min, Max | -28, 28 | -26, 45 |
| | p-value for Comparison to Zero [b] | 0.429 | 0.144 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5.1d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| Month 24 | n | 13 | 13 |
| | Mean | -11.1 | -2.7 |
| | SD | 17.71 | 6.69 |
| | Median | -5.6 | 0.0 |
| | Q1, Q3 | -27.8, 0.0 | -7.4, 0.0 |
| | Min, Max | -44, 17 | -13, 9 |
| | p-value for Comparison to Zero [b] | 0.059 | 0.195 |
| Month 30 | n | 1 | 1 |
| | Mean | -5.6 | -7.4 |
| | SD | | |
| | Median | -5.6 | -7.4 |
| | Q1, Q3 | -5.6, -5.6 | -7.4, -7.4 |
| | Min, Max | -6, -6 | -7, -7 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.5.1d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| PD | n | 29 | 29 |
| | Mean | -1.0 | 1.9 |
| | SD | 18.43 | 12.75 |
| | Median | 5.6 | 0.0 |
| | Q1, Q3 | -11.1, 11.1 | -7.4, 7.4 |
| | Min, Max | -39, 44 | -21, 41 |
| | p-value for Comparison to Zero [b] | 0.844 | 0.802 |
| CR | n | 1 | 1 |
| | Mean | -5.6 | 11.1 |
| | SD | | |
| | Median | -5.6 | 11.1 |
| | Q1, Q3 | -5.6, -5.6 | 11.1, 11.1 |
| | Min, Max | -6, -6 | 11, 11 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 6.5.1d
Change in Scores from Baseline on the QLQ-MY20 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Disease Symptoms | Side Effects |
| End of Study | n | 9 | 9 |
| | Mean | 3.1 | 1.9 |
| | SD | 18.03 | 9.44 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | -11.1, 22.2 | -2.2, 3.7 |
| | Min, Max | -22, 28 | -15, 16 |
| | p-value for Comparison to Zero [b] | 0.484 | 0.563 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.

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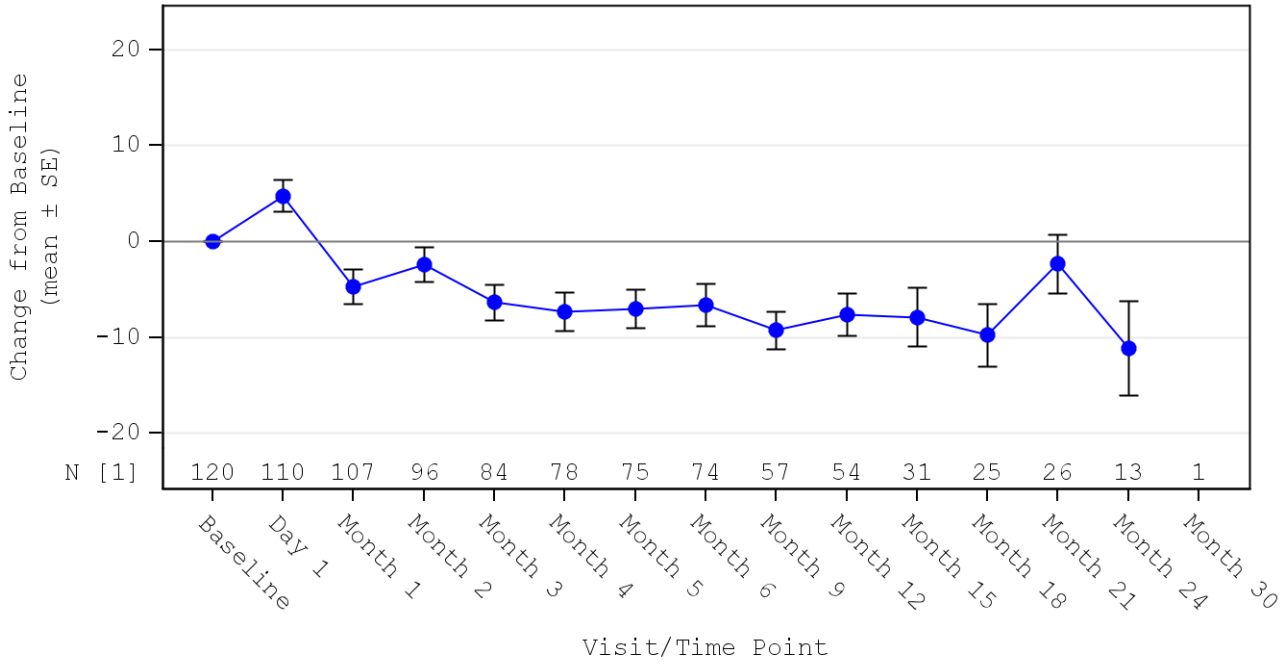
Figure 12.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-MY20 / Disease Symptoms




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_6_2_1d, Tab_6_5_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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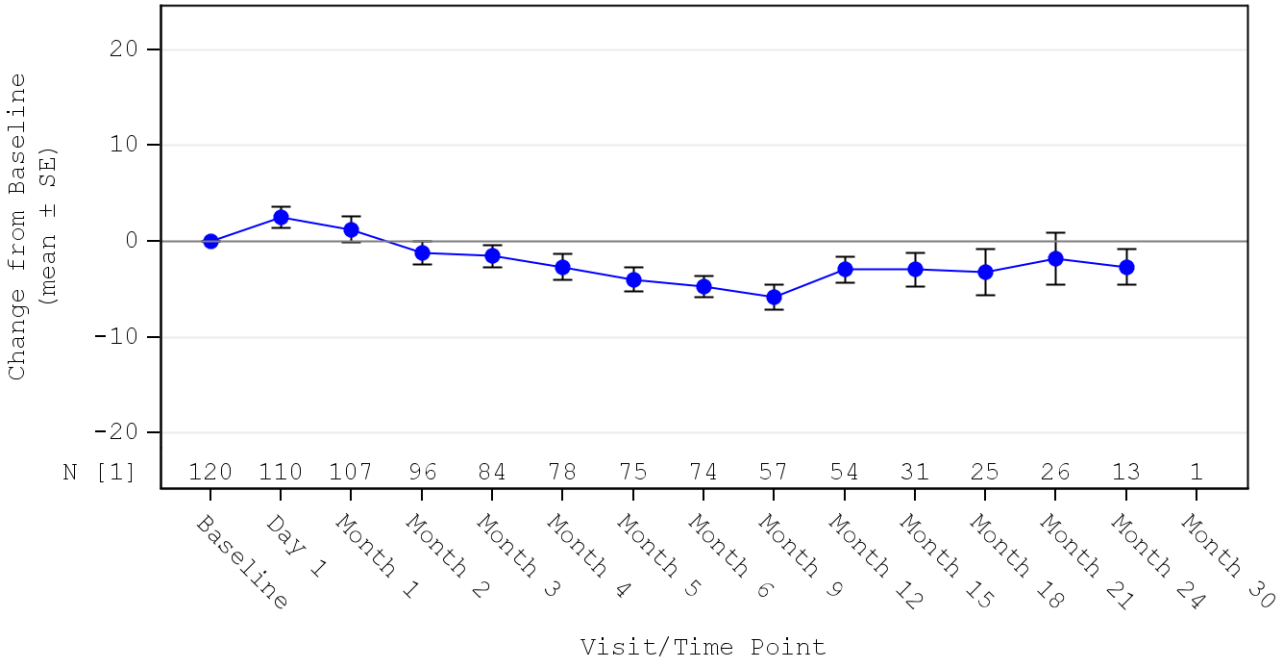
Figure 12.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-MY20 / Side Effects




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_6_2_1d, Tab_6_5_1d.

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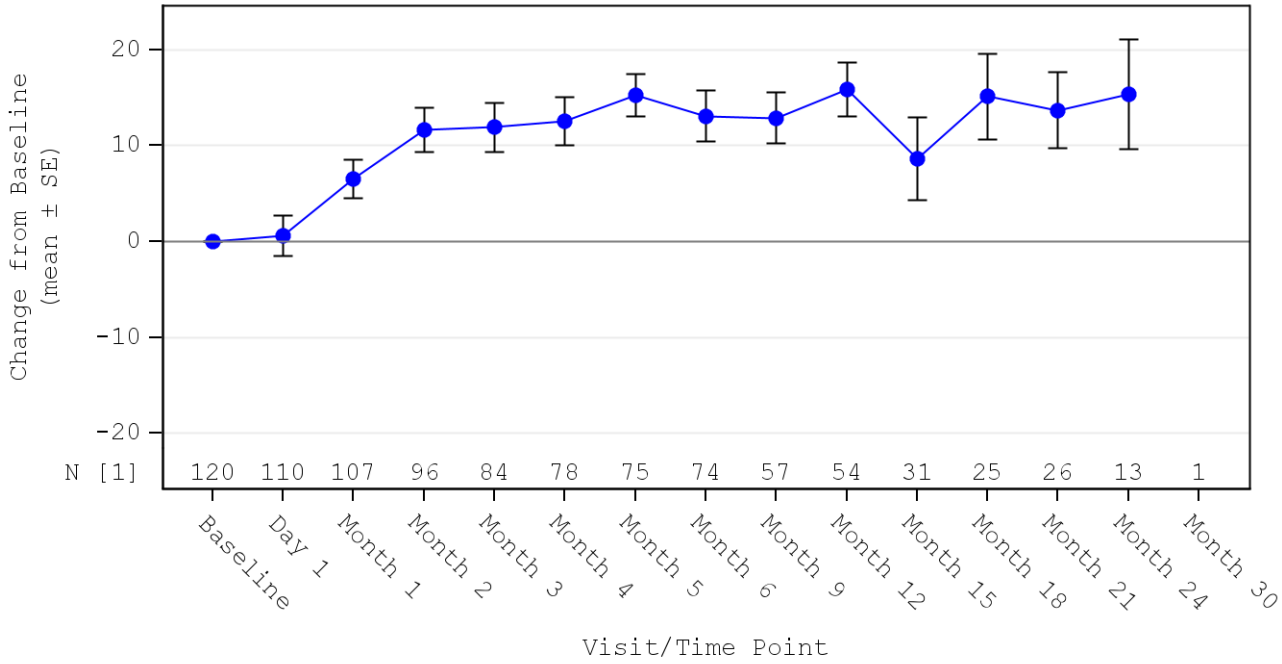
Figure 12.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-MY20 / Future Perspective




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_6_2_1d, Tab_6_5_1d.

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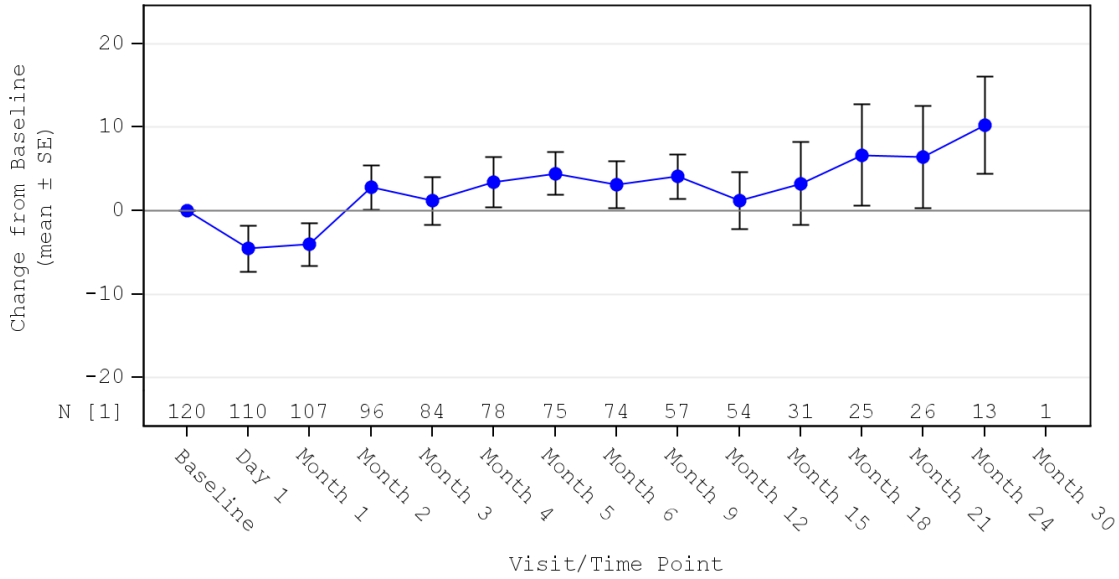
Figure 12.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-MY20 / Body Image




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_6_2_1d, Tab_6_5_1d.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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# 5. Gesundheitszustand erhoben mittels EQ-5D VAS (Datenschnitt vom 21.12.2020)

- Exploratory Responder Definition MCID = 10
- Exploratory Responder Definition MCID = 15
- Responder Definition MCID = 7
- Exploratory Responder Definition MCID = 10 (with baseline defined as the screening visit)
- Exploratory Responder Definition MCID = 15 (with baseline defined as the screening visit)
- Responder Definition MCID = 7 (with baseline defined as screening visit)
- Scores by timepoint
- Change of scores from baseline (with baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy)
- Change of scores from baseline (with baseline defined as the screening visit)

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Table 7.3.2d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Day 1 | n | 111 |
| | Improvement - n(%) | 19 ( 17.1) |
| | No Change - n(%) | 70 ( 63.1) |
| | Deterioration - n(%) | 22 ( 19.8) |
| | Missing | 11 |
| Month 1 | n | 108 |
| | Improvement - n(%) | 31 ( 28.7) |
| | No Change - n(%) | 56 ( 51.9) |
| | Deterioration - n(%) | 21 ( 19.4) |
| | Missing | 14 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.

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Table 7.3.2d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 2 | n | 97 |
| | Improvement - n(%) | 34 ( 35.1) |
| | No Change - n(%) | 46 ( 47.4) |
| | Deterioration - n(%) | 17 ( 17.5) |
| | Missing | 25 |
| Month 3 | n | 84 |
| | Improvement - n(%) | 31 ( 36.9) |
| | No Change - n(%) | 45 ( 53.6) |
| | Deterioration - n(%) | 8 ( 9.5) |
| | Missing | 38 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.

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Table 7.3.2d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 4 | n | 78 |
| | Improvement - n(%) | 34 ( 43.6) |
| | No Change - n(%) | 34 ( 43.6) |
| | Deterioration - n(%) | 10 ( 12.8) |
| | Missing | 44 |
| Month 5 | n | 76 |
| | Improvement - n(%) | 37 ( 48.7) |
| | No Change - n(%) | 35 ( 46.1) |
| | Deterioration - n(%) | 4 ( 5.3) |
| | Missing | 46 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.

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Table 7.3.2d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 6 | n | 75 |
| | Improvement - n(%) | 34 ( 45.3) |
| | No Change - n(%) | 37 ( 49.3) |
| | Deterioration - n(%) | 4 ( 5.3) |
| | Missing | 47 |
| Month 9 | n | 58 |
| | Improvement - n(%) | 36 ( 62.1) |
| | No Change - n(%) | 18 ( 31.0) |
| | Deterioration - n(%) | 4 ( 6.9) |
| | Missing | 64 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.

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Table 7.3.2d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 12 | n | 54 |
| | Improvement - n(%) | 30 ( 55.6) |
| | No Change - n(%) | 21 ( 38.9) |
| | Deterioration - n(%) | 3 ( 5.6) |
| | Missing | 68 |
| Month 15 | n | 31 |
| | Improvement - n(%) | 16 ( 51.6) |
| | No Change - n(%) | 10 ( 32.3) |
| | Deterioration - n(%) | 5 ( 16.1) |
| | Missing | 91 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.

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Table 7.3.2d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 18 | n | 25 |
| | Improvement - n(%) | 15 ( 60.0) |
| | No Change - n(%) | 10 ( 40.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 97 |
| Month 21 | n | 26 |
| | Improvement - n(%) | 9 ( 34.6) |
| | No Change - n(%) | 13 ( 50.0) |
| | Deterioration - n(%) | 4 ( 15.4) |
| | Missing | 96 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.

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Table 7.3.2d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 24 | n | 13 |
| | Improvement - n(%) | 4 ( 30.8) |
| | No Change - n(%) | 8 ( 61.5) |
| | Deterioration - n(%) | 1 ( 7.7) |
| | Missing | 109 |
| Month 30 | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 1 (100.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.

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Table 7.3.2d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| PD | n | 29 |
| | Improvement - n(%) | 7 ( 24.1) |
| | No Change - n(%) | 15 ( 51.7) |
| | Deterioration - n(%) | 7 ( 24.1) |
| | Missing | 93 |
| CR | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 1 (100.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.

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Table 7.3.2d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| End of Study | n | 9 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 8 ( 88.9) |
| | Deterioration - n(%) | 1 ( 11.1) |
| | Missing | 113 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.

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Table 7.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Day 1 | n | 111 |
| | Improvement - n(%) | 13 ( 11.7) |
| | No Change - n(%) | 83 ( 74.8) |
| | Deterioration - n(%) | 15 ( 13.5) |
| | Missing | 11 |
| Month 1 | n | 108 |
| | Improvement - n(%) | 23 ( 21.3) |
| | No Change - n(%) | 77 ( 71.3) |
| | Deterioration - n(%) | 8 ( 7.4) |
| | Missing | 14 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.

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Table 7.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 2 | n | 97 |
| | Improvement - n(%) | 27 ( 27.8) |
| | No Change - n(%) | 59 ( 60.8) |
| | Deterioration - n(%) | 11 ( 11.3) |
| | Missing | 25 |
| Month 3 | n | 84 |
| | Improvement - n(%) | 20 ( 23.8) |
| | No Change - n(%) | 62 ( 73.8) |
| | Deterioration - n(%) | 2 ( 2.4) |
| | Missing | 38 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.

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Table 7.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 4 | n | 78 |
| | Improvement - n(%) | 23 ( 29.5) |
| | No Change - n(%) | 50 ( 64.1) |
| | Deterioration - n(%) | 5 ( 6.4) |
| | Missing | 44 |
| Month 5 | n | 76 |
| | Improvement - n(%) | 25 ( 32.9) |
| | No Change - n(%) | 48 ( 63.2) |
| | Deterioration - n(%) | 3 ( 3.9) |
| | Missing | 46 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.

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Table 7.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 6 | n | 75 |
| | Improvement - n(%) | 20 ( 26.7) |
| | No Change - n(%) | 52 ( 69.3) |
| | Deterioration - n(%) | 3 ( 4.0) |
| | Missing | 47 |
| Month 9 | n | 58 |
| | Improvement - n(%) | 28 ( 48.3) |
| | No Change - n(%) | 26 ( 44.8) |
| | Deterioration - n(%) | 4 ( 6.9) |
| | Missing | 64 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.

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Table 7.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 12 | n | 54 |
| | Improvement - n(%) | 23 ( 42.6) |
| | No Change - n(%) | 30 ( 55.6) |
| | Deterioration - n(%) | 1 ( 1.9) |
| | Missing | 68 |
| Month 15 | n | 31 |
| | Improvement - n(%) | 12 ( 38.7) |
| | No Change - n(%) | 15 ( 48.4) |
| | Deterioration - n(%) | 4 ( 12.9) |
| | Missing | 91 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.

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Table 7.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 18 | n | 25 |
| | Improvement - n(%) | 9 ( 36.0) |
| | No Change - n(%) | 16 ( 64.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 97 |
| Month 21 | n | 26 |
| | Improvement - n(%) | 5 ( 19.2) |
| | No Change - n(%) | 18 ( 69.2) |
| | Deterioration - n(%) | 3 ( 11.5) |
| | Missing | 96 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.

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Table 7.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 24 | n | 13 |
| | Improvement - n(%) | 1 ( 7.7) |
| | No Change - n(%) | 12 ( 92.3) |
| | Deterioration - n(%) | 0 |
| | Missing | 109 |
| Month 30 | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 1 (100.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.

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Table 7.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| PD | n | 29 |
| | Improvement - n(%) | 6 ( 20.7) |
| | No Change - n(%) | 18 ( 62.1) |
| | Deterioration - n(%) | 5 ( 17.2) |
| | Missing | 93 |
| CR | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 1 (100.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.

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Table 7.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| End of Study | n | 9 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 8 ( 88.9) |
| | Deterioration - n(%) | 1 ( 11.1) |
| | Missing | 113 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.

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Table 7.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Day 1 | n | 111 |
| | Improvement - n(%) | 20 ( 18.0) |
| | No Change - n(%) | 64 ( 57.7) |
| | Deterioration - n(%) | 27 ( 24.3) |
| | Missing | 11 |
| Month 1 | n | 108 |
| | Improvement - n(%) | 41 ( 38.0) |
| | No Change - n(%) | 43 ( 39.8) |
| | Deterioration - n(%) | 24 ( 22.2) |
| | Missing | 14 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening.

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Table 7.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 2 | n | 97 |
| | Improvement - n(%) | 39 ( 40.2) |
| | No Change - n(%) | 35 ( 36.1) |
| | Deterioration - n(%) | 23 ( 23.7) |
| | Missing | 25 |
| Month 3 | n | 84 |
| | Improvement - n(%) | 38 ( 45.2) |
| | No Change - n(%) | 32 ( 38.1) |
| | Deterioration - n(%) | 14 ( 16.7) |
| | Missing | 38 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening.

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Table 7.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 4 | n | 78 |
| | Improvement - n(%) | 37 ( 47.4) |
| | No Change - n(%) | 29 ( 37.2) |
| | Deterioration - n(%) | 12 ( 15.4) |
| | Missing | 44 |
| Month 5 | n | 76 |
| | Improvement - n(%) | 49 ( 64.5) |
| | No Change - n(%) | 20 ( 26.3) |
| | Deterioration - n(%) | 7 ( 9.2) |
| | Missing | 46 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening.

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Table 7.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 6 | n | 75 |
| | Improvement - n(%) | 41 ( 54.7) |
| | No Change - n(%) | 28 ( 37.3) |
| | Deterioration - n(%) | 6 ( 8.0) |
| | Missing | 47 |
| Month 9 | n | 58 |
| | Improvement - n(%) | 41 ( 70.7) |
| | No Change - n(%) | 13 ( 22.4) |
| | Deterioration - n(%) | 4 ( 6.9) |
| | Missing | 64 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening.

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Table 7.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 12 | n | 54 |
| | Improvement - n(%) | 34 ( 63.0) |
| | No Change - n(%) | 15 ( 27.8) |
| | Deterioration - n(%) | 5 ( 9.3) |
| | Missing | 68 |
| Month 15 | n | 31 |
| | Improvement - n(%) | 18 ( 58.1) |
| | No Change - n(%) | 8 ( 25.8) |
| | Deterioration - n(%) | 5 ( 16.1) |
| | Missing | 91 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening.

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Table 7.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 18 | n | 25 |
| | Improvement - n(%) | 16 ( 64.0) |
| | No Change - n(%) | 9 ( 36.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 97 |
| Month 21 | n | 26 |
| | Improvement - n(%) | 13 ( 50.0) |
| | No Change - n(%) | 9 ( 34.6) |
| | Deterioration - n(%) | 4 ( 15.4) |
| | Missing | 96 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening.

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Table 7.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 24 | n | 13 |
| | Improvement - n(%) | 4 ( 30.8) |
| | No Change - n(%) | 8 ( 61.5) |
| | Deterioration - n(%) | 1 ( 7.7) |
| | Missing | 109 |
| Month 30 | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 1 (100.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening.

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Table 7.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| PD | n | 29 |
| | Improvement - n(%) | 10 ( 34.5) |
| | No Change - n(%) | 9 ( 31.0) |
| | Deterioration - n(%) | 10 ( 34.5) |
| | Missing | 93 |
| CR | n | 1 |
| | Improvement - n(%) | 1 (100.0) |
| | No Change - n(%) | 0 |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening.

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Table 7.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| End of Study | n | 9 |
| | Improvement - n(%) | 2 ( 22.2) |
| | No Change - n(%) | 5 ( 55.6) |
| | Deterioration - n(%) | 2 ( 22.2) |
| | Missing | 113 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EQ-5D VAS population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening.

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Table 7.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Day 1 | n | 111 |
| | Improvement - n(%) | 17 ( 15.3) |
| | No Change - n(%) | 51 ( 45.9) |
| | Deterioration - n(%) | 43 ( 38.7) |
| | Missing | 11 |
| Month 1 | n | 108 |
| | Improvement - n(%) | 34 ( 31.5) |
| | No Change - n(%) | 44 ( 40.7) |
| | Deterioration - n(%) | 30 ( 27.8) |
| | Missing | 14 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 2 | n | 97 |
| | Improvement - n(%) | 23 ( 23.7) |
| | No Change - n(%) | 50 ( 51.5) |
| | Deterioration - n(%) | 24 ( 24.7) |
| | Missing | 25 |
| Month 3 | n | 84 |
| | Improvement - n(%) | 26 ( 31.0) |
| | No Change - n(%) | 42 ( 50.0) |
| | Deterioration - n(%) | 16 ( 19.0) |
| | Missing | 38 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 4 | n | 78 |
| | Improvement - n(%) | 25 ( 32.1) |
| | No Change - n(%) | 40 ( 51.3) |
| | Deterioration - n(%) | 13 ( 16.7) |
| | Missing | 44 |
| Month 5 | n | 76 |
| | Improvement - n(%) | 32 ( 42.1) |
| | No Change - n(%) | 39 ( 51.3) |
| | Deterioration - n(%) | 5 ( 6.6) |
| | Missing | 46 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 6 | n | 75 |
| | Improvement - n(%) | 33 ( 44.0) |
| | No Change - n(%) | 36 ( 48.0) |
| | Deterioration - n(%) | 6 ( 8.0) |
| | Missing | 47 |
| Month 9 | n | 58 |
| | Improvement - n(%) | 27 ( 46.6) |
| | No Change - n(%) | 25 ( 43.1) |
| | Deterioration - n(%) | 6 ( 10.3) |
| | Missing | 64 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 12 | n | 54 |
| | Improvement - n(%) | 24 ( 44.4) |
| | No Change - n(%) | 24 ( 44.4) |
| | Deterioration - n(%) | 6 ( 11.1) |
| | Missing | 68 |
| Month 15 | n | 31 |
| | Improvement - n(%) | 10 ( 32.3) |
| | No Change - n(%) | 16 ( 51.6) |
| | Deterioration - n(%) | 5 ( 16.1) |
| | Missing | 91 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 18 | n | 25 |
| | Improvement - n(%) | 9 ( 36.0) |
| | No Change - n(%) | 16 ( 64.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 97 |
| Month 21 | n | 26 |
| | Improvement - n(%) | 6 ( 23.1) |
| | No Change - n(%) | 15 ( 57.7) |
| | Deterioration - n(%) | 5 ( 19.2) |
| | Missing | 96 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 24 | n | 13 |
| | Improvement - n(%) | 2 ( 15.4) |
| | No Change - n(%) | 10 ( 76.9) |
| | Deterioration - n(%) | 1 ( 7.7) |
| | Missing | 109 |
| Month 30 | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 1 (100.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| PD | n | 29 |
| | Improvement - n(%) | 10 ( 34.5) |
| | No Change - n(%) | 11 ( 37.9) |
| | Deterioration - n(%) | 8 ( 27.6) |
| | Missing | 93 |
| CR | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 0 |
| | Deterioration - n(%) | 1 (100.0) |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| End of Study | n | 9 |
| | Improvement - n(%) | 1 ( 11.1) |
| | No Change - n(%) | 3 ( 33.3) |
| | Deterioration - n(%) | 5 ( 55.6) |
| | Missing | 113 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Day 1 | n | 111 |
| | Improvement - n(%) | 11 ( 9.9) |
| | No Change - n(%) | 71 ( 64.0) |
| | Deterioration - n(%) | 29 ( 26.1) |
| | Missing | 11 |
| Month 1 | n | 108 |
| | Improvement - n(%) | 24 ( 22.2) |
| | No Change - n(%) | 64 ( 59.3) |
| | Deterioration - n(%) | 20 ( 18.5) |
| | Missing | 14 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 2 | n | 97 |
| | Improvement - n(%) | 17 ( 17.5) |
| | No Change - n(%) | 64 ( 66.0) |
| | Deterioration - n(%) | 16 ( 16.5) |
| | Missing | 25 |
| Month 3 | n | 84 |
| | Improvement - n(%) | 14 ( 16.7) |
| | No Change - n(%) | 64 ( 76.2) |
| | Deterioration - n(%) | 6 ( 7.1) |
| | Missing | 38 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 4 | n | 78 |
| | Improvement - n(%) | 15 ( 19.2) |
| | No Change - n(%) | 57 ( 73.1) |
| | Deterioration - n(%) | 6 ( 7.7) |
| | Missing | 44 |
| Month 5 | n | 76 |
| | Improvement - n(%) | 20 ( 26.3) |
| | No Change - n(%) | 53 ( 69.7) |
| | Deterioration - n(%) | 3 ( 3.9) |
| | Missing | 46 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 6 | n | 75 |
| | Improvement - n(%) | 17 ( 22.7) |
| | No Change - n(%) | 52 ( 69.3) |
| | Deterioration - n(%) | 6 ( 8.0) |
| | Missing | 47 |
| Month 9 | n | 58 |
| | Improvement - n(%) | 18 ( 31.0) |
| | No Change - n(%) | 34 ( 58.6) |
| | Deterioration - n(%) | 6 ( 10.3) |
| | Missing | 64 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 12 | n | 54 |
| | Improvement - n(%) | 16 ( 29.6) |
| | No Change - n(%) | 35 ( 64.8) |
| | Deterioration - n(%) | 3 ( 5.6) |
| | Missing | 68 |
| Month 15 | n | 31 |
| | Improvement - n(%) | 6 ( 19.4) |
| | No Change - n(%) | 20 ( 64.5) |
| | Deterioration - n(%) | 5 ( 16.1) |
| | Missing | 91 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 18 | n | 25 |
| | Improvement - n(%) | 6 ( 24.0) |
| | No Change - n(%) | 19 ( 76.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 97 |
| Month 21 | n | 26 |
| | Improvement - n(%) | 4 ( 15.4) |
| | No Change - n(%) | 19 ( 73.1) |
| | Deterioration - n(%) | 3 ( 11.5) |
| | Missing | 96 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 24 | n | 13 |
| | Improvement - n(%) | 1 ( 7.7) |
| | No Change - n(%) | 12 ( 92.3) |
| | Deterioration - n(%) | 0 |
| | Missing | 109 |
| Month 30 | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 1 (100.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| PD | n | 29 |
| | Improvement - n(%) | 5 ( 17.2) |
| | No Change - n(%) | 18 ( 62.1) |
| | Deterioration - n(%) | 6 ( 20.7) |
| | Missing | 93 |
| CR | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 0 |
| | Deterioration - n(%) | 1 (100.0) |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| End of Study | n | 9 |
| | Improvement - n(%) | 1 ( 11.1) |
| | No Change - n(%) | 5 ( 55.6) |
| | Deterioration - n(%) | 3 ( 33.3) |
| | Missing | 113 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Day 1 | n | 111 |
| | Improvement - n(%) | 28 ( 25.2) |
| | No Change - n(%) | 33 ( 29.7) |
| | Deterioration - n(%) | 50 ( 45.0) |
| | Missing | 11 |
| Month 1 | n | 108 |
| | Improvement - n(%) | 37 ( 34.3) |
| | No Change - n(%) | 33 ( 30.6) |
| | Deterioration - n(%) | 38 ( 35.2) |
| | Missing | 14 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening. Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 2 | n | 97 |
| | Improvement - n(%) | 31 ( 32.0) |
| | No Change - n(%) | 37 ( 38.1) |
| | Deterioration - n(%) | 29 ( 29.9) |
| | Missing | 25 |
| Month 3 | n | 84 |
| | Improvement - n(%) | 31 ( 36.9) |
| | No Change - n(%) | 35 ( 41.7) |
| | Deterioration - n(%) | 18 ( 21.4) |
| | Missing | 38 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening. Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 4 | n | 78 |
| | Improvement - n(%) | 34 ( 43.6) |
| | No Change - n(%) | 28 ( 35.9) |
| | Deterioration - n(%) | 16 ( 20.5) |
| | Missing | 44 |
| Month 5 | n | 76 |
| | Improvement - n(%) | 37 ( 48.7) |
| | No Change - n(%) | 33 ( 43.4) |
| | Deterioration - n(%) | 6 ( 7.9) |
| | Missing | 46 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening. Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 6 | n | 75 |
| | Improvement - n(%) | 37 ( 49.3) |
| | No Change - n(%) | 27 ( 36.0) |
| | Deterioration - n(%) | 11 ( 14.7) |
| | Missing | 47 |
| Month 9 | n | 58 |
| | Improvement - n(%) | 31 ( 53.4) |
| | No Change - n(%) | 20 ( 34.5) |
| | Deterioration - n(%) | 7 ( 12.1) |
| | Missing | 64 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening. Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 12 | n | 54 |
| | Improvement - n(%) | 26 ( 48.1) |
| | No Change - n(%) | 21 ( 38.9) |
| | Deterioration - n(%) | 7 ( 13.0) |
| | Missing | 68 |
| Month 15 | n | 31 |
| | Improvement - n(%) | 12 ( 38.7) |
| | No Change - n(%) | 12 ( 38.7) |
| | Deterioration - n(%) | 7 ( 22.6) |
| | Missing | 91 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening. Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 18 | n | 25 |
| | Improvement - n(%) | 9 ( 36.0) |
| | No Change - n(%) | 13 ( 52.0) |
| | Deterioration - n(%) | 3 ( 12.0) |
| | Missing | 97 |
| Month 21 | n | 26 |
| | Improvement - n(%) | 6 ( 23.1) |
| | No Change - n(%) | 14 ( 53.8) |
| | Deterioration - n(%) | 6 ( 23.1) |
| | Missing | 96 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening. Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 24 | n | 13 |
| | Improvement - n(%) | 3 ( 23.1) |
| | No Change - n(%) | 8 ( 61.5) |
| | Deterioration - n(%) | 2 ( 15.4) |
| | Missing | 109 |
| Month 30 | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 1 (100.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening. Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| PD | n | 29 |
| | Improvement - n(%) | 10 ( 34.5) |
| | No Change - n(%) | 9 ( 31.0) |
| | Deterioration - n(%) | 10 ( 34.5) |
| | Missing | 93 |
| CR | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 0 |
| | Deterioration - n(%) | 1 (100.0) |
| | Missing | 121 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening. Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EQ-5D VAS Score (N=122) Visual Analogue Scale |
|---|---|---|
| End of Study | n | 9 |
| | Improvement - n(%) | 2 ( 22.2) |
| | No Change - n(%) | 2 ( 22.2) |
| | Deterioration - n(%) | 5 ( 55.6) |
| | Missing | 113 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+7 for improvement and <=-7 for worsening. Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 7.1d
Scores on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score (N=122) Visual Analogue Scale |
|---|---|---|
| Screening | n | 117 |
| | Mean | 70.9 |
| | SD | 17.83 |
| | Median | 75.0 |
| | Q1, Q3 | 59.0, 82.0 |
| | Min, Max | 20,100 |
| Baseline Evaluations | n | 122 |
| | Mean | 67.2 |
| | SD | 18.38 |
| | Median | 70.0 |
| | Q1, Q3 | 53.0, 81.0 |
| | Min, Max | 19,100 |
| Day 1 | n | 111 |
| | Mean | 67.0 |
| | SD | 19.17 |
| | Median | 71.0 |
| | Q1, Q3 | 51.0, 81.0 |
| | Min, Max | 9,100 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.
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Table 7.1d
Scores on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 1 | n | 108 |
| | Mean | 70.6 |
| | SD | 18.50 |
| | Median | 70.0 |
| | Q1, Q3 | 59.0, 83.0 |
| | Min, Max | 15,100 |
| Month 2 | n | 97 |
| | Mean | 73.3 |
| | SD | 17.65 |
| | Median | 79.0 |
| | Q1, Q3 | 61.0, 89.0 |
| | Min, Max | 18, 99 |
| Month 3 | n | 84 |
| | Mean | 76.0 |
| | SD | 15.17 |
| | Median | 80.0 |
| | Q1, Q3 | 65.0, 89.0 |
| | Min, Max | 29, 99 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 7.1d
Scores on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 4 | n | 78 |
| | Mean | 77.3 |
| | SD | 14.80 |
| | Median | 80.0 |
| | Q1, Q3 | 70.0, 89.0 |
| | Min, Max | 40,100 |
| Month 5 | n | 76 |
| | Mean | 79.7 |
| | SD | 14.64 |
| | Median | 81.5 |
| | Q1, Q3 | 70.5, 90.0 |
| | Min, Max | 39,100 |
| Month 6 | n | 75 |
| | Mean | 79.7 |
| | SD | 15.37 |
| | Median | 83.0 |
| | Q1, Q3 | 68.0, 91.0 |
| | Min, Max | 40,100 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 7.1d
Scores on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 9 | n | 58 |
| | Mean | 82.0 |
| | SD | 16.46 |
| | Median | 85.0 |
| | Q1, Q3 | 78.0, 91.0 |
| | Min, Max | 6,100 |
| Month 12 | n | 54 |
| | Mean | 80.8 |
| | SD | 14.62 |
| | Median | 81.0 |
| | Q1, Q3 | 71.0, 91.0 |
| | Min, Max | 29,100 |
| Month 15 | n | 31 |
| | Mean | 76.4 |
| | SD | 22.46 |
| | Median | 84.0 |
| | Q1, Q3 | 64.0, 91.0 |
| | Min, Max | 13, 99 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 7.1d
Scores on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 18 | n | 25 |
| | Mean | 84.4 |
| | SD | 12.78 |
| | Median | 89.0 |
| | Q1, Q3 | 80.0, 92.0 |
| | Min, Max | 51,100 |
| Month 21 | n | 26 |
| | Mean | 74.7 |
| | SD | 22.04 |
| | Median | 80.0 |
| | Q1, Q3 | 69.0, 90.0 |
| | Min, Max | 17,100 |
| Month 24 | n | 13 |
| | Mean | 84.8 |
| | SD | 11.92 |
| | Median | 90.0 |
| | Q1, Q3 | 80.0, 92.0 |
| | Min, Max | 60,100 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 7.1d
Scores on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score (N=122) Visual Analogue Scale |
|---|---|---|
| Month 30 | n | 1 |
| | Mean | 96.0 |
| | SD | |
| | Median | 96.0 |
| | Q1, Q3 | 96.0, 96.0 |
| | Min, Max | 96, 96 |
| PD | n | 29 |
| | Mean | 66.2 |
| | SD | 21.59 |
| | Median | 70.0 |
| | Q1, Q3 | 51.0, 80.0 |
| | Min, Max | 16,100 |
| CR | n | 1 |
| | Mean | 60.0 |
| | SD | |
| | Median | 60.0 |
| | Q1, Q3 | 60.0, 60.0 |
| | Min, Max | 60, 60 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 7.1d
Scores on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score (N=122) Visual Analogue Scale |
|---|---|---|
| End of Study | n | 9 |
| | Mean | 74.2 |
| | SD | 11.73 |
| | Median | 76.0 |
| | Q1, Q3 | 71.0, 79.0 |
| | Min, Max | 53, 91 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 7.2d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Day 1 | n | 111 |
| | Mean | -0.9 |
| | SD | 15.61 |
| | Median | 0.0 |
| | Q1, Q3 | -6.0, 5.0 |
| | Min, Max | -50, 56 |
| | p-value for Comparison to Zero [b] | 0.621 |
| Month 1 | n | 108 |
| | Mean | 4.1 |
| | SD | 17.21 |
| | Median | 2.0 |
| | Q1, Q3 | -4.0, 12.5 |
| | Min, Max | -69, 51 |
| | p-value for Comparison to Zero [b] | 0.010 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 7.2d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 2 | n | 97 |
| | Mean | 5.6 |
| | SD | 17.71 |
| | Median | 4.0 |
| | Q1, Q3 | -6.0, 18.0 |
| | Min, Max | -31, 54 |
| | p-value for Comparison to Zero [b] | 0.004 |
| Month 3 | n | 84 |
| | Mean | 7.8 |
| | SD | 14.84 |
| | Median | 5.0 |
| | Q1, Q3 | -1.0, 14.0 |
| | Min, Max | -24, 50 |
| | p-value for Comparison to Zero [b] | <0.001 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.

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Table 7.2d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 4 | n | 78 |
| | Mean | 8.5 |
| | SD | 17.23 |
| | Median | 6.0 |
| | Q1, Q3 | -1.0, 20.0 |
| | Min, Max | -39, 51 |
| | p-value for Comparison to Zero [b] | <0.001 |
| Month 5 | n | 76 |
| | Mean | 11.3 |
| | SD | 15.80 |
| | Median | 9.0 |
| | Q1, Q3 | 1.0, 21.0 |
| | Min, Max | -36, 57 |
| | p-value for Comparison to Zero [b] | <0.001 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 7.2d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 6 | n | 75 |
| | Mean | 9.9 |
| | SD | 14.83 |
| | Median | 8.0 |
| | Q1, Q3 | 0.0, 19.0 |
| | Min, Max | -35, 58 |
| | p-value for Comparison to Zero [b] | <0.001 |
| Month 9 | n | 58 |
| | Mean | 12.0 |
| | SD | 19.82 |
| | Median | 14.0 |
| | Q1, Q3 | 5.0, 23.0 |
| | Min, Max | -64, 58 |
| | p-value for Comparison to Zero [b] | <0.001 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 7.2d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 12 | n | 54 |
| | Mean | 12.7 |
| | SD | 16.72 |
| | Median | 12.0 |
| | Q1, Q3 | 0.0, 22.0 |
| | Min, Max | -41, 58 |
| | p-value for Comparison to Zero [b] | <0.001 |
| Month 15 | n | 31 |
| | Mean | 8.5 |
| | SD | 19.50 |
| | Median | 10.0 |
| | Q1, Q3 | -1.0, 24.0 |
| | Min, Max | -46, 36 |
| | p-value for Comparison to Zero [b] | 0.010 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 7.2d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 18 | n | 25 |
| | Mean | 11.5 |
| | SD | 10.53 |
| | Median | 11.0 |
| | Q1, Q3 | 2.0, 19.0 |
| | Min, Max | -3, 32 |
| | p-value for Comparison to Zero [b] | <0.001 |
| Month 21 | n | 26 |
| | Mean | 4.5 |
| | SD | 16.31 |
| | Median | 6.5 |
| | Q1, Q3 | -1.0, 10.0 |
| | Min, Max | -46, 36 |
| | p-value for Comparison to Zero [b] | 0.073 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 7.2d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 24 | n | 13 |
| | Mean | 4.6 |
| | SD | 10.05 |
| | Median | 1.0 |
| | Q1, Q3 | 0.0, 10.0 |
| | Min, Max | -11, 32 |
| | p-value for Comparison to Zero [b] | 0.111 |
| Month 30 | n | 1 |
| | Mean | 0.0 |
| | SD | |
| | Median | 0.0 |
| | Q1, Q3 | 0.0, 0.0 |
| | Min, Max | 0, 0 |
| | p-value for Comparison to Zero [b] | N/A |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 7.2d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| PD | n | 29 |
| | Mean | -0.4 |
| | SD | 17.28 |
| | Median | 0.0 |
| | Q1, Q3 | -9.0, 8.0 |
| | Min, Max | -55, 31 |
| | p-value for Comparison to Zero [b] | 0.981 |
| CR | n | 1 |
| | Mean | 9.0 |
| | SD | |
| | Median | 9.0 |
| | Q1, Q3 | 9.0, 9.0 |
| | Min, Max | 9, 9 |
| | p-value for Comparison to Zero [b] | 1.000 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 7.2d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| End of Study | n | 9 |
| | Mean | -2.3 |
| | SD | 10.30 |
| | Median | -2.0 |
| | Q1, Q3 | -3.0, 4.0 |
| | Min, Max | -26, 7 |
| | p-value for Comparison to Zero [b] | 0.930 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.

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Table 7.2.1d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Day 1 | n | 111 |
| | Mean | -4.3 |
| | SD | 16.49 |
| | Median | -3.0 |
| | Q1, Q3 | -15.0, 7.0 |
| | Min, Max | -56, 41 |
| | p-value for Comparison to Zero [b] | 0.003 |
| Month 1 | n | 108 |
| | Mean | 0.1 |
| | SD | 19.45 |
| | Median | 0.5 |
| | Q1, Q3 | -10.0, 10.5 |
| | Min, Max | -55, 52 |
| | p-value for Comparison to Zero [b] | 0.784 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 7.2.1d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 2 | n | 97 |
| | Mean | 1.5 |
| | SD | 17.08 |
| | Median | 0.0 |
| | Q1, Q3 | -9.0, 9.0 |
| | Min, Max | -41, 60 |
| | p-value for Comparison to Zero [b] | 0.639 |
| Month 3 | n | 84 |
| | Mean | 4.3 |
| | SD | 14.85 |
| | Median | 3.0 |
| | Q1, Q3 | -4.0, 11.0 |
| | Min, Max | -30, 60 |
| | p-value for Comparison to Zero [b] | 0.017 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 7.2.1d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 4 | n | 78 |
| | Mean | 4.7 |
| | SD | 17.07 |
| | Median | 2.0 |
| | Q1, Q3 | -5.0, 11.0 |
| | Min, Max | -39, 50 |
| | p-value for Comparison to Zero [b] | 0.012 |
| Month 5 | n | 76 |
| | Mean | 7.6 |
| | SD | 16.04 |
| | Median | 6.0 |
| | Q1, Q3 | -1.0, 15.0 |
| | Min, Max | -52, 59 |
| | p-value for Comparison to Zero [b] | <0.001 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 7.2.1d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 6 | n | 75 |
| | Mean | 6.9 |
| | SD | 16.64 |
| | Median | 6.0 |
| | Q1, Q3 | -2.0, 13.0 |
| | Min, Max | -51, 50 |
| | p-value for Comparison to Zero [b] | <0.001 |
| Month 9 | n | 58 |
| | Mean | 8.6 |
| | SD | 21.23 |
| | Median | 9.0 |
| | Q1, Q3 | 0.0, 19.0 |
| | Min, Max | -60, 55 |
| | p-value for Comparison to Zero [b] | <0.001 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 7.2.1d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 12 | n | 54 |
| | Mean | 8.7 |
| | SD | 17.99 |
| | Median | 5.5 |
| | Q1, Q3 | -2.0, 18.0 |
| | Min, Max | -37, 54 |
| | p-value for Comparison to Zero [b] | <0.001 |
| Month 15 | n | 31 |
| | Mean | 3.5 |
| | SD | 20.38 |
| | Median | 3.0 |
| | Q1, Q3 | -5.0, 11.0 |
| | Min, Max | -42, 49 |
| | p-value for Comparison to Zero [b] | 0.215 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 7.2.1d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 18 | n | 25 |
| | Mean | 7.0 |
| | SD | 13.54 |
| | Median | 2.0 |
| | Q1, Q3 | -1.0, 14.0 |
| | Min, Max | -8, 42 |
| | p-value for Comparison to Zero [b] | 0.017 |
| Month 21 | n | 26 |
| | Mean | -0.3 |
| | SD | 14.60 |
| | Median | 0.0 |
| | Q1, Q3 | -6.0, 5.0 |
| | Min, Max | -33, 36 |
| | p-value for Comparison to Zero [b] | 0.934 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 7.2.1d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| Month 24 | n | 13 |
| | Mean | 4.2 |
| | SD | 13.08 |
| | Median | 2.0 |
| | Q1, Q3 | -1.0, 5.0 |
| | Min, Max | -10, 43 |
| | p-value for Comparison to Zero [b] | 0.310 |
| Month 30 | n | 1 |
| | Mean | 6.0 |
| | SD | |
| | Median | 6.0 |
| | Q1, Q3 | 6.0, 6.0 |
| | Min, Max | 6, 6 |
| | p-value for Comparison to Zero [b] | 1.000 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 7.2.1d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| PD | n | 29 |
| | Mean | -2.3 |
| | SD | 21.03 |
| | Median | 0.0 |
| | Q1, Q3 | -11.0, 10.0 |
| | Min, Max | -47, 41 |
| | p-value for Comparison to Zero [b] | 0.824 |
| CR | n | 1 |
| | Mean | -15.0 |
| | SD | |
| | Median | -15.0 |
| | Q1, Q3 | -15.0,-15.0 |
| | Min, Max | -15,-15 |
| | p-value for Comparison to Zero [b] | 1.000 |

CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUL2021 14:20
Analysis Plan: 12MAY2021 Confidential

Table 7.2.1d
Change in Scores from Baseline on the EQ-5D VAS by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EQ-5D Score - Change in Score from Baseline [a] (N=122) Visual Analogue Scale |
|---|---|---|
| End of Study | n | 9 |
| | Mean | -6.3 |
| | SD | 14.59 |
| | Median | -11.0 |
| | Q1, Q3 | -15.0, 1.0 |
| | Min, Max | -26, 21 |
| | p-value for Comparison to Zero [b] | 0.238 |

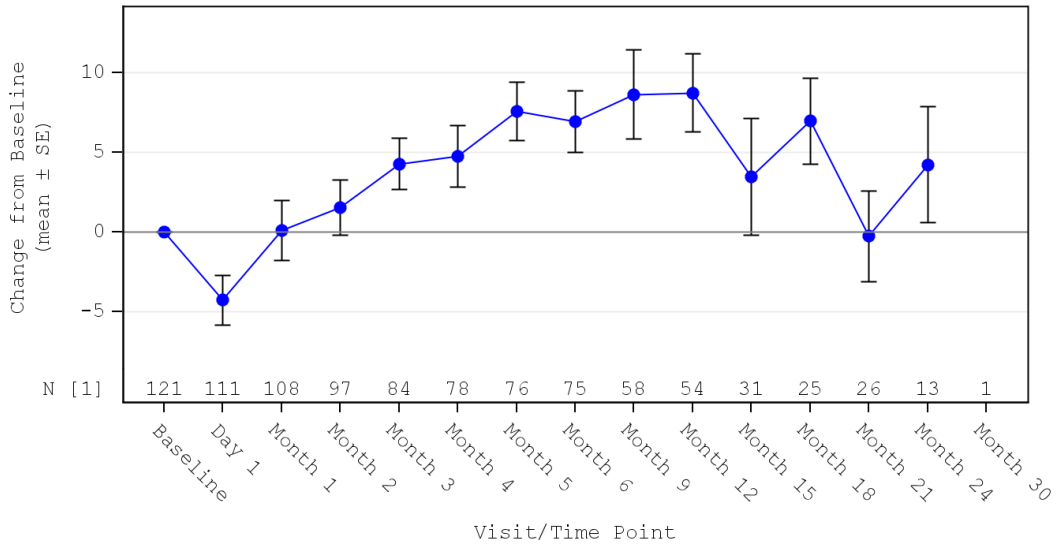
CR = Complete response; EQ-5D VAS = European Quality of Life-Visual Analogue Scale; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUL2021 14:20
Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001

Cut-off date: 21DEC2020

Figure 12.3.1d
Change in Scores from Baseline on the EQ5D Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: EQ-5D / EQ-5D VAS




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Table: Tab_7_2_1d.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
Date/time of run: 30JUL2021 17:03
Analysis Plan: 12MAY2021 Confidential

# 6. Gesundheitsbezogene Lebensqualität

## 6.1 Gesundheitsbezogene Lebensqualität gemessen anhand der Funktionsskalen des EORTC QLQ-C30 (Datenschnitt vom 21.12.2020)

- Exploratory Responder Definition MCID = 15 (Physical functioning, conginitive functioning, global health, role functioning, emotional functioning, social functioning) and MCID = 10 (Financial difficulties)
- Responder Definition MCID = 5 (Physical functioning, global health, emotional functioning)
- Exploratory Responder Definition MCID = 10 (with baseline defined as the screening visit)
- Exploratory Responder Definition MCID = 15 Physical functioning, conginitive functioning, global health, role functioning, emotional functioning, social functioning) and MCID = 10 (Financial difficulties) (with baseline defined as the screening visit)
- Exploratory Responder Definition MCID = 5 (Physical functioning, global health, emotional functioning) (with baseline defined as the screening visit)
- Scores by timepoint
- Change of scores from baseline (with baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy)
- Change of scores from baseline (with baseline defined as the screening visit)

*Anmerkung*: Ergebnisse zu den Symptomskalen Schmerz und Fatigue sind in Abschnitt 6.1 ebenfalls dargestellt.

Table 4.6.3d

Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint

PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 15 ( 13.6) | 38 ( 34.5) | 13 ( 11.8) | 23 ( 20.9) | 14 ( 12.7) |
| | No Change - n(%) | 69 ( 62.7) | 49 ( 44.5) | 82 ( 74.5) | 61 ( 55.5) | 65 ( 59.1) |
| | Deterioration - n(%) | 26 ( 23.6) | 23 ( 20.9) | 15 ( 13.6) | 26 ( 23.6) | 31 ( 28.2) |
| | Missing | 12 | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 26 ( 24.3) | 50 ( 46.7) | 22 ( 20.6) | 32 ( 29.9) | 37 ( 34.6) |
| | No Change - n(%) | 53 ( 49.5) | 37 ( 34.6) | 66 ( 61.7) | 55 ( 51.4) | 50 ( 46.7) |
| | Deterioration - n(%) | 28 ( 26.2) | 20 ( 18.7) | 19 ( 17.8) | 20 ( 18.7) | 20 ( 18.7) |
| | Missing | 15 | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 30 ( 30.9) | 47 ( 48.5) | 24 ( 24.7) | 35 ( 36.1) | 38 ( 39.2) |
| | No Change - n(%) | 56 ( 57.7) | 29 ( 29.9) | 64 ( 66.0) | 48 ( 49.5) | 47 ( 48.5) |
| | Deterioration - n(%) | 11 ( 11.3) | 21 ( 21.6) | 9 ( 9.3) | 14 ( 14.4) | 12 ( 12.4) |
| | Missing | 25 | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 31 ( 36.9) | 45 ( 53.6) | 25 ( 29.8) | 29 ( 34.5) | 33 ( 39.3) |
| | No Change - n(%) | 47 ( 56.0) | 28 ( 33.3) | 55 ( 65.5) | 44 ( 52.4) | 41 ( 48.8) |
| | Deterioration - n(%) | 6 ( 7.1) | 11 ( 13.1) | 4 ( 4.8) | 11 ( 13.1) | 10 ( 11.9) |
| | Missing | 38 | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 27 ( 34.6) | 46 ( 59.0) | 25 ( 32.1) | 25 ( 32.1) | 35 ( 44.9) |
| | No Change - n(%) | 45 ( 57.7) | 19 ( 24.4) | 52 ( 66.7) | 42 ( 53.8) | 36 ( 46.2) |
| | Deterioration - n(%) | 6 ( 7.7) | 13 ( 16.7) | 1 ( 1.3) | 11 ( 14.1) | 7 ( 9.0) |
| | Missing | 44 | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 29 ( 38.2) | 42 ( 55.3) | 25 ( 32.9) | 30 ( 39.5) | 37 ( 48.7) |
| | No Change - n(%) | 39 ( 51.3) | 23 ( 30.3) | 50 ( 65.8) | 36 ( 47.4) | 36 ( 47.4) |
| | Deterioration - n(%) | 8 ( 10.5) | 11 ( 14.5) | 1 ( 1.3) | 10 ( 13.2) | 3 ( 3.9) |
| | Missing | 46 | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 31 ( 41.3) | 41 ( 54.7) | 27 ( 36.0) | 32 ( 42.7) | 37 ( 49.3) |
| | No Change - n(%) | 40 ( 53.3) | 23 ( 30.7) | 47 ( 62.7) | 32 ( 42.7) | 30 ( 40.0) |
| | Deterioration - n(%) | 4 ( 5.3) | 11 ( 14.7) | 1 ( 1.3) | 11 ( 14.7) | 8 ( 10.7) |
| | Missing | 47 | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 30 ( 51.7) | 36 ( 62.1) | 21 ( 36.2) | 24 ( 41.4) | 33 ( 56.9) |
| | No Change - n(%) | 27 ( 46.6) | 16 ( 27.6) | 36 ( 62.1) | 28 ( 48.3) | 22 ( 37.9) |
| | Deterioration - n(%) | 1 ( 1.7) | 6 ( 10.3) | 1 ( 1.7) | 6 ( 10.3) | 3 ( 5.2) |
| | Missing | 64 | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 4.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 27 ( 50.0) | 33 ( 61.1) | 22 ( 40.7) | 20 ( 37.0) | 28 ( 51.9) |
| | No Change - n(%) | 23 ( 42.6) | 14 ( 25.9) | 30 ( 55.6) | 27 ( 50.0) | 21 ( 38.9) |
| | Deterioration - n(%) | 4 ( 7.4) | 7 ( 13.0) | 2 ( 3.7) | 7 ( 13.0) | 5 ( 9.3) |
| | Missing | 68 | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 15 ( 48.4) | 21 ( 67.7) | 11 ( 35.5) | 12 ( 38.7) | 14 ( 45.2) |
| | No Change - n(%) | 15 ( 48.4) | 7 ( 22.6) | 17 ( 54.8) | 13 ( 41.9) | 11 ( 35.5) |
| | Deterioration - n(%) | 1 ( 3.2) | 3 ( 9.7) | 3 ( 9.7) | 6 ( 19.4) | 6 ( 19.4) |
| | Missing | 91 | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
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Table 4.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 13 ( 52.0) | 17 ( 68.0) | 7 ( 28.0) | 10 ( 40.0) | 10 ( 40.0) |
| | No Change - n(%) | 12 ( 48.0) | 3 ( 12.0) | 18 ( 72.0) | 10 ( 40.0) | 13 ( 52.0) |
| | Deterioration - n(%) | 0 | 5 ( 20.0) | 0 | 5 ( 20.0) | 2 ( 8.0) |
| | Missing | 97 | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 11 ( 42.3) | 15 ( 57.7) | 6 ( 23.1) | 9 ( 34.6) | 11 ( 42.3) |
| | No Change - n(%) | 12 ( 46.2) | 6 ( 23.1) | 17 ( 65.4) | 12 ( 46.2) | 10 ( 38.5) |
| | Deterioration - n(%) | 3 ( 11.5) | 5 ( 19.2) | 3 ( 11.5) | 5 ( 19.2) | 5 ( 19.2) |
| | Missing | 96 | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 4 ( 30.8) | 10 ( 76.9) | 1 ( 7.7) | 5 ( 38.5) | 5 ( 38.5) |
| | No Change - n(%) | 8 ( 61.5) | 1 ( 7.7) | 11 ( 84.6) | 6 ( 46.2) | 7 ( 53.8) |
| | Deterioration - n(%) | 1 ( 7.7) | 2 ( 15.4) | 1 ( 7.7) | 2 ( 15.4) | 1 ( 7.7) |
| | Missing | 109 | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) | 0 | 0 | 1 (100.0) |
| | No Change - n(%) | 0 | 0 | 1 (100.0) | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| PD | n | 29 | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 8 ( 27.6) | 14 ( 48.3) | 8 ( 27.6) | 9 ( 31.0) | 5 ( 17.2) |
| | No Change - n(%) | 16 ( 55.2) | 10 ( 34.5) | 16 ( 55.2) | 15 ( 51.7) | 18 ( 62.1) |
| | Deterioration - n(%) | 5 ( 17.2) | 5 ( 17.2) | 5 ( 17.2) | 5 ( 17.2) | 6 ( 20.7) |
| | Missing | 93 | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 1 (100.0) | 0 | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 0 | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 4.6.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| End of Study | n | 9 | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 3 ( 33.3) | 2 ( 22.2) | 3 ( 33.3) | 2 ( 22.2) | 2 ( 22.2) |
| | No Change - n(%) | 6 ( 66.7) | 4 ( 44.4) | 6 ( 66.7) | 4 ( 44.4) | 6 ( 66.7) |
| | Deterioration - n(%) | 0 | 3 ( 33.3) | 0 | 3 ( 33.3) | 1 ( 11.1) |
| | Missing | 113 | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 5.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Day 1 | n | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 23 ( 20.9) | 13 ( 11.8) | 25 ( 22.7) | 11 ( 10.0) |
| | No Change - n(%) | 50 ( 45.5) | 79 ( 71.8) | 41 ( 37.3) | 78 ( 70.9) |
| | Deterioration - n(%) | 37 ( 33.6) | 18 ( 16.4) | 44 ( 40.0) | 21 ( 19.1) |
| | Missing | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 35 ( 32.7) | 24 ( 22.4) | 30 ( 28.0) | 18 ( 16.8) |
| | No Change - n(%) | 34 ( 31.8) | 64 ( 59.8) | 38 ( 35.5) | 64 ( 59.8) |
| | Deterioration - n(%) | 38 ( 35.5) | 19 ( 17.8) | 39 ( 36.4) | 25 ( 23.4) |
| | Missing | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 5.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 2 | n | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 40 ( 41.2) | 28 ( 28.9) | 36 ( 37.1) | 12 ( 12.4) |
| | No Change - n(%) | 36 ( 37.1) | 59 ( 60.8) | 42 ( 43.3) | 69 ( 71.1) |
| | Deterioration - n(%) | 21 ( 21.6) | 10 ( 10.3) | 19 ( 19.6) | 16 ( 16.5) |
| | Missing | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 34 ( 40.5) | 26 ( 31.0) | 37 ( 44.0) | 16 ( 19.0) |
| | No Change - n(%) | 27 ( 32.1) | 50 ( 59.5) | 27 ( 32.1) | 58 ( 69.0) |
| | Deterioration - n(%) | 23 ( 27.4) | 8 ( 9.5) | 20 ( 23.8) | 10 ( 11.9) |
| | Missing | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.

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Table 5.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 4 | n | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 35 ( 44.9) | 25 ( 32.1) | 40 ( 51.3) | 11 ( 14.1) |
| | No Change - n(%) | 31 ( 39.7) | 44 ( 56.4) | 25 ( 32.1) | 56 ( 71.8) |
| | Deterioration - n(%) | 12 ( 15.4) | 9 ( 11.5) | 13 ( 16.7) | 11 ( 14.1) |
| | Missing | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 36 ( 47.4) | 26 ( 34.2) | 44 ( 57.9) | 17 ( 22.4) |
| | No Change - n(%) | 34 ( 44.7) | 46 ( 60.5) | 28 ( 36.8) | 51 ( 67.1) |
| | Deterioration - n(%) | 6 ( 7.9) | 4 ( 5.3) | 4 ( 5.3) | 8 ( 10.5) |
| | Missing | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 5.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 6 | n | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 35 ( 46.7) | 23 ( 30.7) | 45 ( 60.0) | 13 ( 17.3) |
| | No Change - n(%) | 28 ( 37.3) | 49 ( 65.3) | 22 ( 29.3) | 52 ( 69.3) |
| | Deterioration - n(%) | 12 ( 16.0) | 3 ( 4.0) | 8 ( 10.7) | 10 ( 13.3) |
| | Missing | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 34 ( 58.6) | 17 ( 29.3) | 36 ( 62.1) | 10 ( 17.2) |
| | No Change - n(%) | 18 ( 31.0) | 34 ( 58.6) | 15 ( 25.9) | 39 ( 67.2) |
| | Deterioration - n(%) | 6 ( 10.3) | 7 ( 12.1) | 7 ( 12.1) | 9 ( 15.5) |
| | Missing | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.

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Table 5.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 12 | n | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 29 ( 53.7) | 18 ( 33.3) | 27 ( 50.0) | 10 ( 18.5) |
| | No Change - n(%) | 19 ( 35.2) | 33 ( 61.1) | 17 ( 31.5) | 36 ( 66.7) |
| | Deterioration - n(%) | 6 ( 11.1) | 3 ( 5.6) | 10 ( 18.5) | 8 ( 14.8) |
| | Missing | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 14 ( 45.2) | 11 ( 35.5) | 19 ( 61.3) | 6 ( 19.4) |
| | No Change - n(%) | 11 ( 35.5) | 17 ( 54.8) | 6 ( 19.4) | 20 ( 64.5) |
| | Deterioration - n(%) | 6 ( 19.4) | 3 ( 9.7) | 6 ( 19.4) | 5 ( 16.1) |
| | Missing | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.

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Table 5.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 18 | n | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 17 ( 68.0) | 11 ( 44.0) | 15 ( 60.0) | 7 ( 28.0) |
| | No Change - n(%) | 6 ( 24.0) | 14 ( 56.0) | 6 ( 24.0) | 15 ( 60.0) |
| | Deterioration - n(%) | 2 ( 8.0) | 0 | 4 ( 16.0) | 3 ( 12.0) |
| | Missing | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 11 ( 42.3) | 12 ( 46.2) | 16 ( 61.5) | 6 ( 23.1) |
| | No Change - n(%) | 11 ( 42.3) | 11 ( 42.3) | 4 ( 15.4) | 18 ( 69.2) |
| | Deterioration - n(%) | 4 ( 15.4) | 3 ( 11.5) | 6 ( 23.1) | 2 ( 7.7) |
| | Missing | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.

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Table 5.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 24 | n | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 6 ( 46.2) | 2 ( 15.4) | 7 ( 53.8) | 5 ( 38.5) |
| | No Change - n(%) | 6 ( 46.2) | 9 ( 69.2) | 4 ( 30.8) | 7 ( 53.8) |
| | Deterioration - n(%) | 1 ( 7.7) | 2 ( 15.4) | 2 ( 15.4) | 1 ( 7.7) |
| | Missing | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.

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Table 5.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| PD | n | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 8 ( 27.6) | 5 ( 17.2) | 10 ( 34.5) | 8 ( 27.6) |
| | No Change - n(%) | 14 ( 48.3) | 19 ( 65.5) | 13 ( 44.8) | 17 ( 58.6) |
| | Deterioration - n(%) | 7 ( 24.1) | 5 ( 17.2) | 6 ( 20.7) | 4 ( 13.8) |
| | Missing | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 0 | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 1 (100.0) | 0 | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 | 1 (100.0) | 0 |
| | Missing | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.

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Table 5.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| End of Study | n | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 4 ( 44.4) | 1 ( 11.1) | 2 ( 22.2) | 3 ( 33.3) |
| | No Change - n(%) | 4 ( 44.4) | 5 ( 55.6) | 4 ( 44.4) | 2 ( 22.2) |
| | Deterioration - n(%) | 1 ( 11.1) | 3 ( 33.3) | 3 ( 33.3) | 4 ( 44.4) |
| | Missing | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.

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Table 4.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 40 ( 36.4) | 22 ( 20.0) |
| | No Change - n(%) | 31 ( 28.2) | 38 ( 34.5) |
| | Deterioration - n(%) | 39 ( 35.5) | 50 ( 45.5) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 50 ( 46.7) | 46 ( 43.0) |
| | No Change - n(%) | 22 ( 20.6) | 27 ( 25.2) |
| | Deterioration - n(%) | 35 ( 32.7) | 34 ( 31.8) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.

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Table 4.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Month 2 | n | 97 | 97 |
| | Improvement - n(%) | 47 ( 48.5) | 51 ( 52.6) |
| | No Change - n(%) | 27 ( 27.8) | 21 ( 21.6) |
| | Deterioration - n(%) | 23 ( 23.7) | 25 ( 25.8) |
| | Missing | 25 | 25 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 48 ( 57.1) | 48 ( 57.1) |
| | No Change - n(%) | 19 ( 22.6) | 16 ( 19.0) |
| | Deterioration - n(%) | 17 ( 20.2) | 20 ( 23.8) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.

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Table 4.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 46 ( 59.0) | 44 ( 56.4) |
| | No Change - n(%) | 18 ( 23.1) | 19 ( 24.4) |
| | Deterioration - n(%) | 14 ( 17.9) | 15 ( 19.2) |
| | Missing | 44 | 44 |
| Month 5 | n | 76 | 76 |
| | Improvement - n(%) | 46 ( 60.5) | 50 ( 65.8) |
| | No Change - n(%) | 19 ( 25.0) | 16 ( 21.1) |
| | Deterioration - n(%) | 11 ( 14.5) | 10 ( 13.2) |
| | Missing | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Month 6 | n | 75 | 75 |
| | Improvement - n(%) | 50 ( 66.7) | 47 ( 62.7) |
| | No Change - n(%) | 15 ( 20.0) | 17 ( 22.7) |
| | Deterioration - n(%) | 10 ( 13.3) | 11 ( 14.7) |
| | Missing | 47 | 47 |
| Month 9 | n | 58 | 58 |
| | Improvement - n(%) | 35 ( 60.3) | 41 ( 70.7) |
| | No Change - n(%) | 18 ( 31.0) | 10 ( 17.2) |
| | Deterioration - n(%) | 5 ( 8.6) | 7 ( 12.1) |
| | Missing | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.

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Table 4.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| | | Physical Functioning | Global Health/QoL |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 37 ( 68.5) | 40 ( 74.1) |
| | No Change - n(%) | 11 ( 20.4) | 4 ( 7.4) |
| | Deterioration - n(%) | 6 ( 11.1) | 10 ( 18.5) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 18 ( 58.1) | 19 ( 61.3) |
| | No Change - n(%) | 5 ( 16.1) | 3 ( 9.7) |
| | Deterioration - n(%) | 8 ( 25.8) | 9 ( 29.0) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.

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Table 4.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| | | Physical Functioning | Global Health/QoL |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 18 ( 72.0) | 18 ( 72.0) |
| | No Change - n(%) | 5 ( 20.0) | 5 ( 20.0) |
| | Deterioration - n(%) | 2 ( 8.0) | 2 ( 8.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 13 ( 50.0) | 16 ( 61.5) |
| | No Change - n(%) | 8 ( 30.8) | 1 ( 3.8) |
| | Deterioration - n(%) | 5 ( 19.2) | 9 ( 34.6) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.

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Table 4.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| | | Physical Functioning | Global Health/QoL |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 6 ( 46.2) | 10 ( 76.9) |
| | No Change - n(%) | 5 ( 38.5) | 1 ( 7.7) |
| | Deterioration - n(%) | 2 ( 15.4) | 2 ( 15.4) |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.

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Table 4.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| | | Physical Functioning | Global Health/QoL |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 15 ( 51.7) | 15 ( 51.7) |
| | No Change - n(%) | 2 ( 6.9) | 6 ( 20.7) |
| | Deterioration - n(%) | 12 ( 41.4) | 8 ( 27.6) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 4.6.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 5 ( 55.6) | 5 ( 55.6) |
| | No Change - n(%) | 1 ( 11.1) | 2 ( 22.2) |
| | Deterioration - n(%) | 3 ( 33.3) | 2 ( 22.2) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 5.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) |
|---|---|---|
| Visit/Time Point | Responder Category [a] | Emotional Functioning |
| Day 1 | n | 110 |
| | Improvement - n(%) | 31 ( 28.2) |
| | No Change - n(%) | 34 ( 30.9) |
| | Deterioration - n(%) | 45 ( 40.9) |
| | Missing | 12 |
| Month 1 | n | 107 |
| | Improvement - n(%) | 37 ( 34.6) |
| | No Change - n(%) | 37 ( 34.6) |
| | Deterioration - n(%) | 33 ( 30.8) |
| | Missing | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.

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Table 5.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 2 | n | 97 |
| | Improvement - n(%) | 46 ( 47.4) |
| | No Change - n(%) | 32 ( 33.0) |
| | Deterioration - n(%) | 19 ( 19.6) |
| | Missing | 25 |
| Month 3 | n | 84 |
| | Improvement - n(%) | 38 ( 45.2) |
| | No Change - n(%) | 31 ( 36.9) |
| | Deterioration - n(%) | 15 ( 17.9) |
| | Missing | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.

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Table 5.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 4 | n | 78 |
| | Improvement - n(%) | 41 ( 52.6) |
| | No Change - n(%) | 26 ( 33.3) |
| | Deterioration - n(%) | 11 ( 14.1) |
| | Missing | 44 |
| Month 5 | n | 76 |
| | Improvement - n(%) | 40 ( 52.6) |
| | No Change - n(%) | 29 ( 38.2) |
| | Deterioration - n(%) | 7 ( 9.2) |
| | Missing | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.

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Table 5.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 6 | n | 75 |
| | Improvement - n(%) | 38 ( 50.7) |
| | No Change - n(%) | 28 ( 37.3) |
| | Deterioration - n(%) | 9 ( 12.0) |
| | Missing | 47 |
| Month 9 | n | 58 |
| | Improvement - n(%) | 30 ( 51.7) |
| | No Change - n(%) | 17 ( 29.3) |
| | Deterioration - n(%) | 11 ( 19.0) |
| | Missing | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.

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Table 5.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 12 | n | 54 |
| | Improvement - n(%) | 22 ( 40.7) |
| | No Change - n(%) | 28 ( 51.9) |
| | Deterioration - n(%) | 4 ( 7.4) |
| | Missing | 68 |
| Month 15 | n | 31 |
| | Improvement - n(%) | 14 ( 45.2) |
| | No Change - n(%) | 12 ( 38.7) |
| | Deterioration - n(%) | 5 ( 16.1) |
| | Missing | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 5.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 18 | n | 25 |
| | Improvement - n(%) | 14 ( 56.0) |
| | No Change - n(%) | 9 ( 36.0) |
| | Deterioration - n(%) | 2 ( 8.0) |
| | Missing | 97 |
| Month 21 | n | 26 |
| | Improvement - n(%) | 13 ( 50.0) |
| | No Change - n(%) | 8 ( 30.8) |
| | Deterioration - n(%) | 5 ( 19.2) |
| | Missing | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.

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Table 5.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 24 | n | 13 |
| | Improvement - n(%) | 4 ( 30.8) |
| | No Change - n(%) | 6 ( 46.2) |
| | Deterioration - n(%) | 3 ( 23.1) |
| | Missing | 109 |
| Month 30 | n | 1 |
| | Improvement - n(%) | 1 (100.0) |
| | No Change - n(%) | 0 |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.

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Table 5.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) |
|---|---|---|
| Visit/Time Point | Responder Category [a] | Emotional Functioning |
| PD | n | 29 |
| | Improvement - n(%) | 10 ( 34.5) |
| | No Change - n(%) | 11 ( 37.9) |
| | Deterioration - n(%) | 8 ( 27.6) |
| | Missing | 93 |
| CR | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 1 (100.0) |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.

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Table 5.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| End of Study | n | 9 |
| | Improvement - n(%) | 2 ( 22.2) |
| | No Change - n(%) | 3 ( 33.3) |
| | Deterioration - n(%) | 4 ( 44.4) |
| | Missing | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-C30 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.

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Table 4.6.2.1d

Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)

PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 23 ( 20.9) | 36 ( 32.7) | 12 ( 10.9) | 24 ( 21.8) | 8 ( 7.3) |
| | No Change - n(%) | 23 ( 20.9) | 29 ( 26.4) | 53 ( 48.2) | 58 ( 52.7) | 45 ( 40.9) |
| | Deterioration - n(%) | 64 ( 58.2) | 45 ( 40.9) | 45 ( 40.9) | 28 ( 25.5) | 57 ( 51.8) |
| | Missing | 12 | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 26 ( 24.3) | 39 ( 36.4) | 20 ( 18.7) | 31 ( 29.0) | 14 ( 13.1) |
| | No Change - n(%) | 28 ( 26.2) | 33 ( 30.8) | 49 ( 45.8) | 56 ( 52.3) | 53 ( 49.5) |
| | Deterioration - n(%) | 53 ( 49.5) | 35 ( 32.7) | 38 ( 35.5) | 20 ( 18.7) | 40 ( 37.4) |
| | Missing | 15 | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening on Fatigue and Pain; >=+10 for improvement and <=-10 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 35 ( 36.1) | 39 ( 40.2) | 22 ( 22.7) | 32 ( 33.0) | 22 ( 22.7) |
| | No Change - n(%) | 28 ( 28.9) | 29 ( 29.9) | 51 ( 52.6) | 53 ( 54.6) | 55 ( 56.7) |
| | Deterioration - n(%) | 34 ( 35.1) | 29 ( 29.9) | 24 ( 24.7) | 12 ( 12.4) | 20 ( 20.6) |
| | Missing | 25 | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 37 ( 44.0) | 37 ( 44.0) | 24 ( 28.6) | 28 ( 33.3) | 19 ( 22.6) |
| | No Change - n(%) | 27 ( 32.1) | 26 ( 31.0) | 44 ( 52.4) | 43 ( 51.2) | 52 ( 61.9) |
| | Deterioration - n(%) | 20 ( 23.8) | 21 ( 25.0) | 16 ( 19.0) | 13 ( 15.5) | 13 ( 15.5) |
| | Missing | 38 | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening on Fatigue and Pain; >=+10 for improvement and <=-10 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 33 ( 42.3) | 34 ( 43.6) | 18 ( 23.1) | 26 ( 33.3) | 17 ( 21.8) |
| | No Change - n(%) | 22 ( 28.2) | 30 ( 38.5) | 48 ( 61.5) | 43 ( 55.1) | 44 ( 56.4) |
| | Deterioration - n(%) | 23 ( 29.5) | 14 ( 17.9) | 12 ( 15.4) | 9 ( 11.5) | 17 ( 21.8) |
| | Missing | 44 | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 42 ( 55.3) | 36 ( 47.4) | 23 ( 30.3) | 25 ( 32.9) | 21 ( 27.6) |
| | No Change - n(%) | 19 ( 25.0) | 25 ( 32.9) | 42 ( 55.3) | 40 ( 52.6) | 45 ( 59.2) |
| | Deterioration - n(%) | 15 ( 19.7) | 15 ( 19.7) | 11 ( 14.5) | 11 ( 14.5) | 10 ( 13.2) |
| | Missing | 46 | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening on Fatigue and Pain; >=+10 for improvement and <=-10 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 38 ( 50.7) | 36 ( 48.0) | 20 ( 26.7) | 24 ( 32.0) | 24 ( 32.0) |
| | No Change - n(%) | 21 ( 28.0) | 24 ( 32.0) | 45 ( 60.0) | 42 ( 56.0) | 41 ( 54.7) |
| | Deterioration - n(%) | 16 ( 21.3) | 15 ( 20.0) | 10 ( 13.3) | 9 ( 12.0) | 10 ( 13.3) |
| | Missing | 47 | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 36 ( 62.1) | 29 ( 50.0) | 20 ( 34.5) | 19 ( 32.8) | 21 ( 36.2) |
| | No Change - n(%) | 17 ( 29.3) | 21 ( 36.2) | 33 ( 56.9) | 33 ( 56.9) | 33 ( 56.9) |
| | Deterioration - n(%) | 5 ( 8.6) | 8 ( 13.8) | 5 ( 8.6) | 6 ( 10.3) | 4 ( 6.9) |
| | Missing | 64 | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening on Fatigue and Pain; >=+10 for improvement and <=-10 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 31 ( 57.4) | 31 ( 57.4) | 19 ( 35.2) | 13 ( 24.1) | 23 ( 42.6) |
| | No Change - n(%) | 15 ( 27.8) | 14 ( 25.9) | 27 ( 50.0) | 34 ( 63.0) | 25 ( 46.3) |
| | Deterioration - n(%) | 8 ( 14.8) | 9 ( 16.7) | 8 ( 14.8) | 7 ( 13.0) | 6 ( 11.1) |
| | Missing | 68 | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 18 ( 58.1) | 16 ( 51.6) | 9 ( 29.0) | 5 ( 16.1) | 7 ( 22.6) |
| | No Change - n(%) | 8 ( 25.8) | 10 ( 32.3) | 17 ( 54.8) | 21 ( 67.7) | 14 ( 45.2) |
| | Deterioration - n(%) | 5 ( 16.1) | 5 ( 16.1) | 5 ( 16.1) | 5 ( 16.1) | 10 ( 32.3) |
| | Missing | 91 | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening on Fatigue and Pain; >=+10 for improvement and <=-10 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 14 ( 56.0) | 13 ( 52.0) | 6 ( 24.0) | 9 ( 36.0) | 7 ( 28.0) |
| | No Change - n(%) | 7 ( 28.0) | 7 ( 28.0) | 16 ( 64.0) | 13 ( 52.0) | 14 ( 56.0) |
| | Deterioration - n(%) | 4 ( 16.0) | 5 ( 20.0) | 3 ( 12.0) | 3 ( 12.0) | 4 ( 16.0) |
| | Missing | 97 | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 11 ( 42.3) | 12 ( 46.2) | 6 ( 23.1) | 9 ( 34.6) | 7 ( 26.9) |
| | No Change - n(%) | 6 ( 23.1) | 8 ( 30.8) | 15 ( 57.7) | 14 ( 53.8) | 11 ( 42.3) |
| | Deterioration - n(%) | 9 ( 34.6) | 6 ( 23.1) | 5 ( 19.2) | 3 ( 11.5) | 8 ( 30.8) |
| | Missing | 96 | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening on Fatigue and Pain; >=+10 for improvement and <=-10 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 8 ( 61.5) | 7 ( 53.8) | 4 ( 30.8) | 3 ( 23.1) | 6 ( 46.2) |
| | No Change - n(%) | 4 ( 30.8) | 2 ( 15.4) | 7 ( 53.8) | 9 ( 69.2) | 5 ( 38.5) |
| | Deterioration - n(%) | 1 ( 7.7) | 4 ( 30.8) | 2 ( 15.4) | 1 ( 7.7) | 2 ( 15.4) |
| | Missing | 109 | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) | 1 (100.0) | 0 | 1 (100.0) |
| | No Change - n(%) | 0 | 0 | 0 | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening on Fatigue and Pain; >=+10 for improvement and <=-10 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| PD | n | 29 | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 10 ( 34.5) | 12 ( 41.4) | 7 ( 24.1) | 6 ( 20.7) | 2 ( 6.9) |
| | No Change - n(%) | 9 ( 31.0) | 7 ( 24.1) | 14 ( 48.3) | 18 ( 62.1) | 14 ( 48.3) |
| | Deterioration - n(%) | 10 ( 34.5) | 10 ( 34.5) | 8 ( 27.6) | 5 ( 17.2) | 13 ( 44.8) |
| | Missing | 93 | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 0 | 0 | 0 | 0 |
| | No Change - n(%) | 0 | 1 (100.0) | 1 (100.0) | 1 (100.0) | 0 |
| | Deterioration - n(%) | 1 (100.0) | 0 | 0 | 0 | 1 (100.0) |
| | Missing | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening on Fatigue and Pain; >=+10 for improvement and <=-10 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| End of Study | n | 9 | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 1 ( 11.1) | 2 ( 22.2) | 2 ( 22.2) | 0 | 0 |
| | No Change - n(%) | 5 ( 55.6) | 3 ( 33.3) | 2 ( 22.2) | 7 ( 77.8) | 6 ( 66.7) |
| | Deterioration - n(%) | 3 ( 33.3) | 4 ( 44.4) | 5 ( 55.6) | 2 ( 22.2) | 3 ( 33.3) |
| | Missing | 113 | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-10 for improvement and >=+10 for worsening on Fatigue and Pain; >=+10 for improvement and <=-10 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Day 1 | n | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 19 ( 17.3) | 13 ( 11.8) | 25 ( 22.7) | 11 ( 10.0) |
| | No Change - n(%) | 36 ( 32.7) | 72 ( 65.5) | 34 ( 30.9) | 77 ( 70.0) |
| | Deterioration - n(%) | 55 ( 50.0) | 25 ( 22.7) | 51 ( 46.4) | 22 ( 20.0) |
| | Missing | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 27 ( 25.2) | 22 ( 20.6) | 24 ( 22.4) | 12 ( 11.2) |
| | No Change - n(%) | 25 ( 23.4) | 65 ( 60.7) | 37 ( 34.6) | 70 ( 65.4) |
| | Deterioration - n(%) | 55 ( 51.4) | 20 ( 18.7) | 46 ( 43.0) | 25 ( 23.4) |
| | Missing | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 2 | n | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 25 ( 25.8) | 27 ( 27.8) | 26 ( 26.8) | 11 ( 11.3) |
| | No Change - n(%) | 38 ( 39.2) | 60 ( 61.9) | 43 ( 44.3) | 70 ( 72.2) |
| | Deterioration - n(%) | 34 ( 35.1) | 10 ( 10.3) | 28 ( 28.9) | 16 ( 16.5) |
| | Missing | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 28 ( 33.3) | 24 ( 28.6) | 29 ( 34.5) | 15 ( 17.9) |
| | No Change - n(%) | 33 ( 39.3) | 53 ( 63.1) | 34 ( 40.5) | 58 ( 69.0) |
| | Deterioration - n(%) | 23 ( 27.4) | 7 ( 8.3) | 21 ( 25.0) | 11 ( 13.1) |
| | Missing | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 4 | n | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 25 ( 32.1) | 21 ( 26.9) | 34 ( 43.6) | 12 ( 15.4) |
| | No Change - n(%) | 33 ( 42.3) | 47 ( 60.3) | 29 ( 37.2) | 55 ( 70.5) |
| | Deterioration - n(%) | 20 ( 25.6) | 10 ( 12.8) | 15 ( 19.2) | 11 ( 14.1) |
| | Missing | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 33 ( 43.4) | 22 ( 28.9) | 32 ( 42.1) | 14 ( 18.4) |
| | No Change - n(%) | 27 ( 35.5) | 49 ( 64.5) | 37 ( 48.7) | 54 ( 71.1) |
| | Deterioration - n(%) | 16 ( 21.1) | 5 ( 6.6) | 7 ( 9.2) | 8 ( 10.5) |
| | Missing | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 6 | n | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 29 ( 38.7) | 21 ( 28.0) | 33 ( 44.0) | 12 ( 16.0) |
| | No Change - n(%) | 29 ( 38.7) | 46 ( 61.3) | 31 ( 41.3) | 52 ( 69.3) |
| | Deterioration - n(%) | 17 ( 22.7) | 8 ( 10.7) | 11 ( 14.7) | 11 ( 14.7) |
| | Missing | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 28 ( 48.3) | 13 ( 22.4) | 26 ( 44.8) | 10 ( 17.2) |
| | No Change - n(%) | 23 ( 39.7) | 39 ( 67.2) | 26 ( 44.8) | 37 ( 63.8) |
| | Deterioration - n(%) | 7 ( 12.1) | 6 ( 10.3) | 6 ( 10.3) | 11 ( 19.0) |
| | Missing | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 5.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 12 | n | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 24 ( 44.4) | 13 ( 24.1) | 22 ( 40.7) | 11 ( 20.4) |
| | No Change - n(%) | 23 ( 42.6) | 39 ( 72.2) | 20 ( 37.0) | 35 ( 64.8) |
| | Deterioration - n(%) | 7 ( 13.0) | 2 ( 3.7) | 12 ( 22.2) | 8 ( 14.8) |
| | Missing | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 13 ( 41.9) | 11 ( 35.5) | 16 ( 51.6) | 6 ( 19.4) |
| | No Change - n(%) | 10 ( 32.3) | 17 ( 54.8) | 7 ( 22.6) | 19 ( 61.3) |
| | Deterioration - n(%) | 8 ( 25.8) | 3 ( 9.7) | 8 ( 25.8) | 6 ( 19.4) |
| | Missing | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 5.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 18 | n | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 11 ( 44.0) | 9 ( 36.0) | 13 ( 52.0) | 7 ( 28.0) |
| | No Change - n(%) | 11 ( 44.0) | 15 ( 60.0) | 9 ( 36.0) | 16 ( 64.0) |
| | Deterioration - n(%) | 3 ( 12.0) | 1 ( 4.0) | 3 ( 12.0) | 2 ( 8.0) |
| | Missing | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 10 ( 38.5) | 8 ( 30.8) | 12 ( 46.2) | 8 ( 30.8) |
| | No Change - n(%) | 12 ( 46.2) | 15 ( 57.7) | 9 ( 34.6) | 17 ( 65.4) |
| | Deterioration - n(%) | 4 ( 15.4) | 3 ( 11.5) | 5 ( 19.2) | 1 ( 3.8) |
| | Missing | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 5.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 24 | n | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 3 ( 23.1) | 3 ( 23.1) | 7 ( 53.8) | 4 ( 30.8) |
| | No Change - n(%) | 9 ( 69.2) | 8 ( 61.5) | 4 ( 30.8) | 8 ( 61.5) |
| | Deterioration - n(%) | 1 ( 7.7) | 2 ( 15.4) | 2 ( 15.4) | 1 ( 7.7) |
| | Missing | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| PD | n | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 12 ( 41.4) | 5 ( 17.2) | 6 ( 20.7) | 3 ( 10.3) |
| | No Change - n(%) | 6 ( 20.7) | 17 ( 58.6) | 15 ( 51.7) | 18 ( 62.1) |
| | Deterioration - n(%) | 11 ( 37.9) | 7 ( 24.1) | 8 ( 27.6) | 8 ( 27.6) |
| | Missing | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 0 | 0 | 0 |
| | No Change - n(%) | 0 | 1 (100.0) | 0 | 1 (100.0) |
| | Deterioration - n(%) | 1 (100.0) | 0 | 1 (100.0) | 0 |
| | Missing | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| End of Study | n | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 1 ( 11.1) | 0 | 2 ( 22.2) | 2 ( 22.2) |
| | No Change - n(%) | 6 ( 66.7) | 7 ( 77.8) | 5 ( 55.6) | 4 ( 44.4) |
| | Deterioration - n(%) | 2 ( 22.2) | 2 ( 22.2) | 2 ( 22.2) | 3 ( 33.3) |
| | Missing | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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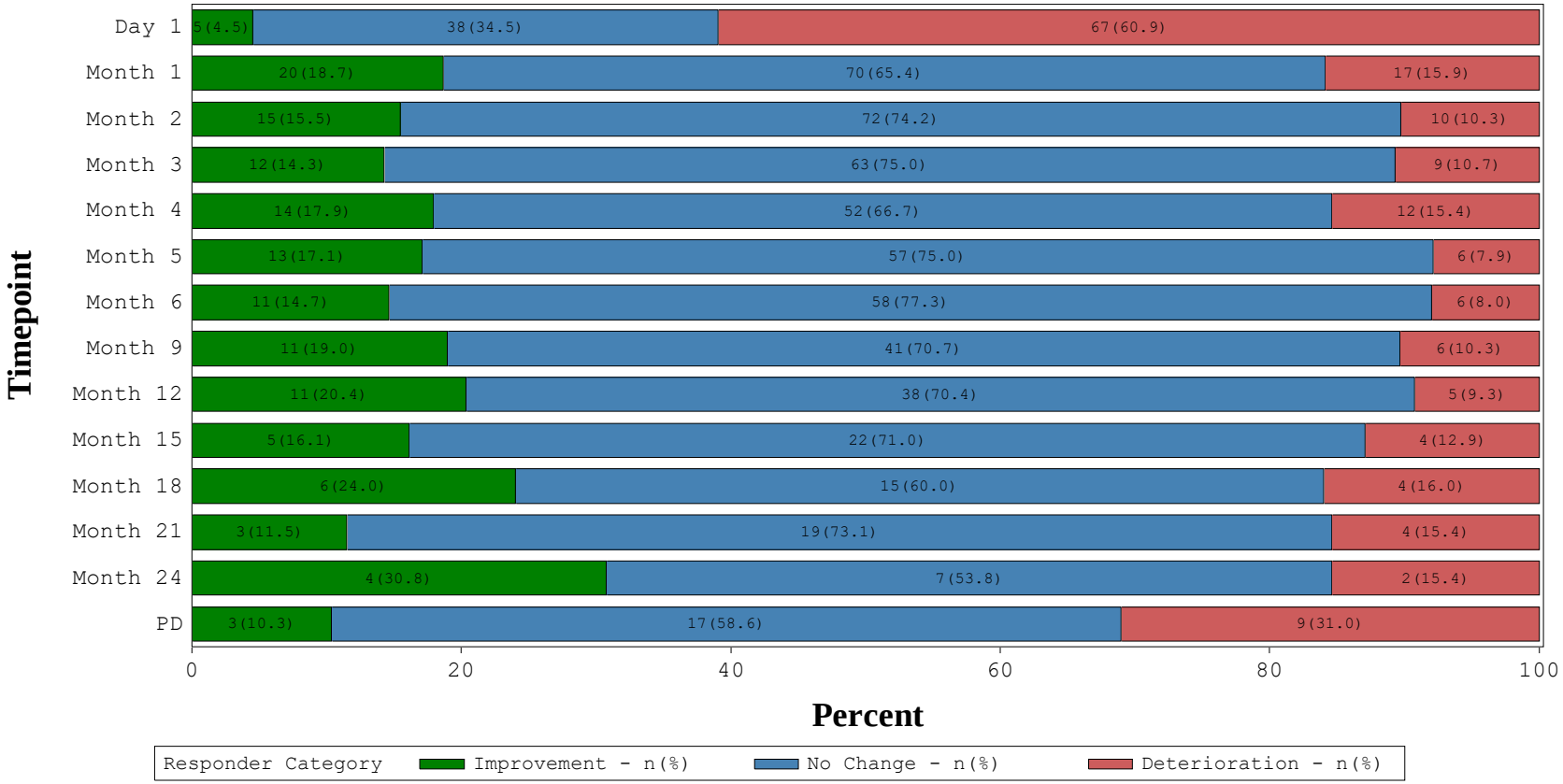
Figure 4.1.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Nausea and Vomiting Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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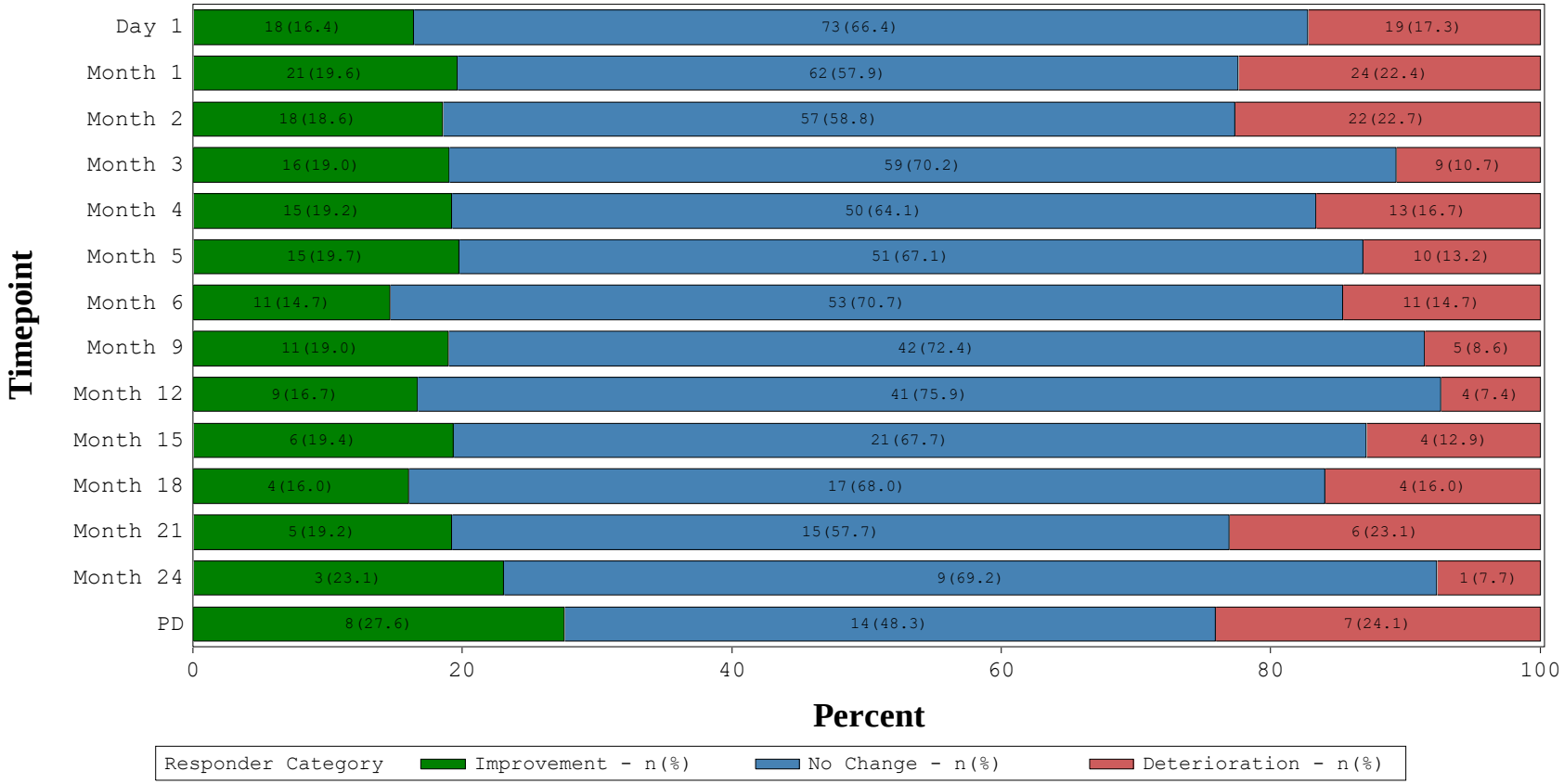
Figure 4.2.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Dyspnoea Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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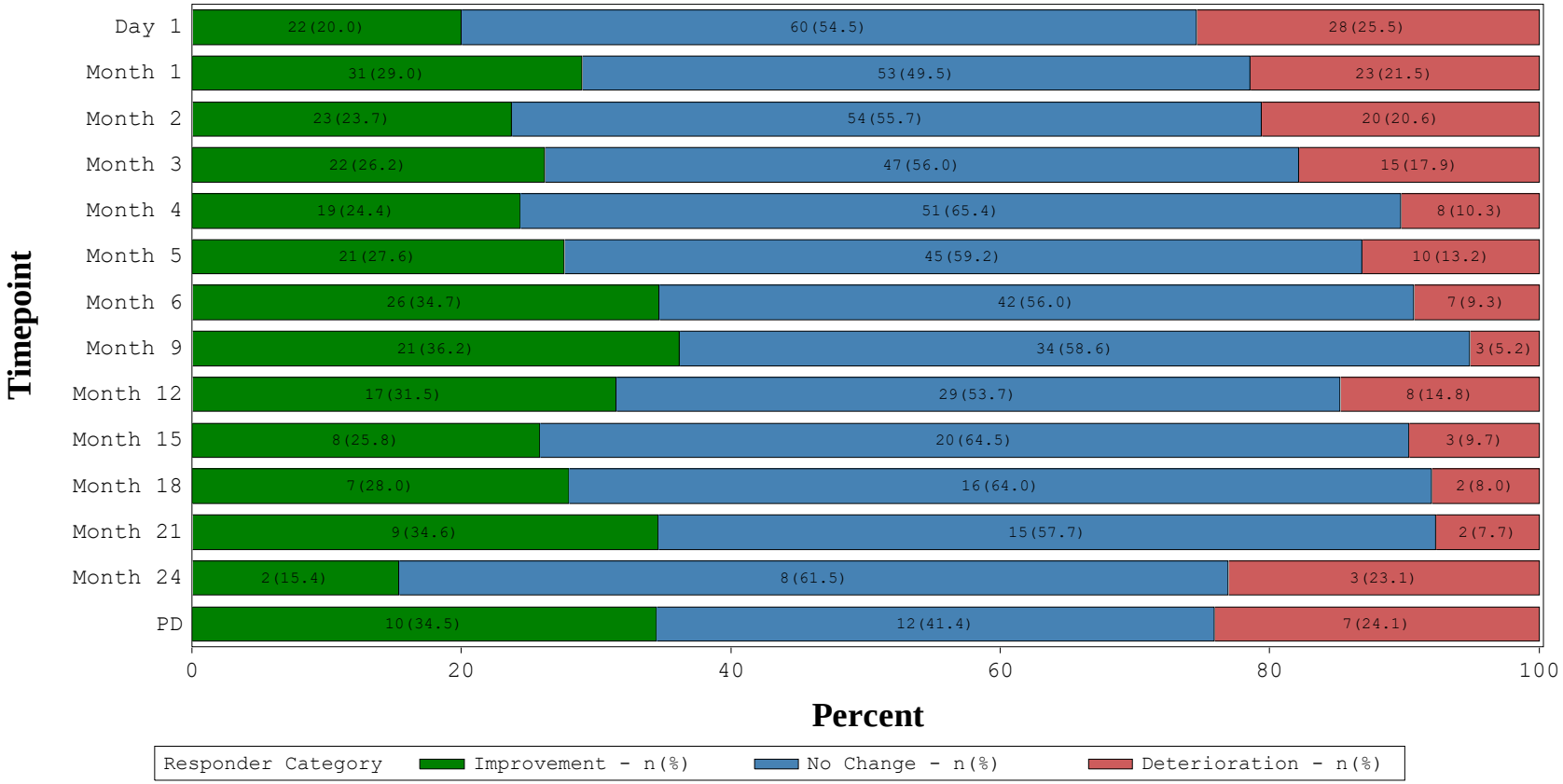
Analysis Plan: 12MAY2021 Confidential

Figure 4.3.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Insomnia Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
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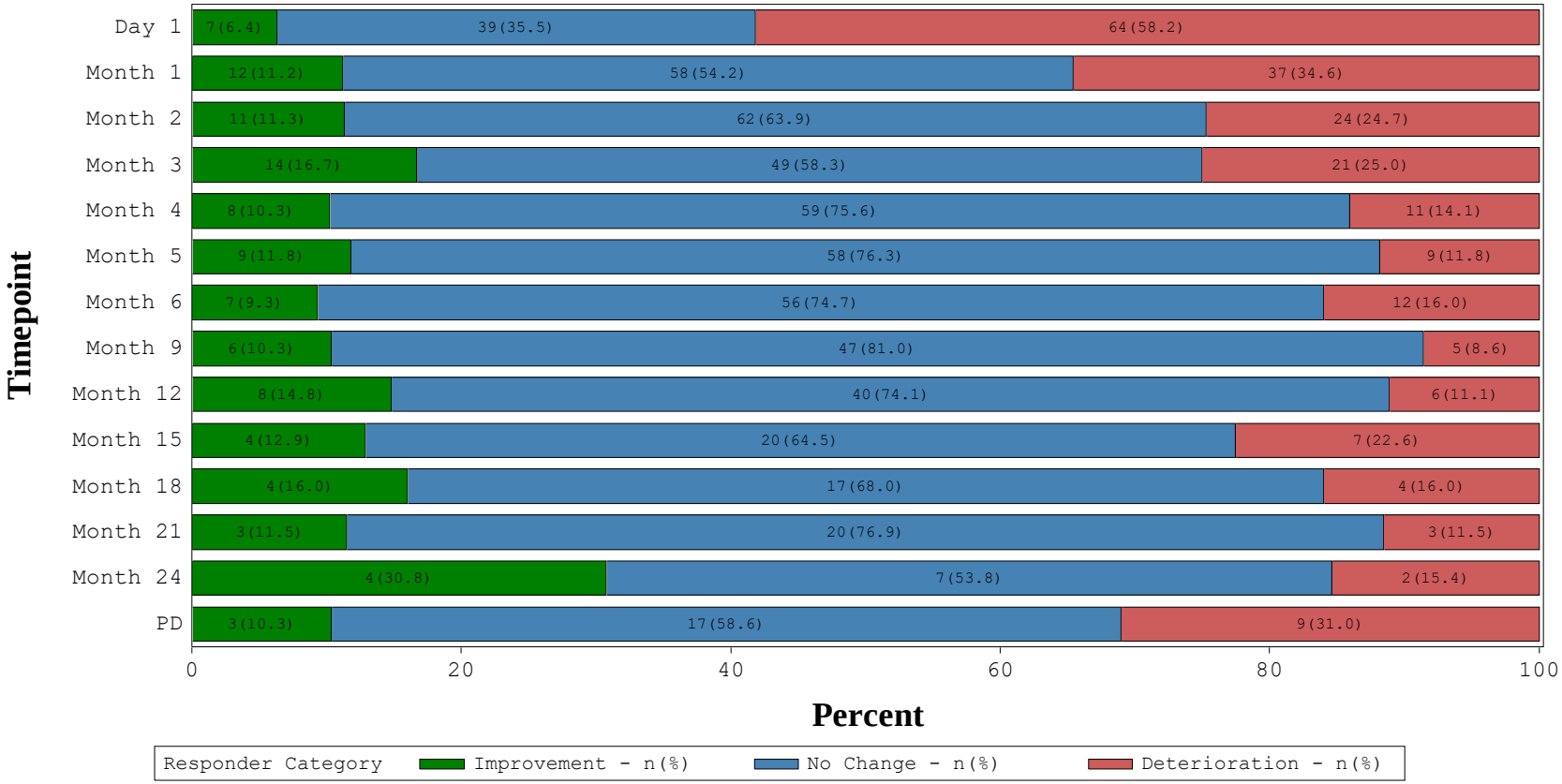
Figure 4.4.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Appetite Loss Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
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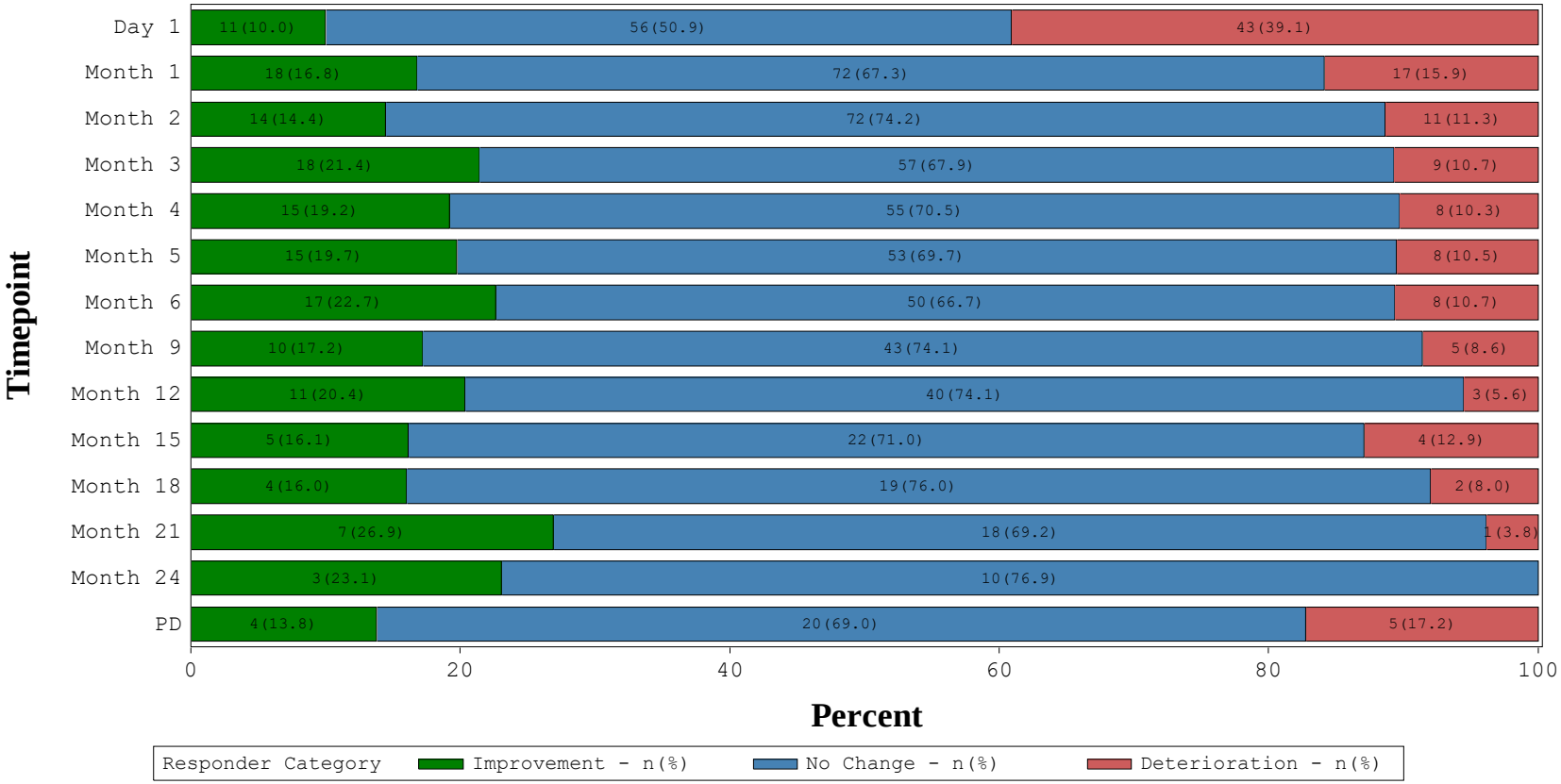
Figure 4.5.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Constipation Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
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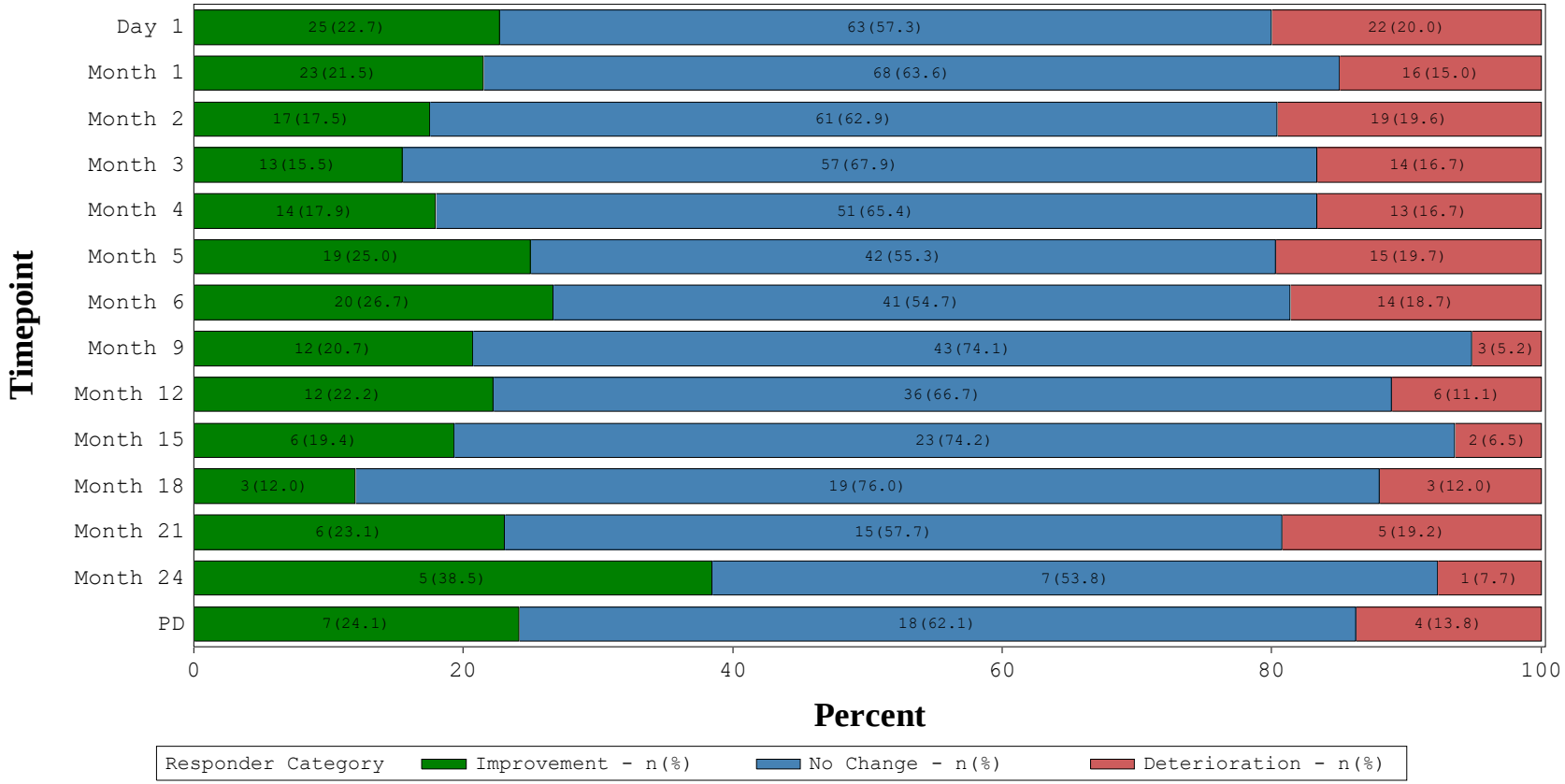
Figure 4.6.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Diarrhoea Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
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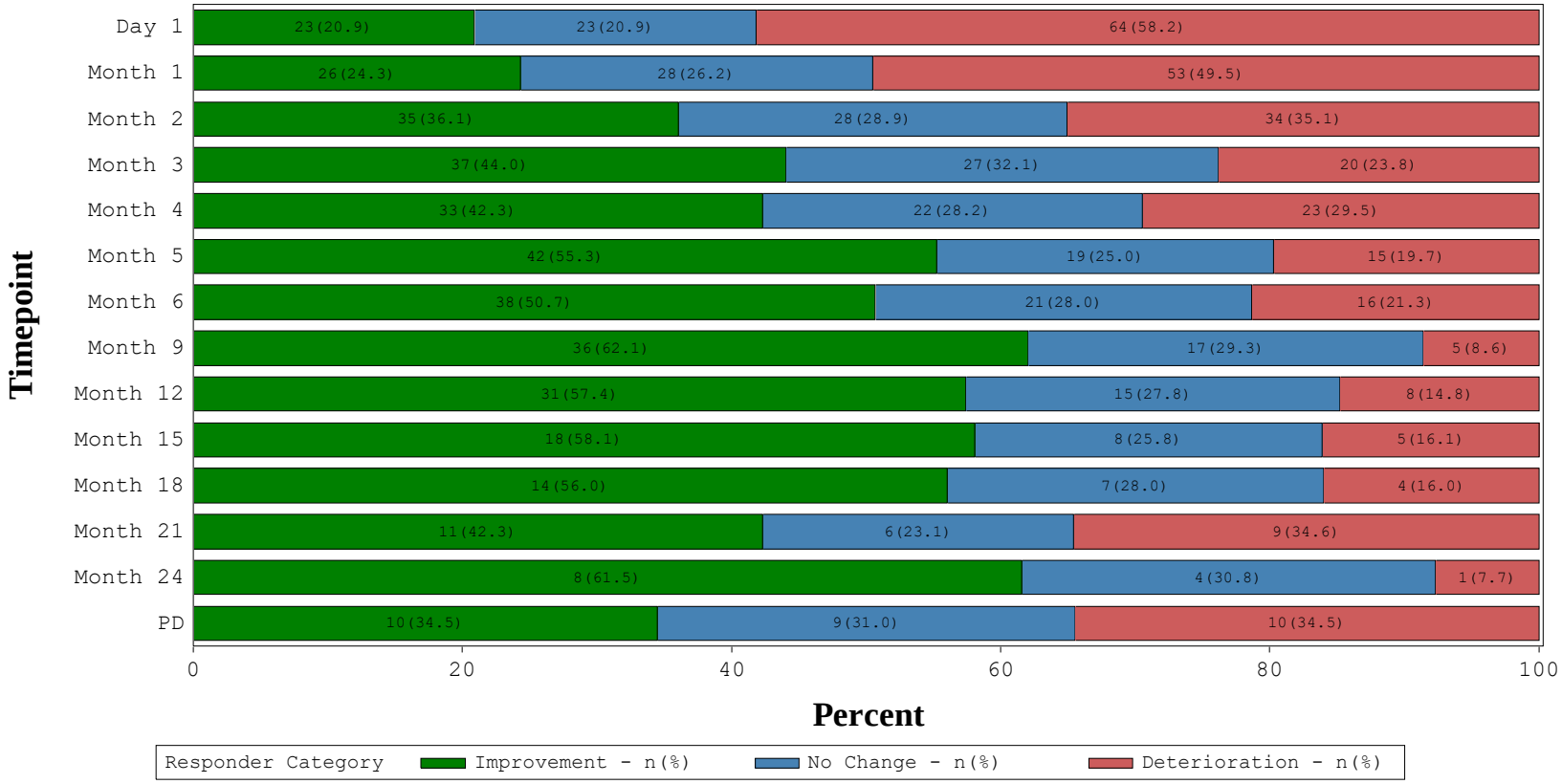
Figure 4.7.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Fatigue Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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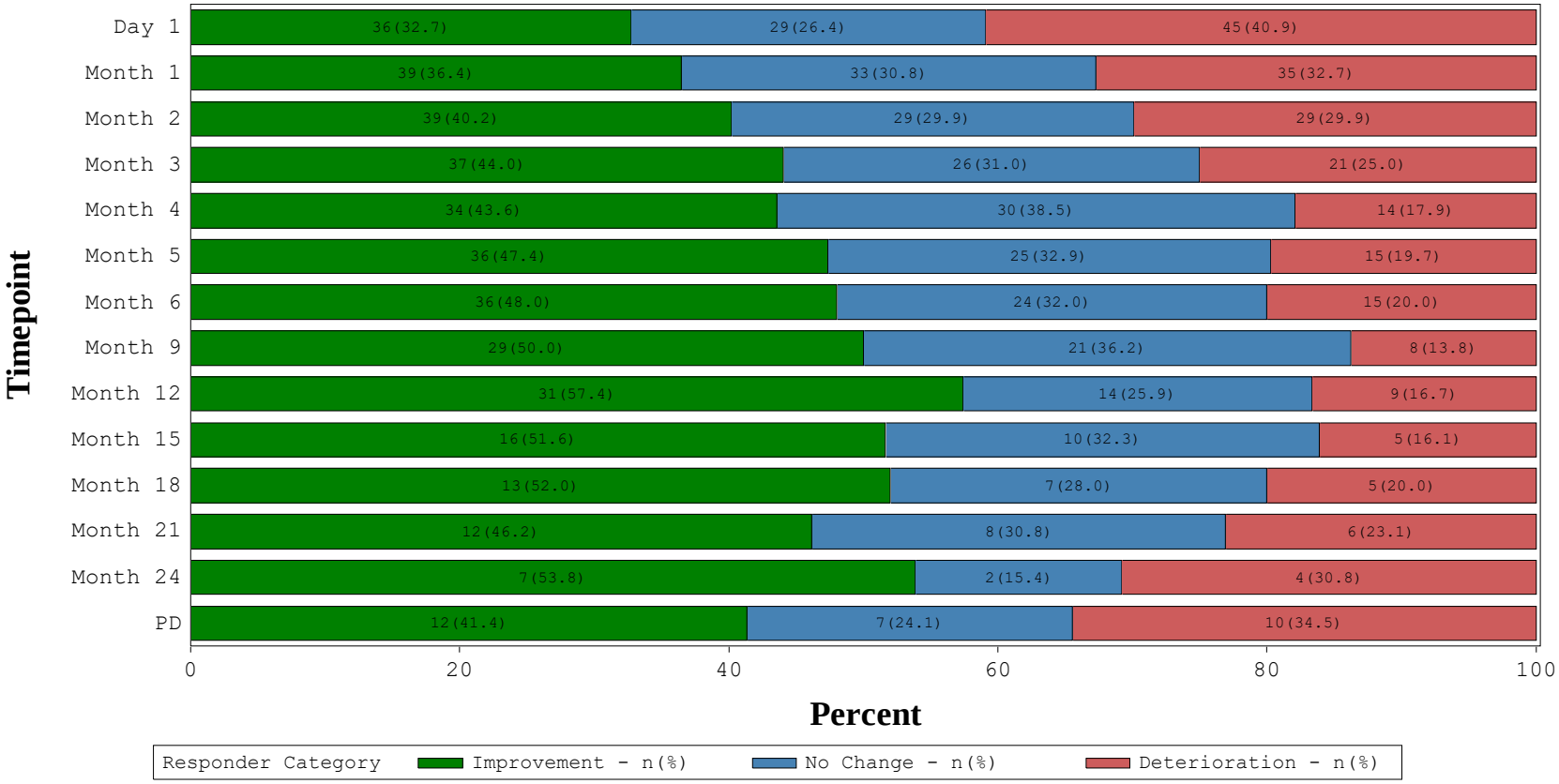
Figure 4.8.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Pain Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
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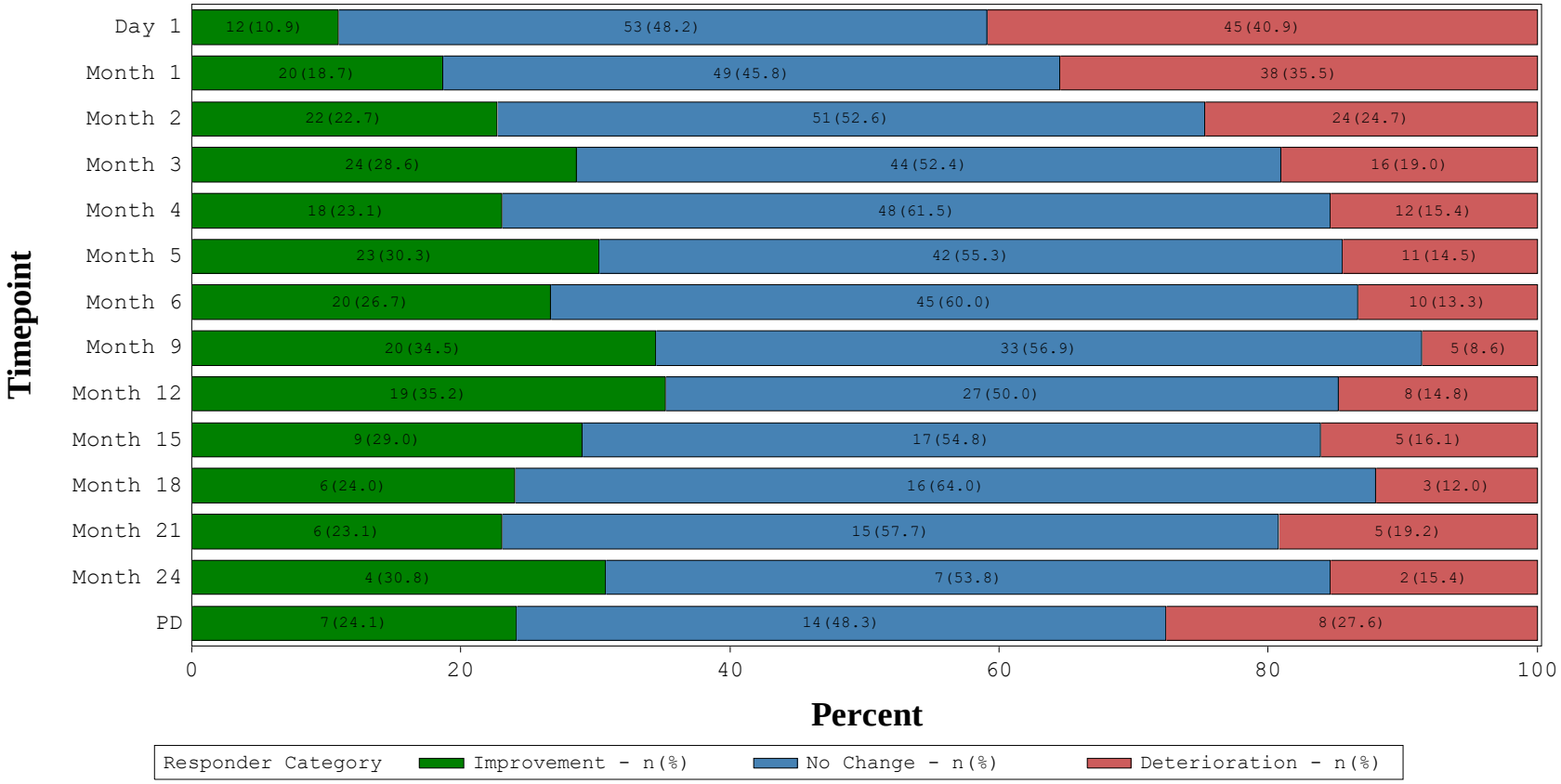
Figure 4.9.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Physical Functioning Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
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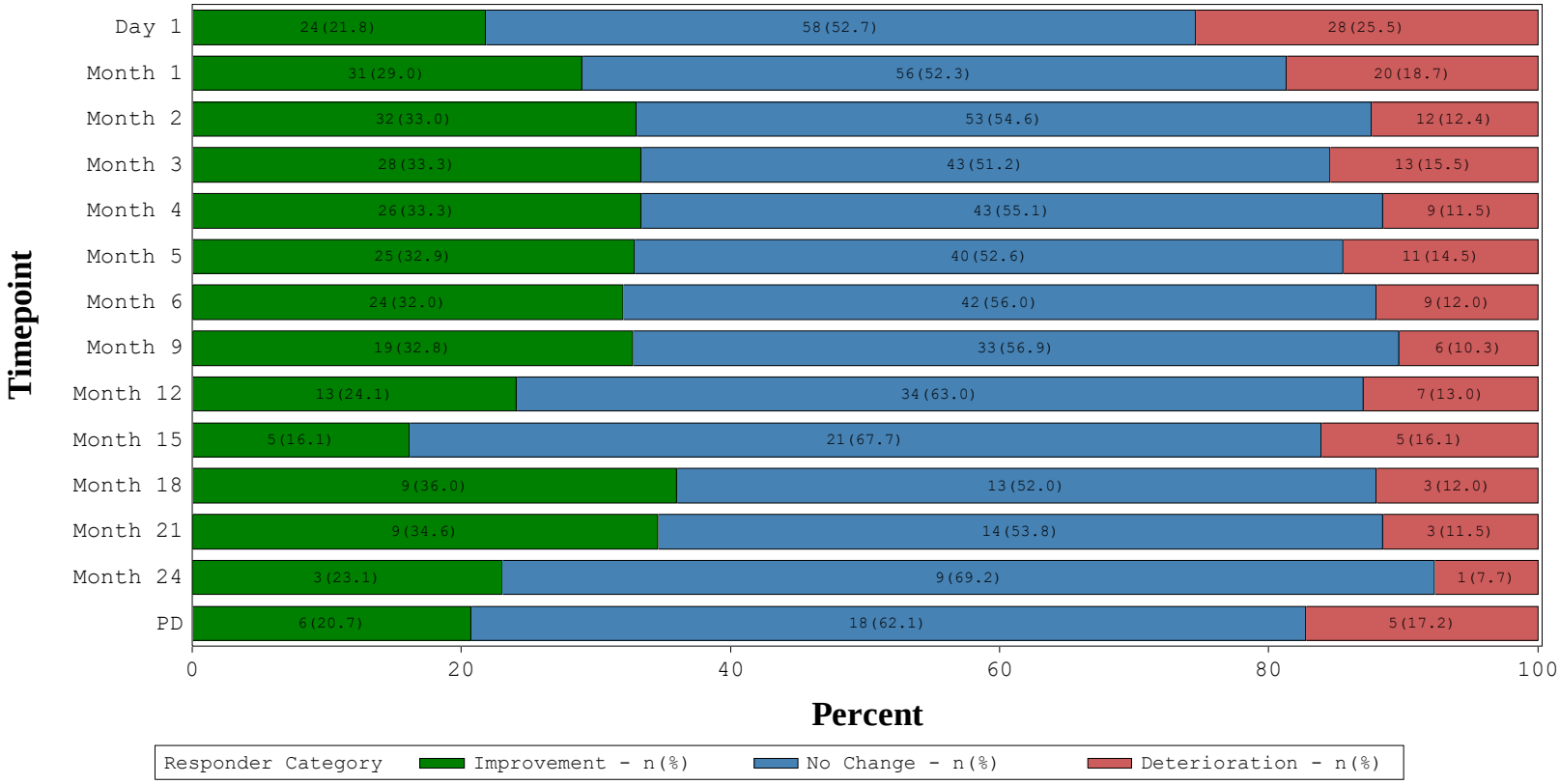
Figure 4.10.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Cognitive Functioning Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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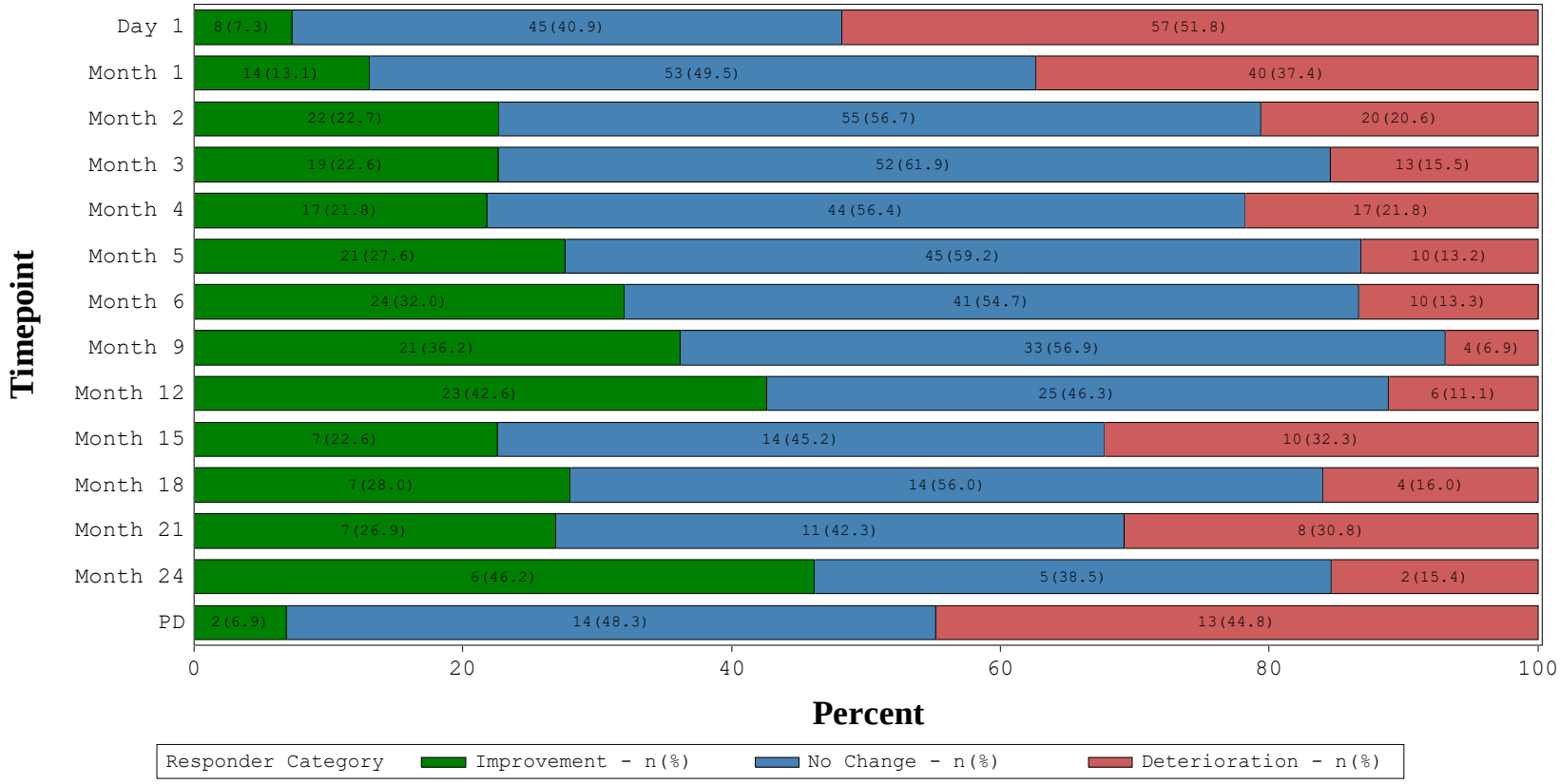
Figure 4.11.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Global Health / QoL Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
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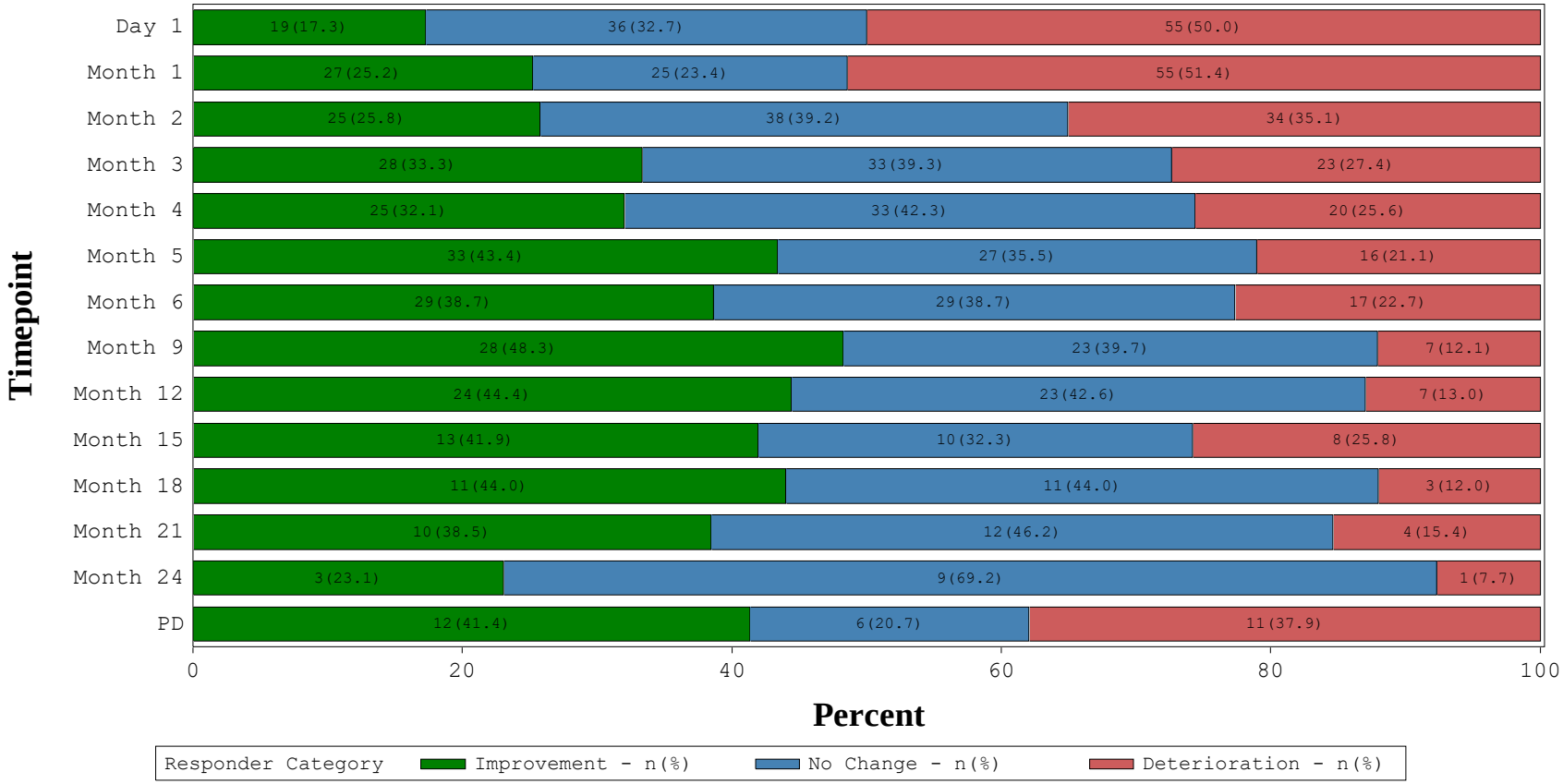
Figure 5.1.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Role Functioning Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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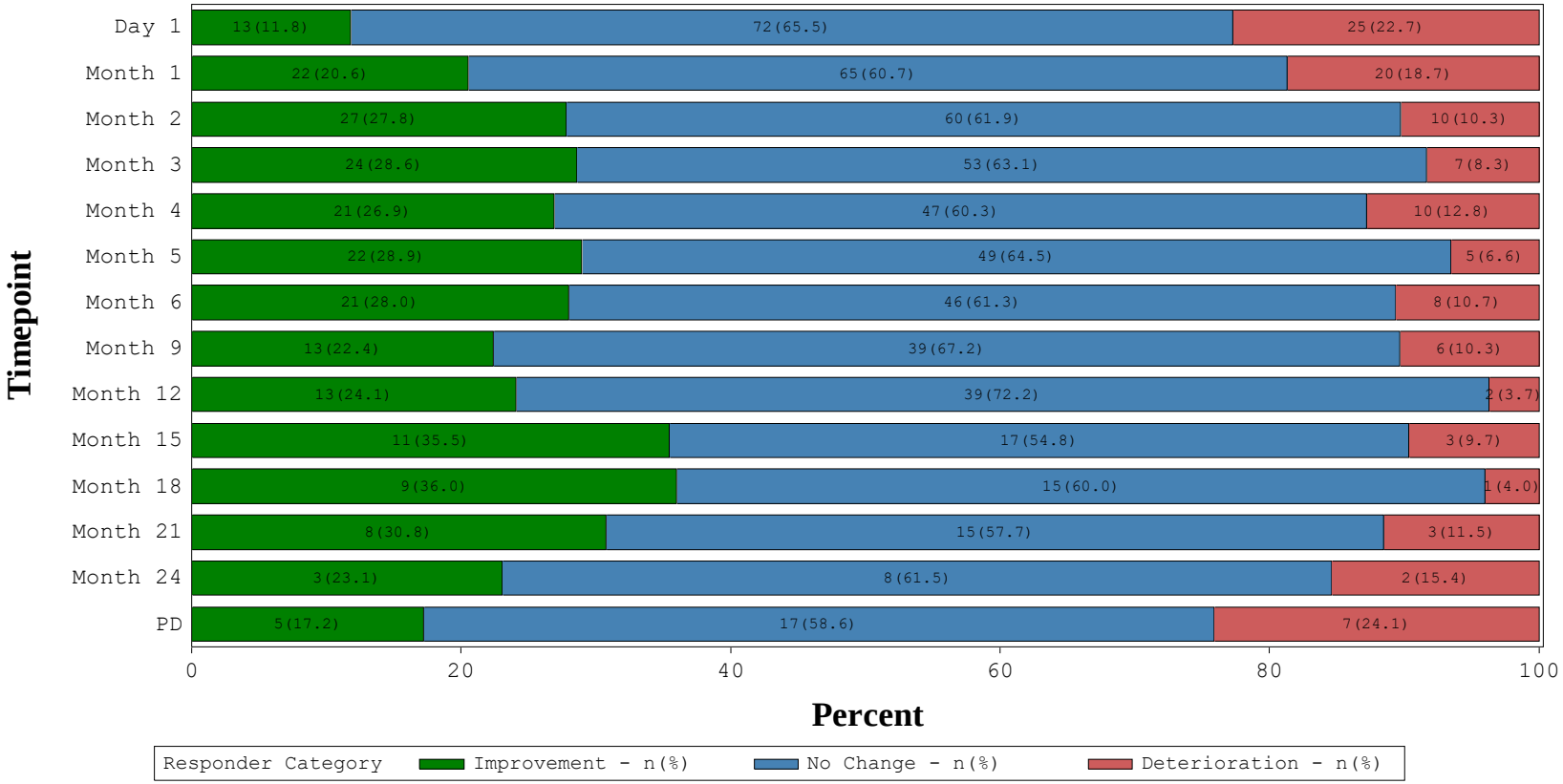
Figure 5.2.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Emotional Functioning Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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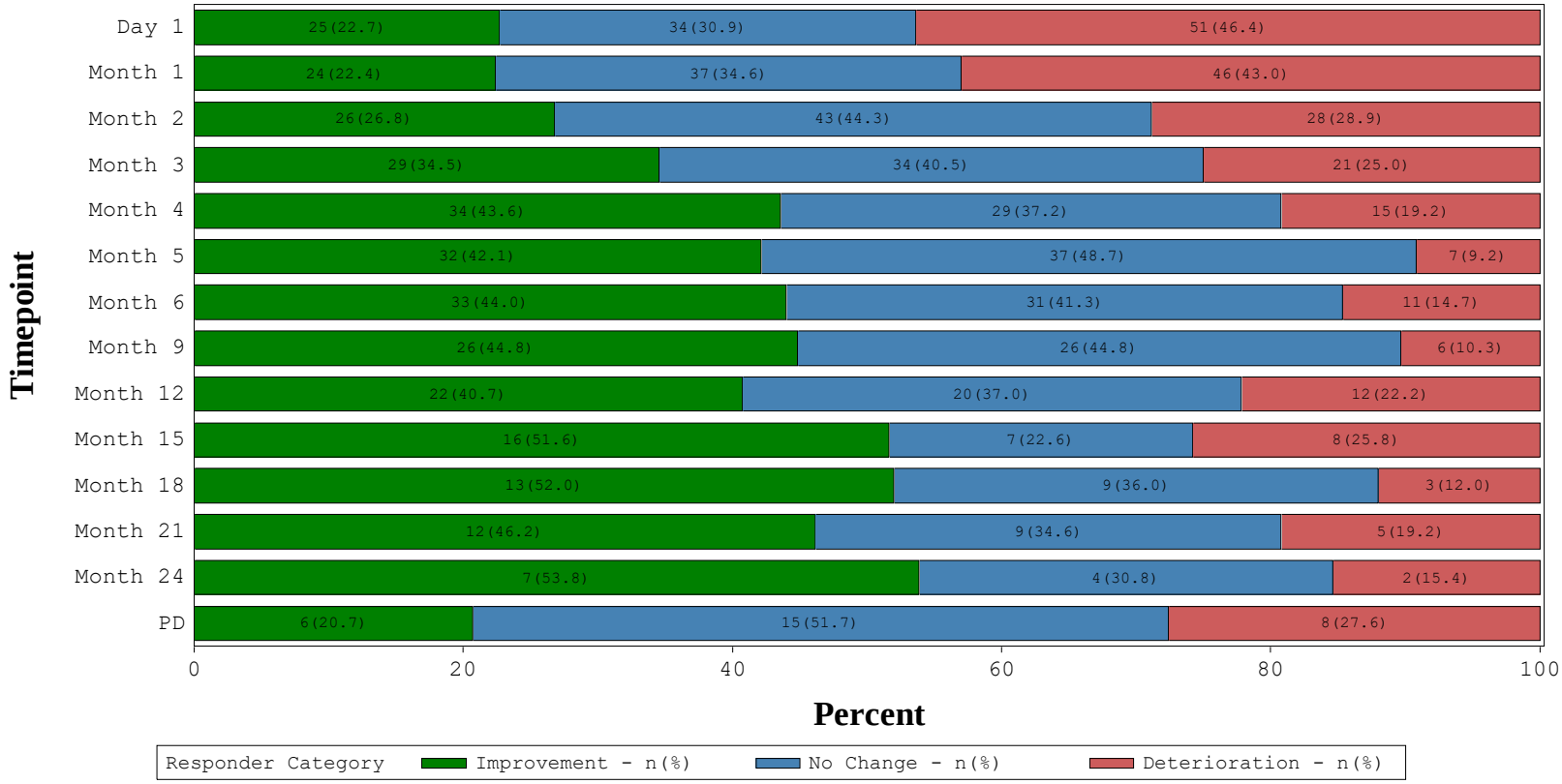
Figure 5.3.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Social Functioning Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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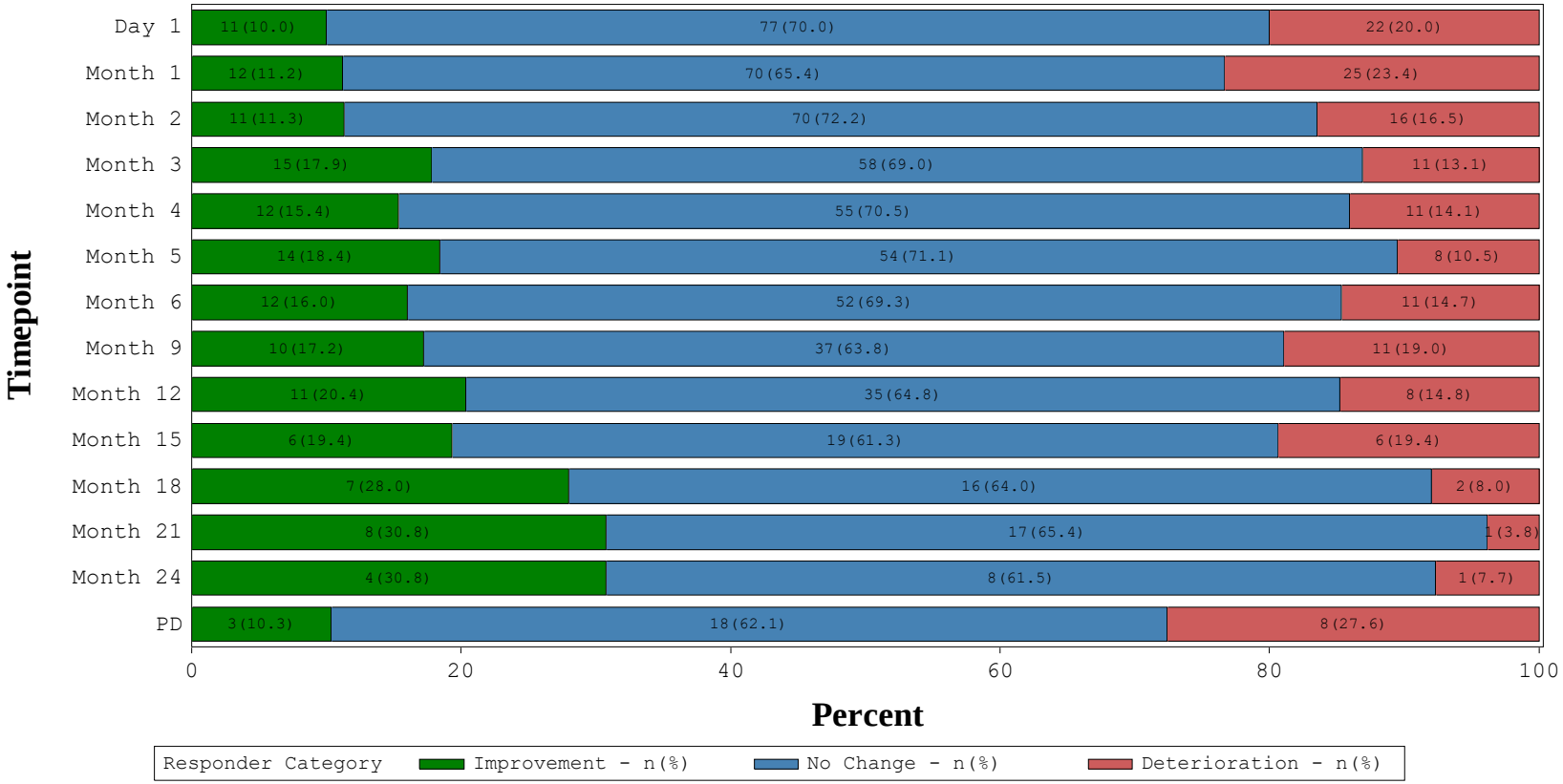
Figure 5.4.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-C30 Financial Difficulties Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: <=-10 for improvement and >=+10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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Table 4.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 13 ( 11.8) | 36 ( 32.7) | 8 ( 7.3) | 24 ( 21.8) | 8 ( 7.3) |
| | No Change - n(%) | 53 ( 48.2) | 29 ( 26.4) | 70 ( 63.6) | 58 ( 52.7) | 45 ( 40.9) |
| | Deterioration - n(%) | 44 ( 40.0) | 45 ( 40.9) | 32 ( 29.1) | 28 ( 25.5) | 57 ( 51.8) |
| | Missing | 12 | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 17 ( 15.9) | 39 ( 36.4) | 8 ( 7.5) | 31 ( 29.0) | 14 ( 13.1) |
| | No Change - n(%) | 53 ( 49.5) | 33 ( 30.8) | 73 ( 68.2) | 56 ( 52.3) | 53 ( 49.5) |
| | Deterioration - n(%) | 37 ( 34.6) | 35 ( 32.7) | 26 ( 24.3) | 20 ( 18.7) | 40 ( 37.4) |
| | Missing | 15 | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 22 ( 22.7) | 39 ( 40.2) | 14 ( 14.4) | 32 ( 33.0) | 22 ( 22.7) |
| | No Change - n(%) | 53 ( 54.6) | 29 ( 29.9) | 69 ( 71.1) | 53 ( 54.6) | 55 ( 56.7) |
| | Deterioration - n(%) | 22 ( 22.7) | 29 ( 29.9) | 14 ( 14.4) | 12 ( 12.4) | 20 ( 20.6) |
| | Missing | 25 | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 21 ( 25.0) | 37 ( 44.0) | 17 ( 20.2) | 28 ( 33.3) | 19 ( 22.6) |
| | No Change - n(%) | 53 ( 63.1) | 26 ( 31.0) | 57 ( 67.9) | 43 ( 51.2) | 52 ( 61.9) |
| | Deterioration - n(%) | 10 ( 11.9) | 21 ( 25.0) | 10 ( 11.9) | 13 ( 15.5) | 13 ( 15.5) |
| | Missing | 38 | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 24 ( 30.8) | 34 ( 43.6) | 16 ( 20.5) | 26 ( 33.3) | 17 ( 21.8) |
| | No Change - n(%) | 42 ( 53.8) | 30 ( 38.5) | 56 ( 71.8) | 43 ( 55.1) | 44 ( 56.4) |
| | Deterioration - n(%) | 12 ( 15.4) | 14 ( 17.9) | 6 ( 7.7) | 9 ( 11.5) | 17 ( 21.8) |
| | Missing | 44 | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 27 ( 35.5) | 36 ( 47.4) | 20 ( 26.3) | 25 ( 32.9) | 21 ( 27.6) |
| | No Change - n(%) | 39 ( 51.3) | 25 ( 32.9) | 50 ( 65.8) | 40 ( 52.6) | 45 ( 59.2) |
| | Deterioration - n(%) | 10 ( 13.2) | 15 ( 19.7) | 6 ( 7.9) | 11 ( 14.5) | 10 ( 13.2) |
| | Missing | 46 | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 22 ( 29.3) | 36 ( 48.0) | 18 ( 24.0) | 24 ( 32.0) | 24 ( 32.0) |
| | No Change - n(%) | 48 ( 64.0) | 24 ( 32.0) | 53 ( 70.7) | 42 ( 56.0) | 41 ( 54.7) |
| | Deterioration - n(%) | 5 ( 6.7) | 15 ( 20.0) | 4 ( 5.3) | 9 ( 12.0) | 10 ( 13.3) |
| | Missing | 47 | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 25 ( 43.1) | 29 ( 50.0) | 15 ( 25.9) | 19 ( 32.8) | 21 ( 36.2) |
| | No Change - n(%) | 33 ( 56.9) | 21 ( 36.2) | 41 ( 70.7) | 33 ( 56.9) | 33 ( 56.9) |
| | Deterioration - n(%) | 0 | 8 ( 13.8) | 2 ( 3.4) | 6 ( 10.3) | 4 ( 6.9) |
| | Missing | 64 | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 16 ( 29.6) | 31 ( 57.4) | 16 ( 29.6) | 13 ( 24.1) | 23 ( 42.6) |
| | No Change - n(%) | 34 ( 63.0) | 14 ( 25.9) | 35 ( 64.8) | 34 ( 63.0) | 25 ( 46.3) |
| | Deterioration - n(%) | 4 ( 7.4) | 9 ( 16.7) | 3 ( 5.6) | 7 ( 13.0) | 6 ( 11.1) |
| | Missing | 68 | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 12 ( 38.7) | 16 ( 51.6) | 6 ( 19.4) | 5 ( 16.1) | 7 ( 22.6) |
| | No Change - n(%) | 15 ( 48.4) | 10 ( 32.3) | 21 ( 67.7) | 21 ( 67.7) | 14 ( 45.2) |
| | Deterioration - n(%) | 4 ( 12.9) | 5 ( 16.1) | 4 ( 12.9) | 5 ( 16.1) | 10 ( 32.3) |
| | Missing | 91 | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 8 ( 32.0) | 13 ( 52.0) | 5 ( 20.0) | 9 ( 36.0) | 7 ( 28.0) |
| | No Change - n(%) | 16 ( 64.0) | 7 ( 28.0) | 20 ( 80.0) | 13 ( 52.0) | 14 ( 56.0) |
| | Deterioration - n(%) | 1 ( 4.0) | 5 ( 20.0) | 0 | 3 ( 12.0) | 4 ( 16.0) |
| | Missing | 97 | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 6 ( 23.1) | 12 ( 46.2) | 5 ( 19.2) | 9 ( 34.6) | 7 ( 26.9) |
| | No Change - n(%) | 14 ( 53.8) | 8 ( 30.8) | 17 ( 65.4) | 14 ( 53.8) | 11 ( 42.3) |
| | Deterioration - n(%) | 6 ( 23.1) | 6 ( 23.1) | 4 ( 15.4) | 3 ( 11.5) | 8 ( 30.8) |
| | Missing | 96 | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 3 ( 23.1) | 7 ( 53.8) | 2 ( 15.4) | 3 ( 23.1) | 6 ( 46.2) |
| | No Change - n(%) | 10 ( 76.9) | 2 ( 15.4) | 11 ( 84.6) | 9 ( 69.2) | 5 ( 38.5) |
| | Deterioration - n(%) | 0 | 4 ( 30.8) | 0 | 1 ( 7.7) | 2 ( 15.4) |
| | Missing | 109 | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) | 0 | 0 | 1 (100.0) |
| | No Change - n(%) | 0 | 0 | 1 (100.0) | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| PD | n | 29 | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 8 ( 27.6) | 12 ( 41.4) | 4 ( 13.8) | 6 ( 20.7) | 2 ( 6.9) |
| | No Change - n(%) | 17 ( 58.6) | 7 ( 24.1) | 19 ( 65.5) | 18 ( 62.1) | 14 ( 48.3) |
| | Deterioration - n(%) | 4 ( 13.8) | 10 ( 34.5) | 6 ( 20.7) | 5 ( 17.2) | 13 ( 44.8) |
| | Missing | 93 | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 0 | 0 | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 1 (100.0) | 1 (100.0) | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 | 1 (100.0) |
| | Missing | 121 | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 4.6.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| End of Study | n | 9 | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 1 ( 11.1) | 2 ( 22.2) | 2 ( 22.2) | 0 | 0 |
| | No Change - n(%) | 5 ( 55.6) | 3 ( 33.3) | 5 ( 55.6) | 7 ( 77.8) | 6 ( 66.7) |
| | Deterioration - n(%) | 3 ( 33.3) | 4 ( 44.4) | 2 ( 22.2) | 2 ( 22.2) | 3 ( 33.3) |
| | Missing | 113 | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: <=-15 for improvement and >=+15 for worsening on Fatigue and Pain; >=+15 for improvement and <=-15 for worsening on Physical and Cognitive Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 5.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Day 1 | n | 110 | 110 | 110 | 110 |
| | Improvement - n(%) | 19 ( 17.3) | 13 ( 11.8) | 25 ( 22.7) | 11 ( 10.0) |
| | No Change - n(%) | 36 ( 32.7) | 72 ( 65.5) | 34 ( 30.9) | 77 ( 70.0) |
| | Deterioration - n(%) | 55 ( 50.0) | 25 ( 22.7) | 51 ( 46.4) | 22 ( 20.0) |
| | Missing | 12 | 12 | 12 | 12 |
| Month 1 | n | 107 | 107 | 107 | 107 |
| | Improvement - n(%) | 27 ( 25.2) | 22 ( 20.6) | 24 ( 22.4) | 12 ( 11.2) |
| | No Change - n(%) | 25 ( 23.4) | 65 ( 60.7) | 37 ( 34.6) | 70 ( 65.4) |
| | Deterioration - n(%) | 55 ( 51.4) | 20 ( 18.7) | 46 ( 43.0) | 25 ( 23.4) |
| | Missing | 15 | 15 | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 2 | n | 97 | 97 | 97 | 97 |
| | Improvement - n(%) | 25 ( 25.8) | 27 ( 27.8) | 26 ( 26.8) | 11 ( 11.3) |
| | No Change - n(%) | 38 ( 39.2) | 60 ( 61.9) | 43 ( 44.3) | 70 ( 72.2) |
| | Deterioration - n(%) | 34 ( 35.1) | 10 ( 10.3) | 28 ( 28.9) | 16 ( 16.5) |
| | Missing | 25 | 25 | 25 | 25 |
| Month 3 | n | 84 | 84 | 84 | 84 |
| | Improvement - n(%) | 28 ( 33.3) | 24 ( 28.6) | 29 ( 34.5) | 15 ( 17.9) |
| | No Change - n(%) | 33 ( 39.3) | 53 ( 63.1) | 34 ( 40.5) | 58 ( 69.0) |
| | Deterioration - n(%) | 23 ( 27.4) | 7 ( 8.3) | 21 ( 25.0) | 11 ( 13.1) |
| | Missing | 38 | 38 | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 4 | n | 78 | 78 | 78 | 78 |
| | Improvement - n(%) | 25 ( 32.1) | 21 ( 26.9) | 34 ( 43.6) | 12 ( 15.4) |
| | No Change - n(%) | 33 ( 42.3) | 47 ( 60.3) | 29 ( 37.2) | 55 ( 70.5) |
| | Deterioration - n(%) | 20 ( 25.6) | 10 ( 12.8) | 15 ( 19.2) | 11 ( 14.1) |
| | Missing | 44 | 44 | 44 | 44 |
| Month 5 | n | 76 | 76 | 76 | 76 |
| | Improvement - n(%) | 33 ( 43.4) | 22 ( 28.9) | 32 ( 42.1) | 14 ( 18.4) |
| | No Change - n(%) | 27 ( 35.5) | 49 ( 64.5) | 37 ( 48.7) | 54 ( 71.1) |
| | Deterioration - n(%) | 16 ( 21.1) | 5 ( 6.6) | 7 ( 9.2) | 8 ( 10.5) |
| | Missing | 46 | 46 | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 6 | n | 75 | 75 | 75 | 75 |
| | Improvement - n(%) | 29 ( 38.7) | 21 ( 28.0) | 33 ( 44.0) | 12 ( 16.0) |
| | No Change - n(%) | 29 ( 38.7) | 46 ( 61.3) | 31 ( 41.3) | 52 ( 69.3) |
| | Deterioration - n(%) | 17 ( 22.7) | 8 ( 10.7) | 11 ( 14.7) | 11 ( 14.7) |
| | Missing | 47 | 47 | 47 | 47 |
| Month 9 | n | 58 | 58 | 58 | 58 |
| | Improvement - n(%) | 28 ( 48.3) | 13 ( 22.4) | 26 ( 44.8) | 10 ( 17.2) |
| | No Change - n(%) | 23 ( 39.7) | 39 ( 67.2) | 26 ( 44.8) | 37 ( 63.8) |
| | Deterioration - n(%) | 7 ( 12.1) | 6 ( 10.3) | 6 ( 10.3) | 11 ( 19.0) |
| | Missing | 64 | 64 | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 12 | n | 54 | 54 | 54 | 54 |
| | Improvement - n(%) | 24 ( 44.4) | 13 ( 24.1) | 22 ( 40.7) | 11 ( 20.4) |
| | No Change - n(%) | 23 ( 42.6) | 39 ( 72.2) | 20 ( 37.0) | 35 ( 64.8) |
| | Deterioration - n(%) | 7 ( 13.0) | 2 ( 3.7) | 12 ( 22.2) | 8 ( 14.8) |
| | Missing | 68 | 68 | 68 | 68 |
| Month 15 | n | 31 | 31 | 31 | 31 |
| | Improvement - n(%) | 13 ( 41.9) | 11 ( 35.5) | 16 ( 51.6) | 6 ( 19.4) |
| | No Change - n(%) | 10 ( 32.3) | 17 ( 54.8) | 7 ( 22.6) | 19 ( 61.3) |
| | Deterioration - n(%) | 8 ( 25.8) | 3 ( 9.7) | 8 ( 25.8) | 6 ( 19.4) |
| | Missing | 91 | 91 | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 5.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 18 | n | 25 | 25 | 25 | 25 |
| | Improvement - n(%) | 11 ( 44.0) | 9 ( 36.0) | 13 ( 52.0) | 7 ( 28.0) |
| | No Change - n(%) | 11 ( 44.0) | 15 ( 60.0) | 9 ( 36.0) | 16 ( 64.0) |
| | Deterioration - n(%) | 3 ( 12.0) | 1 ( 4.0) | 3 ( 12.0) | 2 ( 8.0) |
| | Missing | 97 | 97 | 97 | 97 |
| Month 21 | n | 26 | 26 | 26 | 26 |
| | Improvement - n(%) | 10 ( 38.5) | 8 ( 30.8) | 12 ( 46.2) | 8 ( 30.8) |
| | No Change - n(%) | 12 ( 46.2) | 15 ( 57.7) | 9 ( 34.6) | 17 ( 65.4) |
| | Deterioration - n(%) | 4 ( 15.4) | 3 ( 11.5) | 5 ( 19.2) | 1 ( 3.8) |
| | Missing | 96 | 96 | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 5.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 24 | n | 13 | 13 | 13 | 13 |
| | Improvement - n(%) | 3 ( 23.1) | 3 ( 23.1) | 7 ( 53.8) | 4 ( 30.8) |
| | No Change - n(%) | 9 ( 69.2) | 8 ( 61.5) | 4 ( 30.8) | 8 ( 61.5) |
| | Deterioration - n(%) | 1 ( 7.7) | 2 ( 15.4) | 2 ( 15.4) | 1 ( 7.7) |
| | Missing | 109 | 109 | 109 | 109 |
| Month 30 | n | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 | 0 | 0 |
| | Missing | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 5.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| PD | n | 29 | 29 | 29 | 29 |
| | Improvement - n(%) | 12 ( 41.4) | 5 ( 17.2) | 6 ( 20.7) | 3 ( 10.3) |
| | No Change - n(%) | 6 ( 20.7) | 17 ( 58.6) | 15 ( 51.7) | 18 ( 62.1) |
| | Deterioration - n(%) | 11 ( 37.9) | 7 ( 24.1) | 8 ( 27.6) | 8 ( 27.6) |
| | Missing | 93 | 93 | 93 | 93 |
| CR | n | 1 | 1 | 1 | 1 |
| | Improvement - n(%) | 0 | 0 | 0 | 0 |
| | No Change - n(%) | 0 | 1 (100.0) | 0 | 1 (100.0) |
| | Deterioration - n(%) | 1 (100.0) | 0 | 1 (100.0) | 0 |
| | Missing | 121 | 121 | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| End of Study | n | 9 | 9 | 9 | 9 |
| | Improvement - n(%) | 1 ( 11.1) | 0 | 2 ( 22.2) | 2 ( 22.2) |
| | No Change - n(%) | 6 ( 66.7) | 7 ( 77.8) | 5 ( 55.6) | 4 ( 44.4) |
| | Deterioration - n(%) | 2 ( 22.2) | 2 ( 22.2) | 2 ( 22.2) | 3 ( 33.3) |
| | Missing | 113 | 113 | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening on Role, Emotional and Social Functioning; <=-10 for improvement and >=+10 for worsening on Financial Difficulties.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 25 ( 22.7) | 15 ( 13.6) |
| | No Change - n(%) | 25 ( 22.7) | 21 ( 19.1) |
| | Deterioration - n(%) | 60 ( 54.5) | 74 ( 67.3) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 32 ( 29.9) | 28 ( 26.2) |
| | No Change - n(%) | 23 ( 21.5) | 22 ( 20.6) |
| | Deterioration - n(%) | 52 ( 48.6) | 57 ( 53.3) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Month 2 | n | 97 | 97 |
| | Improvement - n(%) | 33 ( 34.0) | 34 ( 35.1) |
| | No Change - n(%) | 26 ( 26.8) | 25 ( 25.8) |
| | Deterioration - n(%) | 38 ( 39.2) | 38 ( 39.2) |
| | Missing | 25 | 25 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 35 ( 41.7) | 33 ( 39.3) |
| | No Change - n(%) | 21 ( 25.0) | 26 ( 31.0) |
| | Deterioration - n(%) | 28 ( 33.3) | 25 ( 29.8) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 33 ( 42.3) | 28 ( 35.9) |
| | No Change - n(%) | 22 ( 28.2) | 27 ( 34.6) |
| | Deterioration - n(%) | 23 ( 29.5) | 23 ( 29.5) |
| | Missing | 44 | 44 |
| Month 5 | n | 76 | 76 |
| | Improvement - n(%) | 29 ( 38.2) | 36 ( 47.4) |
| | No Change - n(%) | 29 ( 38.2) | 19 ( 25.0) |
| | Deterioration - n(%) | 18 ( 23.7) | 21 ( 27.6) |
| | Missing | 46 | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Month 6 | n | 75 | 75 |
| | Improvement - n(%) | 36 ( 48.0) | 39 ( 52.0) |
| | No Change - n(%) | 24 ( 32.0) | 19 ( 25.3) |
| | Deterioration - n(%) | 15 ( 20.0) | 17 ( 22.7) |
| | Missing | 47 | 47 |
| Month 9 | n | 58 | 58 |
| | Improvement - n(%) | 29 ( 50.0) | 35 ( 60.3) |
| | No Change - n(%) | 19 ( 32.8) | 16 ( 27.6) |
| | Deterioration - n(%) | 10 ( 17.2) | 7 ( 12.1) |
| | Missing | 64 | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 30 ( 55.6) | 33 ( 61.1) |
| | No Change - n(%) | 13 ( 24.1) | 12 ( 22.2) |
| | Deterioration - n(%) | 11 ( 20.4) | 9 ( 16.7) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 13 ( 41.9) | 11 ( 35.5) |
| | No Change - n(%) | 11 ( 35.5) | 10 ( 32.3) |
| | Deterioration - n(%) | 7 ( 22.6) | 10 ( 32.3) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 14 ( 56.0) | 8 ( 32.0) |
| | No Change - n(%) | 5 ( 20.0) | 12 ( 48.0) |
| | Deterioration - n(%) | 6 ( 24.0) | 5 ( 20.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 9 ( 34.6) | 8 ( 30.8) |
| | No Change - n(%) | 10 ( 38.5) | 8 ( 30.8) |
| | Deterioration - n(%) | 7 ( 26.9) | 10 ( 38.5) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 6 ( 46.2) | 7 ( 53.8) |
| | No Change - n(%) | 4 ( 30.8) | 3 ( 23.1) |
| | Deterioration - n(%) | 3 ( 23.1) | 3 ( 23.1) |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 10 ( 34.5) | 7 ( 24.1) |
| | No Change - n(%) | 5 ( 17.2) | 6 ( 20.7) |
| | Deterioration - n(%) | 14 ( 48.3) | 16 ( 55.2) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 0 |
| | Deterioration - n(%) | 0 | 1 (100.0) |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.6.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Physical Functioning | Global Health/QoL |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 3 ( 33.3) | 2 ( 22.2) |
| | No Change - n(%) | 1 ( 11.1) | 3 ( 33.3) |
| | Deterioration - n(%) | 5 ( 55.6) | 4 ( 44.4) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+5 for improvement and <=-5 for worsening on Physical Functioning and Global Health/QoL.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) |
|---|---|---|
| Visit/Time Point | Responder Category [a] | Emotional Functioning |
| Day 1 | n | 110 |
| | Improvement - n(%) | 32 ( 29.1) |
| | No Change - n(%) | 35 ( 31.8) |
| | Deterioration - n(%) | 43 ( 39.1) |
| | Missing | 12 |
| Month 1 | n | 107 |
| | Improvement - n(%) | 40 ( 37.4) |
| | No Change - n(%) | 31 ( 29.0) |
| | Deterioration - n(%) | 36 ( 33.6) |
| | Missing | 15 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 2 | n | 97 |
| | Improvement - n(%) | 50 ( 51.5) |
| | No Change - n(%) | 26 ( 26.8) |
| | Deterioration - n(%) | 21 ( 21.6) |
| | Missing | 25 |
| Month 3 | n | 84 |
| | Improvement - n(%) | 41 ( 48.8) |
| | No Change - n(%) | 29 ( 34.5) |
| | Deterioration - n(%) | 14 ( 16.7) |
| | Missing | 38 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 4 | n | 78 |
| | Improvement - n(%) | 39 ( 50.0) |
| | No Change - n(%) | 26 ( 33.3) |
| | Deterioration - n(%) | 13 ( 16.7) |
| | Missing | 44 |
| Month 5 | n | 76 |
| | Improvement - n(%) | 39 ( 51.3) |
| | No Change - n(%) | 28 ( 36.8) |
| | Deterioration - n(%) | 9 ( 11.8) |
| | Missing | 46 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 5.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 6 | n | 75 |
| | Improvement - n(%) | 35 ( 46.7) |
| | No Change - n(%) | 29 ( 38.7) |
| | Deterioration - n(%) | 11 ( 14.7) |
| | Missing | 47 |
| Month 9 | n | 58 |
| | Improvement - n(%) | 24 ( 41.4) |
| | No Change - n(%) | 23 ( 39.7) |
| | Deterioration - n(%) | 11 ( 19.0) |
| | Missing | 64 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 12 | n | 54 |
| | Improvement - n(%) | 24 ( 44.4) |
| | No Change - n(%) | 22 ( 40.7) |
| | Deterioration - n(%) | 8 ( 14.8) |
| | Missing | 68 |
| Month 15 | n | 31 |
| | Improvement - n(%) | 13 ( 41.9) |
| | No Change - n(%) | 11 ( 35.5) |
| | Deterioration - n(%) | 7 ( 22.6) |
| | Missing | 91 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 18 | n | 25 |
| | Improvement - n(%) | 10 ( 40.0) |
| | No Change - n(%) | 11 ( 44.0) |
| | Deterioration - n(%) | 4 ( 16.0) |
| | Missing | 97 |
| Month 21 | n | 26 |
| | Improvement - n(%) | 13 ( 50.0) |
| | No Change - n(%) | 7 ( 26.9) |
| | Deterioration - n(%) | 6 ( 23.1) |
| | Missing | 96 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| Month 24 | n | 13 |
| | Improvement - n(%) | 6 ( 46.2) |
| | No Change - n(%) | 4 ( 30.8) |
| | Deterioration - n(%) | 3 ( 23.1) |
| | Missing | 109 |
| Month 30 | n | 1 |
| | Improvement - n(%) | 1 (100.0) |
| | No Change - n(%) | 0 |
| | Deterioration - n(%) | 0 |
| | Missing | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-C30 Subscale Score (N=122) Emotional Functioning |
|---|---|---|
| PD | n | 29 |
| | Improvement - n(%) | 10 ( 34.5) |
| | No Change - n(%) | 6 ( 20.7) |
| | Deterioration - n(%) | 13 ( 44.8) |
| | Missing | 93 |
| CR | n | 1 |
| | Improvement - n(%) | 0 |
| | No Change - n(%) | 0 |
| | Deterioration - n(%) | 1 (100.0) |
| | Missing | 121 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 5.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) |
|---|---|---|
| Visit/Time Point | Responder Category [a] | Emotional Functioning |
| End of Study | n | 9 |
| | Improvement - n(%) | 1 ( 11.1) |
| | No Change - n(%) | 5 ( 55.6) |
| | Deterioration - n(%) | 3 ( 33.3) |
| | Missing | 113 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline: >=+5 for improvement and <=-5 for worsening on Emotional Functioning.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 4.4d
Scores on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Screening | n | 117 | 117 | 117 | 117 | 117 |
| | Mean | 34.3 | 34.2 | 77.6 | 83.3 | 68.9 |
| | SD | 22.15 | 27.58 | 19.87 | 17.51 | 18.03 |
| | Median | 33.3 | 33.3 | 80.0 | 83.3 | 66.7 |
| | Q1, Q3 | 22.2, 44.4 | 16.7, 50.0 | 66.7, 93.3 | 66.7,100.0 | 58.3, 83.3 |
| | Min, Max | 0,100 | 0,100 | 20,100 | 33,100 | 25,100 |
| Baseline Evaluations | n | 122 | 122 | 122 | 122 | 122 |
| | Mean | 40.1 | 40.7 | 68.6 | 81.8 | 60.3 |
| | SD | 24.64 | 28.02 | 25.61 | 20.78 | 20.78 |
| | Median | 33.3 | 33.3 | 73.3 | 83.3 | 66.7 |
| | Q1, Q3 | 22.2, 55.6 | 16.7, 50.0 | 53.3, 86.7 | 66.7,100.0 | 50.0, 75.0 |
| | Min, Max | 0,100 | 0,100 | 0,100 | 17,100 | 0,100 |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 |
| | Mean | 44.9 | 36.4 | 69.0 | 82.4 | 55.5 |
| | SD | 23.38 | 25.36 | 23.22 | 21.04 | 20.79 |
| | Median | 38.9 | 33.3 | 73.3 | 83.3 | 58.3 |
| | Q1, Q3 | 33.3, 66.7 | 16.7, 50.0 | 60.0, 86.7 | 66.7,100.0 | 41.7, 66.7 |
| | Min, Max | 0,100 | 0,100 | 0,100 | 17,100 | 0,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
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Table 4.4d
Scores on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 |
| | Mean | 41.4 | 32.1 | 70.2 | 85.2 | 63.9 |
| | SD | 24.21 | 26.47 | 25.30 | 21.76 | 20.31 |
| | Median | 33.3 | 33.3 | 80.0 | 100.0 | 66.7 |
| | Q1, Q3 | 22.2, 66.7 | 16.7, 50.0 | 53.3, 93.3 | 83.3,100.0 | 50.0, 75.0 |
| | Min, Max | 0,100 | 0,100 | 0,100 | 0,100 | 8,100 |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 |
| | Mean | 31.6 | 30.6 | 76.2 | 88.7 | 69.6 |
| | SD | 23.31 | 25.99 | 20.79 | 15.13 | 19.91 |
| | Median | 33.3 | 33.3 | 80.0 | 100.0 | 75.0 |
| | Q1, Q3 | 11.1, 44.4 | 16.7, 50.0 | 66.7, 93.3 | 83.3,100.0 | 58.3, 83.3 |
| | Min, Max | 0,100 | 0,100 | 7,100 | 33,100 | 8,100 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 |
| | Mean | 27.9 | 27.4 | 80.3 | 88.1 | 70.4 |
| | SD | 20.30 | 25.56 | 17.34 | 15.65 | 18.36 |
| | Median | 33.3 | 16.7 | 86.7 | 100.0 | 75.0 |
| | Q1, Q3 | 11.1, 33.3 | 0.0, 33.3 | 73.3, 93.3 | 83.3,100.0 | 66.7, 83.3 |
| | Min, Max | 0, 78 | 0,100 | 20,100 | 33,100 | 17,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.4d
Scores on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 |
| | Mean | 28.6 | 25.9 | 80.8 | 87.2 | 72.5 |
| | SD | 21.68 | 23.82 | 18.26 | 18.20 | 17.67 |
| | Median | 33.3 | 16.7 | 86.7 | 100.0 | 75.0 |
| | Q1, Q3 | 11.1, 33.3 | 0.0, 33.3 | 73.3, 93.3 | 83.3,100.0 | 66.7, 83.3 |
| | Min, Max | 0,100 | 0, 83 | 33,100 | 17,100 | 17,100 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 |
| | Mean | 24.3 | 25.0 | 82.6 | 89.0 | 76.1 |
| | SD | 21.83 | 23.33 | 17.35 | 17.12 | 16.24 |
| | Median | 22.2 | 16.7 | 86.7 | 100.0 | 75.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 | 73.3, 93.3 | 83.3,100.0 | 66.7, 83.3 |
| | Min, Max | 0,100 | 0,100 | 27,100 | 17,100 | 25,100 |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 |
| | Mean | 24.3 | 25.8 | 83.8 | 88.0 | 75.6 |
| | SD | 23.65 | 25.45 | 18.01 | 16.34 | 17.51 |
| | Median | 22.2 | 16.7 | 86.7 | 100.0 | 83.3 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 | 73.3,100.0 | 83.3,100.0 | 66.7, 83.3 |
| | Min, Max | 0,100 | 0,100 | 27,100 | 17,100 | 17,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.4d
Scores on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 |
| | Mean | 17.2 | 21.8 | 83.3 | 89.9 | 79.6 |
| | SD | 18.05 | 19.80 | 18.62 | 15.90 | 17.39 |
| | Median | 11.1 | 16.7 | 86.7 | 100.0 | 83.3 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 | 73.3,100.0 | 83.3,100.0 | 75.0, 91.7 |
| | Min, Max | 0, 67 | 0, 67 | 13,100 | 33,100 | 17,100 |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 |
| | Mean | 23.0 | 25.0 | 82.8 | 86.4 | 77.8 |
| | SD | 21.57 | 23.96 | 19.06 | 19.45 | 18.95 |
| | Median | 22.2 | 16.7 | 86.7 | 100.0 | 83.3 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 | 80.0,100.0 | 83.3,100.0 | 66.7, 91.7 |
| | Min, Max | 0, 78 | 0, 83 | 20,100 | 17,100 | 25,100 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 |
| | Mean | 25.4 | 25.8 | 78.5 | 83.3 | 71.0 |
| | SD | 26.94 | 24.66 | 25.28 | 23.57 | 25.26 |
| | Median | 22.2 | 33.3 | 86.7 | 100.0 | 75.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 | 73.3,100.0 | 66.7,100.0 | 58.3, 83.3 |
| | Min, Max | 0,100 | 0,100 | 13,100 | 17,100 | 0,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.4d
Scores on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 |
| | Mean | 18.7 | 21.3 | 84.5 | 87.3 | 78.7 |
| | SD | 16.58 | 18.95 | 14.62 | 20.57 | 17.69 |
| | Median | 22.2 | 16.7 | 86.7 | 100.0 | 83.3 |
| | Q1, Q3 | 0.0, 22.2 | 0.0, 33.3 | 73.3,100.0 | 83.3,100.0 | 75.0, 91.7 |
| | Min, Max | 0, 56 | 0, 67 | 53,100 | 33,100 | 42,100 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 |
| | Mean | 26.9 | 21.8 | 78.5 | 87.2 | 72.8 |
| | SD | 30.82 | 22.98 | 26.89 | 21.76 | 28.14 |
| | Median | 22.2 | 16.7 | 86.7 | 100.0 | 83.3 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 | 73.3,100.0 | 83.3,100.0 | 66.7,100.0 |
| | Min, Max | 0,100 | 0, 83 | 7,100 | 17,100 | 0,100 |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 |
| | Mean | 18.8 | 25.6 | 82.6 | 87.2 | 84.6 |
| | SD | 19.45 | 26.89 | 20.64 | 16.88 | 17.30 |
| | Median | 11.1 | 16.7 | 86.7 | 100.0 | 83.3 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 | 66.7,100.0 | 66.7,100.0 | 75.0,100.0 |
| | Min, Max | 0, 56 | 0, 83 | 33,100 | 67,100 | 42,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.4d
Scores on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 |
| | Mean | 0.0 | 16.7 | 93.3 | 50.0 | 83.3 |
| | SD | | | | | |
| | Median | 0.0 | 16.7 | 93.3 | 50.0 | 83.3 |
| | Q1, Q3 | 0.0, 0.0 | 16.7, 16.7 | 93.3, 93.3 | 50.0, 50.0 | 83.3, 83.3 |
| | Min, Max | 0, 0 | 17, 17 | 93, 93 | 50, 50 | 83, 83 |
| PD | n | 29 | 29 | 29 | 29 | 29 |
| | Mean | 32.6 | 35.6 | 73.8 | 87.9 | 62.6 |
| | SD | 22.01 | 24.69 | 21.15 | 14.70 | 21.43 |
| | Median | 33.3 | 33.3 | 80.0 | 100.0 | 66.7 |
| | Q1, Q3 | 22.2, 44.4 | 16.7, 50.0 | 66.7, 86.7 | 83.3,100.0 | 50.0, 75.0 |
| | Min, Max | 0,100 | 0,100 | 13,100 | 50,100 | 8,100 |
| CR | n | 1 | 1 | 1 | 1 | 1 |
| | Mean | 44.4 | 16.7 | 80.0 | 100.0 | 50.0 |
| | SD | | | | | |
| | Median | 44.4 | 16.7 | 80.0 | 100.0 | 50.0 |
| | Q1, Q3 | 44.4, 44.4 | 16.7, 16.7 | 80.0, 80.0 | 100.0,100.0 | 50.0, 50.0 |
| | Min, Max | 44, 44 | 17, 17 | 80, 80 | 100,100 | 50, 50 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.4d
Scores on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| End of Study | n | 9 | 9 | 9 | 9 | 9 |
| | Mean | 27.2 | 25.9 | 83.0 | 85.2 | 72.2 |
| | SD | 17.67 | 18.84 | 13.79 | 17.57 | 14.43 |
| | Median | 33.3 | 16.7 | 86.7 | 83.3 | 75.0 |
| | Q1, Q3 | 22.2, 33.3 | 16.7, 33.3 | 66.7, 93.3 | 83.3,100.0 | 58.3, 83.3 |
| | Min, Max | 0, 56 | 0, 67 | 67,100 | 50,100 | 50, 92 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 5.1d
Scores on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Screening | n | 117 | 117 | 117 | 117 |
| | Mean | 72.9 | 78.1 | 69.8 | 19.9 |
| | SD | 25.78 | 20.98 | 25.61 | 28.39 |
| | Median | 66.7 | 83.3 | 66.7 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 66.7, 91.7 | 50.0,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 0,100 | 0,100 | 0,100 |
| Baseline Evaluations | n | 122 | 122 | 122 | 122 |
| | Mean | 64.2 | 77.1 | 64.9 | 21.9 |
| | SD | 30.20 | 21.36 | 27.26 | 28.99 |
| | Median | 66.7 | 83.3 | 66.7 | 0.0 |
| | Q1, Q3 | 50.0, 83.3 | 66.7, 91.7 | 50.0, 83.3 | 0.0, 33.3 |
| | Min, Max | 0,100 | 0,100 | 0,100 | 0,100 |
| Day 1 | n | 110 | 110 | 110 | 110 |
| | Mean | 60.2 | 75.5 | 59.4 | 23.9 |
| | SD | 31.21 | 20.79 | 31.81 | 31.65 |
| | Median | 66.7 | 83.3 | 66.7 | 0.0 |
| | Q1, Q3 | 33.3, 83.3 | 66.7, 91.7 | 33.3, 83.3 | 0.0, 33.3 |
| | Min, Max | 0,100 | 8,100 | 0,100 | 0,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
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Table 5.1d
Scores on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| | | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 1 | n | 107 | 107 | 107 | 107 |
| | Mean | 63.6 | 79.1 | 61.5 | 23.4 |
| | SD | 30.30 | 21.06 | 29.71 | 29.39 |
| | Median | 66.7 | 83.3 | 66.7 | 0.0 |
| | Q1, Q3 | 33.3, 83.3 | 66.7,100.0 | 50.0, 83.3 | 0.0, 33.3 |
| | Min, Max | 0,100 | 17,100 | 0,100 | 0,100 |
| Month 2 | n | 97 | 97 | 97 | 97 |
| | Mean | 70.8 | 83.8 | 71.3 | 19.9 |
| | SD | 28.87 | 19.50 | 25.88 | 27.91 |
| | Median | 66.7 | 91.7 | 66.7 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 75.0,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 0,100 | 0,100 | 0,100 |
| Month 3 | n | 84 | 84 | 84 | 84 |
| | Mean | 73.4 | 85.2 | 73.8 | 16.3 |
| | SD | 28.36 | 18.17 | 25.78 | 24.54 |
| | Median | 66.7 | 91.7 | 66.7 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 75.0,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 0,100 | 0,100 | 0,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.1d
Scores on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| | | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 4 | n | 78 | 78 | 78 | 78 |
| | Mean | 76.3 | 84.7 | 79.1 | 16.7 |
| | SD | 22.23 | 16.53 | 24.09 | 22.63 |
| | Median | 66.7 | 91.7 | 83.3 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 75.0,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 42,100 | 0,100 | 0,100 |
| Month 5 | n | 76 | 76 | 76 | 76 |
| | Mean | 80.7 | 86.3 | 83.6 | 12.7 |
| | SD | 25.54 | 16.93 | 20.82 | 23.07 |
| | Median | 100.0 | 91.7 | 100.0 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 75.0,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 17,100 | 33,100 | 0,100 |
| Month 6 | n | 75 | 75 | 75 | 75 |
| | Mean | 78.4 | 84.8 | 81.8 | 17.3 |
| | SD | 24.78 | 16.23 | 19.98 | 24.73 |
| | Median | 83.3 | 91.7 | 83.3 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 66.7,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 17,100 | 42,100 | 33,100 | 0,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.1d
Scores on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| | | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 9 | n | 58 | 58 | 58 | 58 |
| | Mean | 84.2 | 85.2 | 84.5 | 14.4 |
| | SD | 22.82 | 18.67 | 21.82 | 17.78 |
| | Median | 100.0 | 91.7 | 100.0 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 75.0,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 33,100 | 33,100 | 0, 67 |
| Month 12 | n | 54 | 54 | 54 | 54 |
| | Mean | 81.2 | 86.4 | 79.0 | 17.3 |
| | SD | 25.71 | 15.80 | 23.39 | 24.00 |
| | Median | 100.0 | 91.7 | 83.3 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 75.0,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 33,100 | 33,100 | 0,100 |
| Month 15 | n | 31 | 31 | 31 | 31 |
| | Mean | 74.2 | 85.2 | 77.4 | 16.1 |
| | SD | 35.44 | 23.04 | 29.36 | 20.85 |
| | Median | 100.0 | 91.7 | 83.3 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 83.3,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 0,100 | 0,100 | 0, 67 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 5.1d
Scores on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| | | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 18 | n | 25 | 25 | 25 | 25 |
| | Mean | 82.7 | 87.7 | 85.3 | 13.3 |
| | SD | 25.68 | 16.34 | 19.44 | 23.57 |
| | Median | 100.0 | 100.0 | 100.0 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 75.0,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 50,100 | 33,100 | 0,100 |
| Month 21 | n | 26 | 26 | 26 | 26 |
| | Mean | 82.7 | 85.6 | 80.8 | 12.8 |
| | SD | 29.62 | 22.06 | 28.94 | 16.54 |
| | Median | 100.0 | 91.7 | 100.0 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 75.0,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 0,100 | 0,100 | 0, 33 |
| Month 24 | n | 13 | 13 | 13 | 13 |
| | Mean | 80.8 | 85.9 | 84.6 | 17.9 |
| | SD | 30.31 | 14.59 | 27.61 | 22.01 |
| | Median | 100.0 | 91.7 | 100.0 | 0.0 |
| | Q1, Q3 | 66.7,100.0 | 66.7,100.0 | 83.3,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 67,100 | 17,100 | 0, 67 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 5.1d
Scores on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| | | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 30 | n | 1 | 1 | 1 | 1 |
| | Mean | 100.0 | 66.7 | 100.0 | 0.0 |
| | SD | | | | |
| | Median | 100.0 | 66.7 | 100.0 | 0.0 |
| | Q1, Q3 | 100.0,100.0 | 66.7, 66.7 | 100.0,100.0 | 0.0, 0.0 |
| | Min, Max | 100,100 | 67, 67 | 100,100 | 0, 0 |
| PD | n | 29 | 29 | 29 | 29 |
| | Mean | 65.5 | 78.2 | 69.5 | 17.2 |
| | SD | 29.52 | 19.47 | 28.20 | 26.16 |
| | Median | 66.7 | 75.0 | 66.7 | 0.0 |
| | Q1, Q3 | 66.7, 83.3 | 66.7, 91.7 | 50.0,100.0 | 0.0, 33.3 |
| | Min, Max | 0,100 | 25,100 | 0,100 | 0,100 |
| CR | n | 1 | 1 | 1 | 1 |
| | Mean | 66.7 | 83.3 | 50.0 | 0.0 |
| | SD | | | | |
| | Median | 66.7 | 83.3 | 50.0 | 0.0 |
| | Q1, Q3 | 66.7, 66.7 | 83.3, 83.3 | 50.0, 50.0 | 0.0, 0.0 |
| | Min, Max | 67, 67 | 83, 83 | 50, 50 | 0, 0 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 5.1d
Scores on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score (N=122) | | | |
|---|---|---|---|---|---|
| | | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| End of Study | n | 9 | 9 | 9 | 9 |
| | Mean | 83.3 | 81.5 | 85.2 | 29.6 |
| | SD | 18.63 | 14.89 | 17.57 | 35.14 |
| | Median | 83.3 | 75.0 | 100.0 | 33.3 |
| | Q1, Q3 | 66.7,100.0 | 66.7,100.0 | 66.7,100.0 | 0.0, 33.3 |
| | Min, Max | 50,100 | 67,100 | 67,100 | 0,100 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome.

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Table 4.5d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 |
| | Mean | 4.4 | -3.8 | -0.5 | -0.2 | -4.9 |
| | SD | 18.87 | 19.64 | 18.30 | 16.67 | 16.91 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -11.1, 11.1 | -16.7, 0.0 | -6.7, 6.7 | 0.0, 0.0 | -16.7, 0.0 |
| | Min, Max | -44, 56 | -100, 33 | -53, 53 | -50, 50 | -50, 42 |
| | p-value for Comparison to Zero [b] | 0.010 | 0.089 | 0.990 | 0.781 | 0.002 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 |
| | Mean | 1.1 | -9.0 | 1.9 | 2.8 | 4.4 |
| | SD | 24.61 | 26.23 | 22.41 | 20.28 | 20.10 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -11.1, 22.2 | -16.7, 0.0 | -6.7, 13.3 | 0.0, 16.7 | -8.3, 16.7 |
| | Min, Max | -56, 67 | -100, 67 | -80, 73 | -67, 83 | -33, 83 |
| | p-value for Comparison to Zero [b] | 0.539 | 0.001 | 0.214 | 0.224 | 0.057 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.5d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 |
| | Mean | -8.0 | -8.8 | 6.2 | 6.7 | 8.2 |
| | SD | 23.83 | 29.27 | 19.01 | 18.11 | 20.39 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 8.3 |
| | Q1, Q3 | -22.2, 11.1 | -16.7, 0.0 | 0.0, 13.3 | 0.0, 16.7 | -8.3, 16.7 |
| | Min, Max | -89, 33 | -100, 67 | -67, 67 | -33, 83 | -42, 67 |
| | p-value for Comparison to Zero [b] | 0.002 | 0.008 | <0.001 | <0.001 | <0.001 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 |
| | Mean | -10.2 | -12.3 | 9.9 | 5.6 | 9.0 |
| | SD | 24.59 | 26.90 | 18.73 | 17.61 | 20.50 |
| | Median | -11.1 | -16.7 | 6.7 | 0.0 | 8.3 |
| | Q1, Q3 | -22.2, 11.1 | -16.7, 0.0 | 0.0, 20.0 | 0.0, 16.7 | 0.0, 16.7 |
| | Min, Max | -89, 44 | -100, 50 | -20, 73 | -33, 83 | -42, 67 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | <0.001 | 0.002 | <0.001 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.5d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 |
| | Mean | -10.3 | -16.0 | 11.7 | 4.5 | 11.6 |
| | SD | 23.88 | 26.52 | 18.83 | 18.55 | 21.67 |
| | Median | 0.0 | -16.7 | 6.7 | 0.0 | 8.3 |
| | Q1, Q3 | -22.2, 0.0 | -33.3, 0.0 | 0.0, 20.0 | 0.0, 16.7 | 0.0, 25.0 |
| | Min, Max | -89, 56 | -100, 33 | -20, 87 | -50, 83 | -42, 67 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | <0.001 | 0.047 | <0.001 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 |
| | Mean | -14.8 | -16.2 | 12.8 | 7.2 | 14.9 |
| | SD | 25.81 | 26.94 | 19.41 | 18.12 | 19.40 |
| | Median | -11.1 | -16.7 | 6.7 | 0.0 | 8.3 |
| | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 20.0 | 0.0, 16.7 | 0.0, 25.0 |
| | Min, Max | -89, 44 | -100, 50 | -20, 87 | -33, 83 | -25, 75 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | <0.001 | 0.001 | <0.001 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.5d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 |
| | Mean | -15.3 | -14.7 | 14.0 | 6.4 | 12.4 |
| | SD | 24.49 | 26.28 | 18.52 | 16.64 | 19.25 |
| | Median | -11.1 | -16.7 | 6.7 | 0.0 | 8.3 |
| | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 26.7 | 0.0, 16.7 | 0.0, 25.0 |
| | Min, Max | -89, 67 | -83, 50 | -20, 53 | -33, 67 | -42, 58 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | <0.001 | 0.001 | <0.001 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 |
| | Mean | -21.8 | -17.8 | 13.3 | 6.9 | 15.8 |
| | SD | 24.62 | 24.36 | 19.10 | 14.98 | 21.04 |
| | Median | -22.2 | -16.7 | 6.7 | 0.0 | 16.7 |
| | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 26.7 | 0.0, 16.7 | 0.0, 25.0 |
| | Min, Max | -89, 22 | -83, 33 | -47, 53 | -33, 50 | -42, 67 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.5d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 |
| | Mean | -16.7 | -17.6 | 13.6 | 4.3 | 14.2 |
| | SD | 25.15 | 26.19 | 19.25 | 17.79 | 21.76 |
| | Median | -16.7 | -16.7 | 10.0 | 0.0 | 16.7 |
| | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 26.7 | 0.0, 16.7 | 0.0, 33.3 |
| | Min, Max | -89, 33 | -67, 50 | -40, 60 | -50, 50 | -42, 58 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | <0.001 | 0.075 | <0.001 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 |
| | Mean | -16.8 | -22.0 | 9.5 | 2.7 | 7.5 |
| | SD | 28.53 | 24.11 | 22.63 | 22.81 | 22.40 |
| | Median | -11.1 | -33.3 | 6.7 | 0.0 | 8.3 |
| | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 | -6.7, 26.7 | 0.0, 16.7 | -8.3, 25.0 |
| | Min, Max | -89, 67 | -67, 33 | -40, 53 | -50, 50 | -33, 50 |
| | p-value for Comparison to Zero [b] | 0.001 | <0.001 | 0.018 | 0.508 | 0.106 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.5d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 |
| | Mean | -19.1 | -17.3 | 13.3 | 4.0 | 11.0 |
| | SD | 19.12 | 25.68 | 16.10 | 20.00 | 17.47 |
| | Median | -22.2 | -16.7 | 6.7 | 0.0 | 8.3 |
| | Q1, Q3 | -33.3,-11.1 | -33.3, 0.0 | 0.0, 20.0 | 0.0, 16.7 | 0.0, 25.0 |
| | Min, Max | -67, 11 | -50, 33 | -7, 60 | -33, 33 | -42, 42 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.003 | <0.001 | 0.480 | 0.003 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 |
| | Mean | -11.1 | -14.1 | 4.9 | 3.2 | 5.4 |
| | SD | 29.98 | 28.55 | 23.06 | 18.27 | 23.09 |
| | Median | -11.1 | -16.7 | 3.3 | 0.0 | 8.3 |
| | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 13.3 | 0.0, 16.7 | -8.3, 25.0 |
| | Min, Max | -89, 67 | -83, 50 | -47, 60 | -50, 33 | -67, 42 |
| | p-value for Comparison to Zero [b] | 0.054 | 0.008 | 0.249 | 0.341 | 0.165 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.5d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 |
| | Mean | -8.5 | -14.1 | 4.1 | 3.8 | 7.7 |
| | SD | 16.45 | 16.45 | 14.28 | 16.88 | 15.39 |
| | Median | -11.1 | -16.7 | 0.0 | 0.0 | 8.3 |
| | Q1, Q3 | -22.2, 0.0 | -16.7,-16.7 | 0.0, 6.7 | 0.0, 16.7 | 8.3, 16.7 |
| | Min, Max | -33, 22 | -33, 17 | -20, 40 | -33, 33 | -33, 25 |
| | p-value for Comparison to Zero [b] | 0.086 | 0.032 | 0.422 | 0.469 | 0.071 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 |
| | Mean | -33.3 | -16.7 | 13.3 | 0.0 | 16.7 |
| | SD | | | | | |
| | Median | -33.3 | -16.7 | 13.3 | 0.0 | 16.7 |
| | Q1, Q3 | -33.3,-33.3 | -16.7,-16.7 | 13.3, 13.3 | 0.0, 0.0 | 16.7, 16.7 |
| | Min, Max | -33,-33 | -17,-17 | 13, 13 | 0, 0 | 17, 17 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 | 1.000 | N/A | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.5d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| PD | n | 29 | 29 | 29 | 29 | 29 |
| | Mean | -4.2 | -8.6 | 3.2 | 2.3 | 1.7 |
| | SD | 28.08 | 27.32 | 23.68 | 18.75 | 19.59 |
| | Median | -11.1 | 0.0 | 6.7 | 0.0 | 8.3 |
| | Q1, Q3 | -22.2, 11.1 | -16.7, 0.0 | -6.7, 20.0 | 0.0, 16.7 | -8.3, 8.3 |
| | Min, Max | -78, 67 | -67, 67 | -67, 47 | -50, 50 | -58, 42 |
| | p-value for Comparison to Zero [b] | 0.271 | 0.082 | 0.321 | 0.386 | 0.467 |
| CR | n | 1 | 1 | 1 | 1 | 1 |
| | Mean | 11.1 | -33.3 | 6.7 | 0.0 | 8.3 |
| | SD | | | | | |
| | Median | 11.1 | -33.3 | 6.7 | 0.0 | 8.3 |
| | Q1, Q3 | 11.1, 11.1 | -33.3,-33.3 | 6.7, 6.7 | 0.0, 0.0 | 8.3, 8.3 |
| | Min, Max | 11, 11 | -33,-33 | 7, 7 | 0, 0 | 8, 8 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 | 1.000 | N/A | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.5d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| End of Study | n | 9 | 9 | 9 | 9 | 9 |
| | Mean | -12.3 | 1.9 | 5.9 | -3.7 | 4.6 |
| | SD | 14.10 | 13.03 | 11.76 | 16.20 | 15.65 |
| | Median | -11.1 | 0.0 | 6.7 | 0.0 | 8.3 |
| | Q1, Q3 | -22.2, 0.0 | 0.0, 16.7 | -6.7, 20.0 | -16.7, 0.0 | 0.0, 8.3 |
| | Min, Max | -33, 0 | -17, 17 | -7, 20 | -33, 17 | -25, 25 |
| | p-value for Comparison to Zero [b] | 0.063 | 1.000 | 0.227 | 0.688 | 0.406 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.

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Table 5.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Day 1 | n | 110 | 110 | 110 | 110 |
| | Mean | -5.5 | -2.0 | -6.4 | 3.3 |
| | SD | 25.35 | 16.75 | 24.31 | 23.87 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 0.0 | -8.3, 8.3 | -16.7, 0.0 | 0.0, 0.0 |
| | Min, Max | -83, 50 | -75, 42 | -67, 67 | -100,100 |
| | p-value for Comparison to Zero [b] | 0.020 | 0.264 | 0.007 | 0.059 |
| Month 1 | n | 107 | 107 | 107 | 107 |
| | Mean | -1.7 | 2.1 | -3.9 | 3.4 |
| | SD | 31.13 | 19.66 | 24.82 | 27.83 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -33.3, 16.7 | -8.3, 8.3 | -16.7, 16.7 | 0.0, 0.0 |
| | Min, Max | -83, 83 | -50, 67 | -67, 50 | -100, 67 |
| | p-value for Comparison to Zero [b] | 0.506 | 0.540 | 0.069 | 0.137 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 5.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 2 | n | 97 | 97 | 97 | 97 |
| | Mean | 5.2 | 7.3 | 7.0 | 1.0 |
| | SD | 29.00 | 18.68 | 23.67 | 21.22 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 | 0.0, 16.7 | 0.0, 0.0 |
| | Min, Max | -83, 83 | -33, 67 | -50, 67 | -100, 67 |
| | p-value for Comparison to Zero [b] | 0.086 | <0.001 | 0.006 | 0.364 |
| Month 3 | n | 84 | 84 | 84 | 84 |
| | Mean | 6.7 | 7.6 | 8.9 | -1.2 |
| | SD | 28.36 | 19.84 | 27.31 | 22.22 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 33.3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -67,100 | -42, 67 | -67, 67 | -33,100 |
| | p-value for Comparison to Zero [b] | 0.050 | <0.001 | 0.005 | 0.656 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 5.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 4 | n | 78 | 78 | 78 | 78 |
| | Mean | 12.0 | 8.2 | 14.7 | -0.4 |
| | SD | 25.33 | 21.55 | 26.04 | 21.15 |
| | Median | 0.0 | 8.3 | 16.7 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -33,100 | -50, 67 | -33, 67 | -67, 67 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | <0.001 | 0.852 |
| Month 5 | n | 76 | 76 | 76 | 76 |
| | Mean | 15.8 | 9.9 | 19.7 | -4.4 |
| | SD | 26.09 | 18.94 | 24.75 | 19.88 |
| | Median | 0.0 | 8.3 | 16.7 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -33,100 | -58, 67 | -17, 83 | -67, 33 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | <0.001 | 0.106 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 6 | n | 75 | 75 | 75 | 75 |
| | Mean | 13.1 | 8.4 | 17.6 | -0.9 |
| | SD | 28.51 | 17.89 | 24.95 | 19.74 |
| | Median | 0.0 | 8.3 | 16.7 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -50,100 | -50, 58 | -50, 67 | -33, 67 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | <0.001 | 0.761 |
| Month 9 | n | 58 | 58 | 58 | 58 |
| | Mean | 17.2 | 7.8 | 19.3 | -1.7 |
| | SD | 29.94 | 18.98 | 25.90 | 22.01 |
| | Median | 16.7 | 8.3 | 16.7 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -67, 83 | -25, 58 | -33, 67 | -67, 33 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.004 | <0.001 | 0.521 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 12 | n | 54 | 54 | 54 | 54 |
| | Mean | 15.1 | 8.3 | 12.0 | -1.2 |
| | SD | 29.37 | 16.90 | 24.75 | 22.40 |
| | Median | 16.7 | 0.0 | 8.3 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -67, 67 | -42, 50 | -33, 67 | -67, 67 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | 0.005 | 0.678 |
| Month 15 | n | 31 | 31 | 31 | 31 |
| | Mean | 11.8 | 8.6 | 12.4 | -0.0 |
| | SD | 34.75 | 23.22 | 31.90 | 22.77 |
| | Median | 0.0 | 0.0 | 16.7 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -67, 83 | -58, 50 | -67, 67 | -33, 67 |
| | p-value for Comparison to Zero [b] | 0.076 | 0.033 | 0.033 | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 5.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| | | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 18 | n | 25 | 25 | 25 | 25 |
| | Mean | 16.7 | 13.0 | 14.0 | -5.3 |
| | SD | 22.57 | 15.61 | 25.31 | 20.82 |
| | Median | 16.7 | 8.3 | 16.7 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 25.0 | 0.0, 33.3 | -33.3, 0.0 |
| | Min, Max | -33, 67 | -8, 42 | -33, 67 | -33, 33 |
| | p-value for Comparison to Zero [b] | 0.003 | <0.001 | 0.014 | 0.344 |
| Month 21 | n | 26 | 26 | 26 | 26 |
| | Mean | 7.1 | 9.9 | 7.1 | -5.1 |
| | SD | 22.20 | 19.58 | 34.37 | 18.12 |
| | Median | 0.0 | 4.2 | 16.7 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 25.0 | 0.0, 16.7 | 0.0, 0.0 |
| | Min, Max | -50, 50 | -25, 50 | -100, 67 | -33, 33 |
| | p-value for Comparison to Zero [b] | 0.113 | 0.016 | 0.262 | 0.289 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 5.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 24 | n | 13 | 13 | 13 | 13 |
| | Mean | 10.3 | 1.9 | 10.3 | -10.3 |
| | SD | 23.11 | 15.27 | 25.04 | 21.01 |
| | Median | 0.0 | 0.0 | 16.7 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 8.3 | 0.0, 33.3 | -33.3, 0.0 |
| | Min, Max | -33, 67 | -25, 33 | -33, 50 | -33, 33 |
| | p-value for Comparison to Zero [b] | 0.156 | 0.766 | 0.195 | 0.188 |
| Month 30 | n | 1 | 1 | 1 | 1 |
| | Mean | 33.3 | 33.3 | 66.7 | -66.7 |
| | SD | | | | |
| | Median | 33.3 | 33.3 | 66.7 | -66.7 |
| | Q1, Q3 | 33.3, 33.3 | 33.3, 33.3 | 66.7, 66.7 | -66.7,-66.7 |
| | Min, Max | 33, 33 | 33, 33 | 67, 67 | -67,-67 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 5.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| PD | n | 29 | 29 | 29 | 29 |
| | Mean | 0.6 | -0.9 | 4.0 | -4.6 |
| | SD | 26.53 | 17.30 | 25.84 | 21.31 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | -8.3, 8.3 | 0.0, 16.7 | -33.3, 0.0 |
| | Min, Max | -67, 67 | -50, 33 | -67, 67 | -33, 33 |
| | p-value for Comparison to Zero [b] | 0.946 | 0.840 | 0.304 | 0.307 |
| CR | n | 1 | 1 | 1 | 1 |
| | Mean | 0.0 | 0.0 | -16.7 | 0.0 |
| | SD | | | | |
| | Median | 0.0 | 0.0 | -16.7 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 | -16.7,-16.7 | 0.0, 0.0 |
| | Min, Max | 0, 0 | 0, 0 | -17,-17 | 0, 0 |
| | p-value for Comparison to Zero [b] | N/A | N/A | 1.000 | N/A |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| End of Study | n | 9 | 9 | 9 | 9 |
| | Mean | 7.4 | -5.6 | 1.9 | 3.7 |
| | SD | 14.70 | 15.02 | 28.19 | 30.93 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | -16.7, 0.0 | -16.7, 0.0 | -33.3, 33.3 |
| | Min, Max | -17, 33 | -33, 17 | -33, 67 | -33, 33 |
| | p-value for Comparison to Zero [b] | 0.188 | 0.344 | 1.000 | 0.766 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.

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Table 4.5.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Day 1 | n | 110 | 110 | 110 | 110 | 110 |
| | Mean | 10.8 | 3.3 | -9.2 | -1.1 | -13.5 |
| | SD | 23.48 | 24.81 | 21.64 | 18.65 | 18.58 |
| | Median | 11.1 | 0.0 | -6.7 | 0.0 | -16.7 |
| | Q1, Q3 | 0.0, 22.2 | -16.7, 16.7 | -20.0, 0.0 | -16.7, 0.0 | -25.0, 0.0 |
| | Min, Max | -44, 78 | -67, 67 | -87, 53 | -67, 50 | -83, 33 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.143 | <0.001 | 0.625 | <0.001 |
| Month 1 | n | 107 | 107 | 107 | 107 | 107 |
| | Mean | 7.6 | -2.8 | -6.4 | 1.6 | -5.1 |
| | SD | 24.35 | 26.65 | 20.92 | 20.67 | 19.75 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | -8.3 |
| | Q1, Q3 | 0.0, 22.2 | -16.7, 16.7 | -13.3, 6.7 | 0.0, 16.7 | -16.7, 8.3 |
| | Min, Max | -44, 89 | -67, 67 | -80, 47 | -67, 50 | -50, 83 |
| | p-value for Comparison to Zero [b] | 0.002 | 0.406 | 0.017 | 0.435 | 0.003 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.5.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 2 | n | 97 | 97 | 97 | 97 | 97 |
| | Mean | -1.4 | -2.6 | -0.5 | 5.5 | 0.1 |
| | SD | 24.44 | 27.88 | 17.68 | 17.30 | 18.42 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -11.1, 11.1 | -16.7, 16.7 | -6.7, 6.7 | 0.0, 16.7 | -8.3, 8.3 |
| | Min, Max | -78, 67 | -67, 83 | -80, 67 | -33, 67 | -50, 50 |
| | p-value for Comparison to Zero [b] | 0.551 | 0.406 | 0.738 | 0.002 | 0.874 |
| Month 3 | n | 84 | 84 | 84 | 84 | 84 |
| | Mean | -5.7 | -6.5 | 3.8 | 4.8 | 1.5 |
| | SD | 22.78 | 26.13 | 17.29 | 15.21 | 19.50 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 0.0 | -16.7, 8.3 | -6.7, 13.3 | 0.0, 16.7 | -8.3, 8.3 |
| | Min, Max | -78, 56 | -83, 50 | -27, 67 | -17, 67 | -58, 58 |
| | p-value for Comparison to Zero [b] | 0.013 | 0.005 | 0.074 | 0.011 | 0.303 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.5.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 4 | n | 78 | 78 | 78 | 78 | 78 |
| | Mean | -3.7 | -9.8 | 3.9 | 4.3 | 1.5 |
| | SD | 21.83 | 26.92 | 16.31 | 14.57 | 19.73 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -22.2, 11.1 | -33.3, 0.0 | -6.7, 6.7 | 0.0, 16.7 | -8.3, 8.3 |
| | Min, Max | -67, 56 | -83, 50 | -27, 80 | -33, 50 | -50, 67 |
| | p-value for Comparison to Zero [b] | 0.081 | 0.001 | 0.061 | 0.073 | 0.481 |
| Month 5 | n | 76 | 76 | 76 | 76 | 76 |
| | Mean | -8.6 | -9.9 | 5.9 | 4.6 | 5.3 |
| | SD | 23.35 | 27.65 | 17.95 | 16.69 | 16.93 |
| | Median | -11.1 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -22.2, 0.0 | -33.3, 0.0 | 0.0, 20.0 | 0.0, 16.7 | -8.3, 16.7 |
| | Min, Max | -78, 44 | -83, 67 | -27, 80 | -33, 67 | -25, 50 |
| | p-value for Comparison to Zero [b] | 0.002 | <0.001 | 0.006 | 0.072 | 0.015 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.5.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 6 | n | 75 | 75 | 75 | 75 | 75 |
| | Mean | -8.4 | -9.8 | 7.0 | 4.2 | 6.0 |
| | SD | 22.29 | 24.52 | 17.60 | 14.78 | 18.05 |
| | Median | -11.1 | 0.0 | 0.0 | 0.0 | 8.3 |
| | Q1, Q3 | -22.2, 0.0 | -33.3, 0.0 | 0.0, 13.3 | 0.0, 16.7 | 0.0, 16.7 |
| | Min, Max | -67, 67 | -67, 33 | -20, 80 | -33, 67 | -50, 50 |
| | p-value for Comparison to Zero [b] | 0.005 | <0.001 | 0.002 | 0.028 | 0.003 |
| Month 9 | n | 58 | 58 | 58 | 58 | 58 |
| | Mean | -16.1 | -12.6 | 7.6 | 6.0 | 9.5 |
| | SD | 19.76 | 22.14 | 18.16 | 15.52 | 18.37 |
| | Median | -11.1 | -8.3 | 3.3 | 0.0 | 8.3 |
| | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 | 0.0, 20.0 | 0.0, 16.7 | 0.0, 16.7 |
| | Min, Max | -78, 11 | -67, 33 | -53, 67 | -17, 67 | -42, 67 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | <0.001 | 0.019 | <0.001 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
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Table 4.5.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 12 | n | 54 | 54 | 54 | 54 | 54 |
| | Mean | -9.7 | -9.9 | 7.2 | 2.5 | 8.0 |
| | SD | 20.48 | 23.69 | 17.56 | 15.66 | 18.88 |
| | Median | -11.1 | -16.7 | 6.7 | 0.0 | 8.3 |
| | Q1, Q3 | -22.2, 0.0 | -16.7, 0.0 | 0.0, 20.0 | 0.0, 0.0 | 0.0, 16.7 |
| | Min, Max | -78, 44 | -50, 50 | -47, 40 | -50, 50 | -42, 42 |
| | p-value for Comparison to Zero [b] | <0.001 | <0.001 | 0.003 | 0.337 | 0.001 |
| Month 15 | n | 31 | 31 | 31 | 31 | 31 |
| | Mean | -6.5 | -10.8 | 1.9 | -1.6 | -2.2 |
| | SD | 23.09 | 22.17 | 19.41 | 18.44 | 21.08 |
| | Median | -11.1 | -16.7 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -22.2, 0.0 | -33.3, 0.0 | 0.0, 13.3 | 0.0, 0.0 | -16.7, 8.3 |
| | Min, Max | -33, 67 | -50, 33 | -53, 40 | -50, 50 | -50, 42 |
| | p-value for Comparison to Zero [b] | 0.045 | 0.032 | 0.325 | 0.713 | 0.590 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.5.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 18 | n | 25 | 25 | 25 | 25 | 25 |
| | Mean | -8.0 | -8.0 | 5.9 | 3.3 | 3.3 |
| | SD | 17.43 | 21.58 | 13.79 | 18.00 | 18.32 |
| | Median | -11.1 | -16.7 | 6.7 | 0.0 | 0.0 |
| | Q1, Q3 | -22.2, 0.0 | -16.7, 0.0 | 0.0, 6.7 | 0.0, 16.7 | 0.0, 16.7 |
| | Min, Max | -33, 44 | -50, 33 | -13, 40 | -50, 33 | -33, 42 |
| | p-value for Comparison to Zero [b] | 0.018 | 0.086 | 0.037 | 0.271 | 0.373 |
| Month 21 | n | 26 | 26 | 26 | 26 | 26 |
| | Mean | 0.4 | -5.8 | -1.0 | 1.9 | -1.9 |
| | SD | 26.01 | 21.05 | 21.47 | 19.05 | 20.32 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -11.1, 11.1 | -16.7, 0.0 | -6.7, 6.7 | 0.0, 16.7 | -16.7, 16.7 |
| | Min, Max | -44, 67 | -50, 50 | -67, 40 | -67, 33 | -42, 42 |
| | p-value for Comparison to Zero [b] | 0.965 | 0.025 | 0.974 | 0.325 | 0.514 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.5.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| | | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| Month 24 | n | 13 | 13 | 13 | 13 | 13 |
| | Mean | -9.4 | -5.1 | 5.1 | 2.6 | 8.3 |
| | SD | 11.87 | 20.84 | 13.92 | 9.25 | 19.84 |
| | Median | -11.1 | -16.7 | 0.0 | 0.0 | 8.3 |
| | Q1, Q3 | -11.1, 0.0 | -16.7, 16.7 | 0.0, 13.3 | 0.0, 0.0 | 0.0, 16.7 |
| | Min, Max | -33, 11 | -33, 33 | -13, 33 | -17, 17 | -25, 42 |
| | p-value for Comparison to Zero [b] | 0.012 | 0.353 | 0.305 | 0.375 | 0.172 |
| Month 30 | n | 1 | 1 | 1 | 1 | 1 |
| | Mean | -33.3 | -16.7 | 13.3 | 0.0 | 16.7 |
| | SD | | | | | |
| | Median | -33.3 | -16.7 | 13.3 | 0.0 | 16.7 |
| | Q1, Q3 | -33.3,-33.3 | -16.7,-16.7 | 13.3, 13.3 | 0.0, 0.0 | 16.7, 16.7 |
| | Min, Max | -33,-33 | -17,-17 | 13, 13 | 0, 0 | 17, 17 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 | 1.000 | N/A | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.5.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| PD | n | 29 | 29 | 29 | 29 | 29 |
| | Mean | 0.0 | -1.1 | -4.1 | 1.7 | -10.1 |
| | SD | 25.20 | 29.86 | 25.22 | 17.45 | 20.09 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 | -8.3 |
| | Q1, Q3 | -22.2, 11.1 | -16.7, 16.7 | -13.3, 6.7 | 0.0, 0.0 | -16.7, 0.0 |
| | Min, Max | -56, 78 | -67, 83 | -80, 53 | -33, 50 | -58, 33 |
| | p-value for Comparison to Zero [b] | 0.720 | 0.547 | 0.495 | 0.504 | 0.007 |
| CR | n | 1 | 1 | 1 | 1 | 1 |
| | Mean | 11.1 | 0.0 | 0.0 | 0.0 | -33.3 |
| | SD | | | | | |
| | Median | 11.1 | 0.0 | 0.0 | 0.0 | -33.3 |
| | Q1, Q3 | 11.1, 11.1 | 0.0, 0.0 | 0.0, 0.0 | 0.0, 0.0 | -33.3,-33.3 |
| | Min, Max | 11, 11 | 0, 0 | 0, 0 | 0, 0 | -33,-33 |
| | p-value for Comparison to Zero [b] | 1.000 | N/A | N/A | N/A | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 4.5.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Primary Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | | |
|---|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Fatigue | Pain | Physical Functioning | Cognitive Functioning | Global Health/QoL |
| End of Study | n | 9 | 9 | 9 | 9 | 9 |
| | Mean | 8.6 | 9.3 | -3.0 | -3.7 | -7.4 |
| | SD | 20.62 | 22.22 | 17.36 | 7.35 | 14.70 |
| | Median | 0.0 | 0.0 | -13.3 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 22.2 | 0.0, 16.7 | -13.3, 6.7 | 0.0, 0.0 | -16.7, 0.0 |
| | Min, Max | -22, 44 | -17, 50 | -20, 27 | -17, 0 | -33, 8 |
| | p-value for Comparison to Zero [b] | 0.375 | 0.438 | 0.750 | 0.500 | 0.250 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Day 1 | n | 110 | 110 | 110 | 110 |
| | Mean | -13.6 | -2.8 | -10.0 | 4.5 |
| | SD | 26.83 | 17.96 | 29.80 | 22.34 |
| | Median | -8.3 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -33.3, 0.0 | -8.3, 8.3 | -33.3, 0.0 | 0.0, 0.0 |
| | Min, Max | -100, 33 | -75, 50 | -100, 83 | -67, 67 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.048 | <0.001 | 0.016 |
| Month 1 | n | 107 | 107 | 107 | 107 |
| | Mean | -9.8 | 1.1 | -8.6 | 5.3 |
| | SD | 28.95 | 20.06 | 29.53 | 25.14 |
| | Median | -16.7 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -33.3, 16.7 | -8.3, 8.3 | -33.3, 0.0 | 0.0, 0.0 |
| | Min, Max | -83, 67 | -67, 67 | -100, 83 | -67,100 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.953 | 0.001 | 0.051 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 2 | n | 97 | 97 | 97 | 97 |
| | Mean | -3.3 | 6.0 | 1.7 | 1.7 |
| | SD | 26.31 | 17.79 | 28.10 | 23.26 |
| | Median | 0.0 | 8.3 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 16.7 | 0.0, 16.7 | -16.7, 16.7 | 0.0, 0.0 |
| | Min, Max | -100, 67 | -42, 67 | -67,100 | -100, 67 |
| | p-value for Comparison to Zero [b] | 0.313 | <0.001 | 0.798 | 0.370 |
| Month 3 | n | 84 | 84 | 84 | 84 |
| | Mean | 1.6 | 5.8 | 3.8 | -1.2 |
| | SD | 22.35 | 17.11 | 25.53 | 22.22 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 16.7 | 0.0, 16.7 | -8.3, 16.7 | 0.0, 0.0 |
| | Min, Max | -50, 67 | -50, 75 | -67, 67 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.817 | <0.001 | 0.318 | 0.423 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 4 | n | 78 | 78 | 78 | 78 |
| | Mean | 4.3 | 7.4 | 9.6 | -1.3 |
| | SD | 22.38 | 21.23 | 25.84 | 22.44 |
| | Median | 0.0 | 4.2 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 16.7 | 0.0, 16.7 | 0.0, 16.7 | 0.0, 0.0 |
| | Min, Max | -33, 67 | -50,100 | -33, 83 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.096 | 0.002 | 0.008 | 0.490 |
| Month 5 | n | 76 | 76 | 76 | 76 |
| | Mean | 8.8 | 6.9 | 13.2 | -3.5 |
| | SD | 25.31 | 17.76 | 25.29 | 22.16 |
| | Median | 0.0 | 8.3 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 | 0.0, 25.0 | 0.0, 0.0 |
| | Min, Max | -50, 83 | -58, 92 | -33,100 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.011 | <0.001 | <0.001 | 0.175 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 6 | n | 75 | 75 | 75 | 75 |
| | Mean | 6.7 | 6.7 | 12.4 | -0.4 |
| | SD | 24.35 | 18.33 | 25.72 | 25.41 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -50, 83 | -33, 83 | -33,100 | -67,100 |
| | p-value for Comparison to Zero [b] | 0.054 | 0.001 | <0.001 | 0.664 |
| Month 9 | n | 58 | 58 | 58 | 58 |
| | Mean | 12.1 | 5.5 | 13.2 | -1.7 |
| | SD | 24.54 | 20.97 | 24.93 | 25.30 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 8.3 | 0.0, 16.7 | 0.0, 0.0 |
| | Min, Max | -33, 83 | -50,100 | -33, 67 | -67, 33 |
| | p-value for Comparison to Zero [b] | <0.001 | 0.044 | <0.001 | 0.553 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 12 | n | 54 | 54 | 54 | 54 |
| | Mean | 7.7 | 5.4 | 7.1 | -3.1 |
| | SD | 22.13 | 14.58 | 25.20 | 25.30 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 8.3 | 0.0, 33.3 | 0.0, 0.0 |
| | Min, Max | -50, 67 | -42, 67 | -50, 67 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.023 | <0.001 | 0.056 | 0.378 |
| Month 15 | n | 31 | 31 | 31 | 31 |
| | Mean | 2.7 | 4.8 | 3.2 | -1.1 |
| | SD | 27.25 | 24.89 | 29.00 | 23.54 |
| | Median | 0.0 | 0.0 | 16.7 | 0.0 |
| | Q1, Q3 | -16.7, 16.7 | 0.0, 16.7 | -16.7, 33.3 | 0.0, 0.0 |
| | Min, Max | -67, 50 | -67, 67 | -67, 33 | -67, 33 |
| | p-value for Comparison to Zero [b] | 0.648 | 0.160 | 0.424 | 0.694 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 18 | n | 25 | 25 | 25 | 25 |
| | Mean | 6.7 | 7.3 | 10.7 | -9.3 |
| | SD | 18.00 | 17.57 | 23.51 | 24.57 |
| | Median | 0.0 | 0.0 | 16.7 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 | 0.0, 33.3 | -33.3, 0.0 |
| | Min, Max | -33, 33 | -17, 75 | -33, 67 | -67, 33 |
| | p-value for Comparison to Zero [b] | 0.094 | 0.018 | 0.083 | 0.117 |
| Month 21 | n | 26 | 26 | 26 | 26 |
| | Mean | 3.2 | 7.4 | 4.5 | -11.5 |
| | SD | 21.09 | 27.01 | 29.27 | 22.98 |
| | Median | 0.0 | 4.2 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 | 0.0, 16.7 | -33.3, 0.0 |
| | Min, Max | -67, 33 | -67, 83 | -67, 67 | -67, 33 |
| | p-value for Comparison to Zero [b] | 0.210 | 0.081 | 0.570 | 0.031 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| | | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| Month 24 | n | 13 | 13 | 13 | 13 |
| | Mean | 5.1 | 1.9 | 11.5 | -7.7 |
| | SD | 14.25 | 12.80 | 22.96 | 19.97 |
| | Median | 0.0 | 0.0 | 16.7 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 8.3 | 0.0, 33.3 | -33.3, 0.0 |
| | Min, Max | -17, 33 | -25, 17 | -33, 50 | -33, 33 |
| | p-value for Comparison to Zero [b] | 0.375 | 0.484 | 0.109 | 0.313 |
| Month 30 | n | 1 | 1 | 1 | 1 |
| | Mean | 33.3 | 16.7 | 50.0 | -33.3 |
| | SD | | | | |
| | Median | 33.3 | 16.7 | 50.0 | -33.3 |
| | Q1, Q3 | 33.3, 33.3 | 16.7, 16.7 | 50.0, 50.0 | -33.3,-33.3 |
| | Min, Max | 33, 33 | 17, 17 | 50, 50 | -33,-33 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 5.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| PD | n | 29 | 29 | 29 | 29 |
| | Mean | -2.3 | -2.6 | -0.0 | 4.6 |
| | SD | 35.56 | 19.68 | 32.43 | 23.10 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | -16.7, 16.7 | -8.3, 8.3 | -16.7, 0.0 | 0.0, 33.3 |
| | Min, Max | -100, 67 | -50, 50 | -67, 83 | -67, 33 |
| | p-value for Comparison to Zero [b] | 0.918 | 0.552 | 0.845 | 0.432 |
| CR | n | 1 | 1 | 1 | 1 |
| | Mean | -16.7 | -8.3 | -16.7 | 0.0 |
| | SD | | | | |
| | Median | -16.7 | -8.3 | -16.7 | 0.0 |
| | Q1, Q3 | -16.7,-16.7 | -8.3, -8.3 | -16.7,-16.7 | 0.0, 0.0 |
| | Min, Max | -17,-17 | -8, -8 | -17,-17 | 0, 0 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 | 1.000 | N/A |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUL2021 14:20
Analysis Plan: 12MAY2021 Confidential

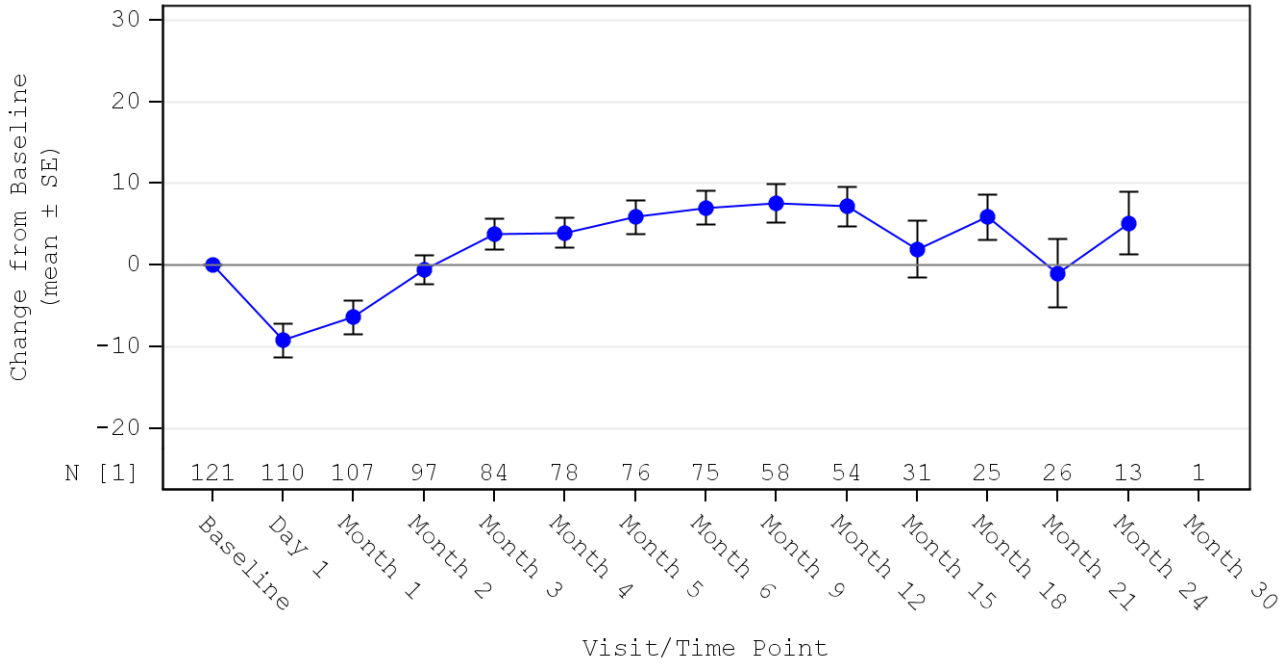
Table 5.2.1d
Change in Scores from Baseline on the EORTC QLQ-C30 Functional Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-C30 Subscale Score - Change in Score from Baseline [a] (N=122) | | | |
|---|---|---|---|---|---|
| Visit/Time Point | Parameter | Role Functioning | Emotional Functioning | Social Functioning | Financial Difficulties |
| End of Study | n | 9 | 9 | 9 | 9 |
| | Mean | -3.7 | -5.6 | -1.9 | 3.7 |
| | SD | 13.89 | 12.50 | 21.15 | 26.06 |
| | Median | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -8.3, 0.0 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | -33, 17 | -33, 8 | -33, 33 | -33, 33 |
| | p-value for Comparison to Zero [b] | 0.750 | 0.375 | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer – Quality of Life Core questionnaire; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUL2021 14:20
Analysis Plan: 12MAY2021 Confidential

Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Physical Functioning




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
Date/time of run: 30JUL2021 17:03
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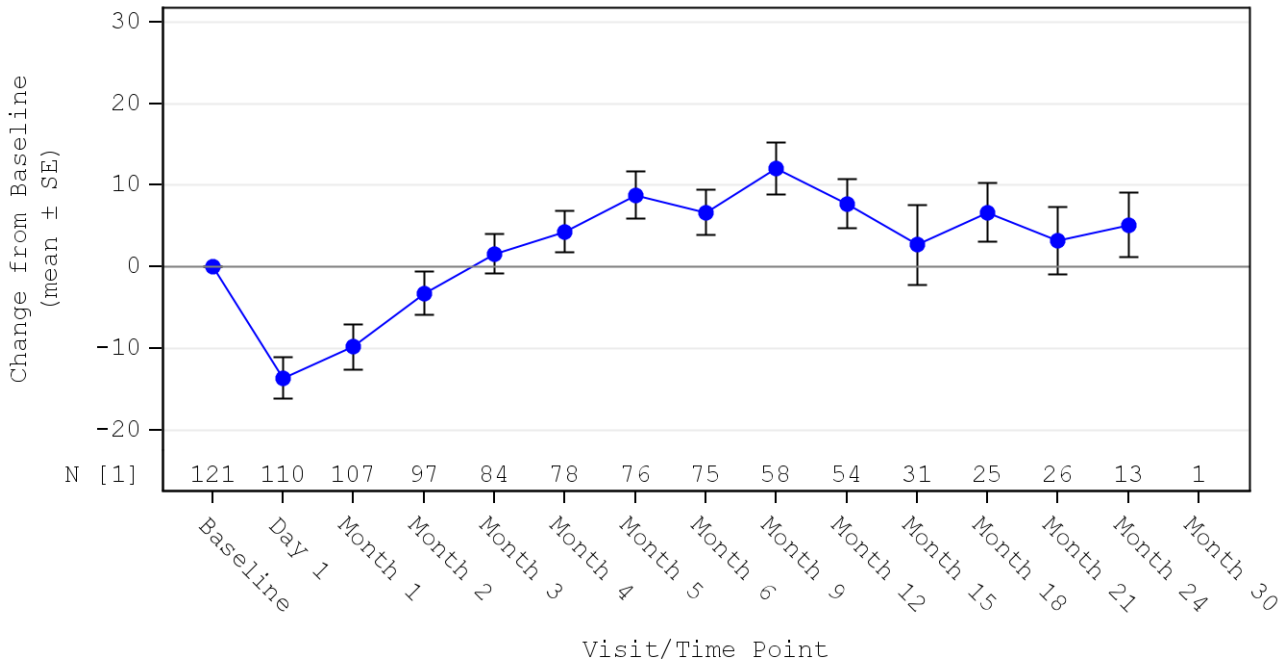
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Role Functioning




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
Date/time of run: 30JUL2021 17:03
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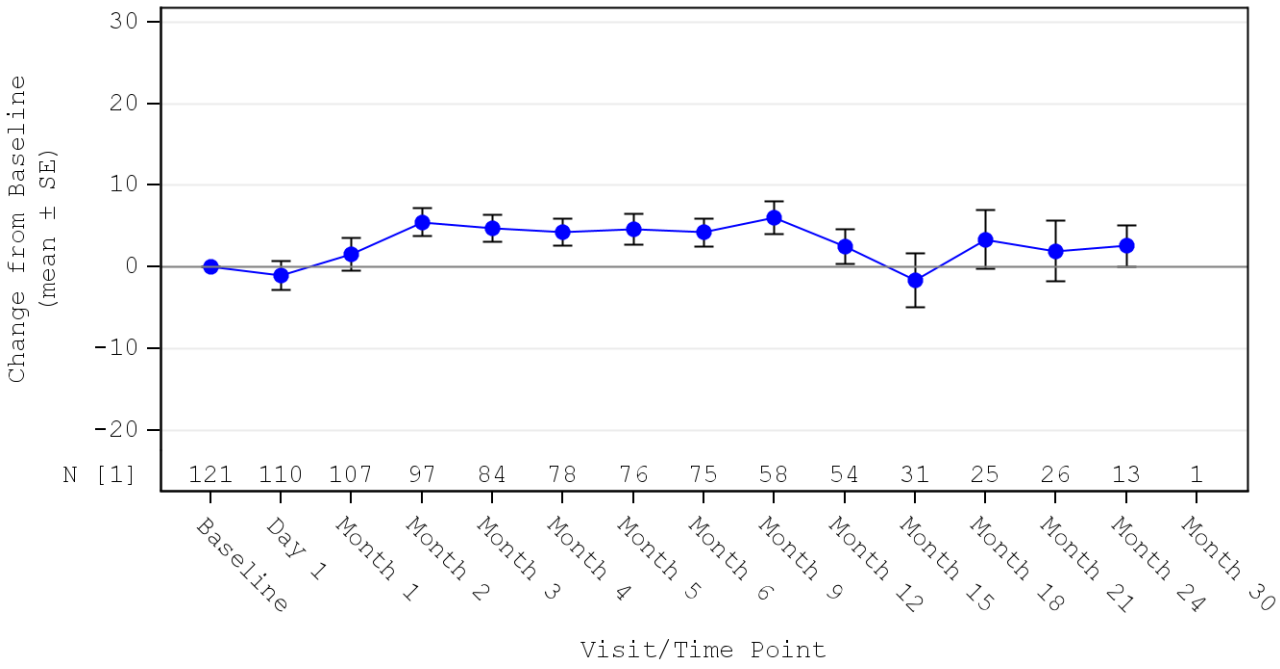
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Cognitive Functioning




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
Date/time of run: 30JUL2021 17:03
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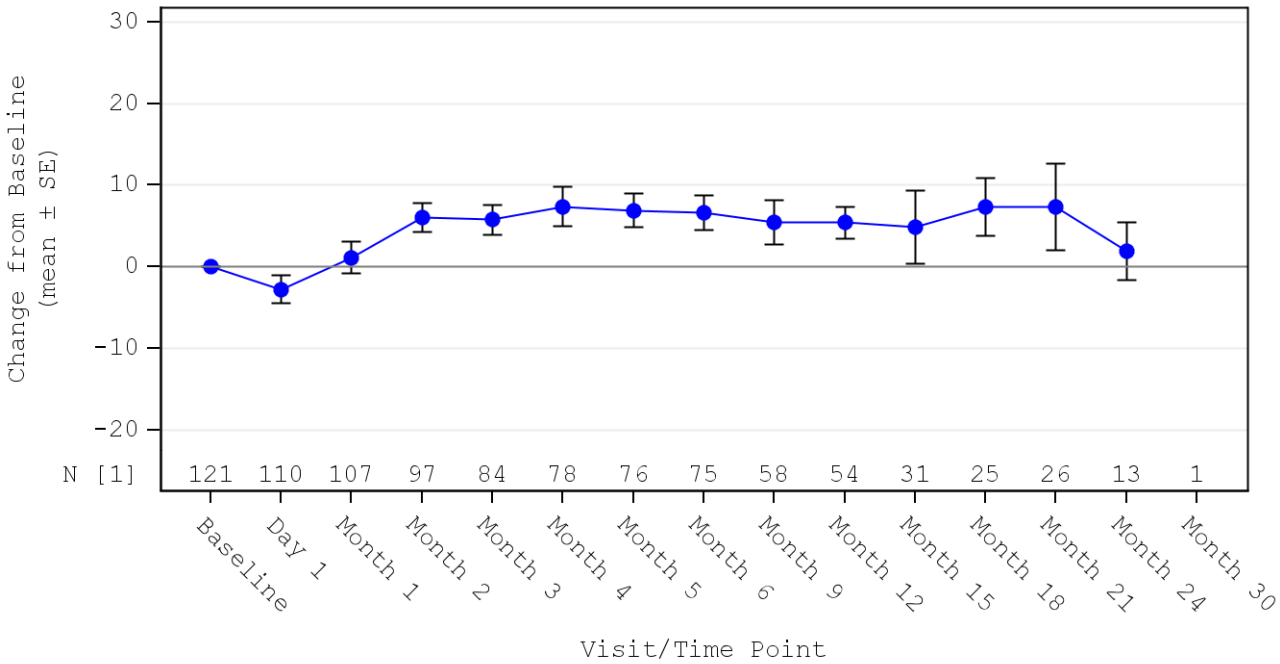
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Emotional Functioning




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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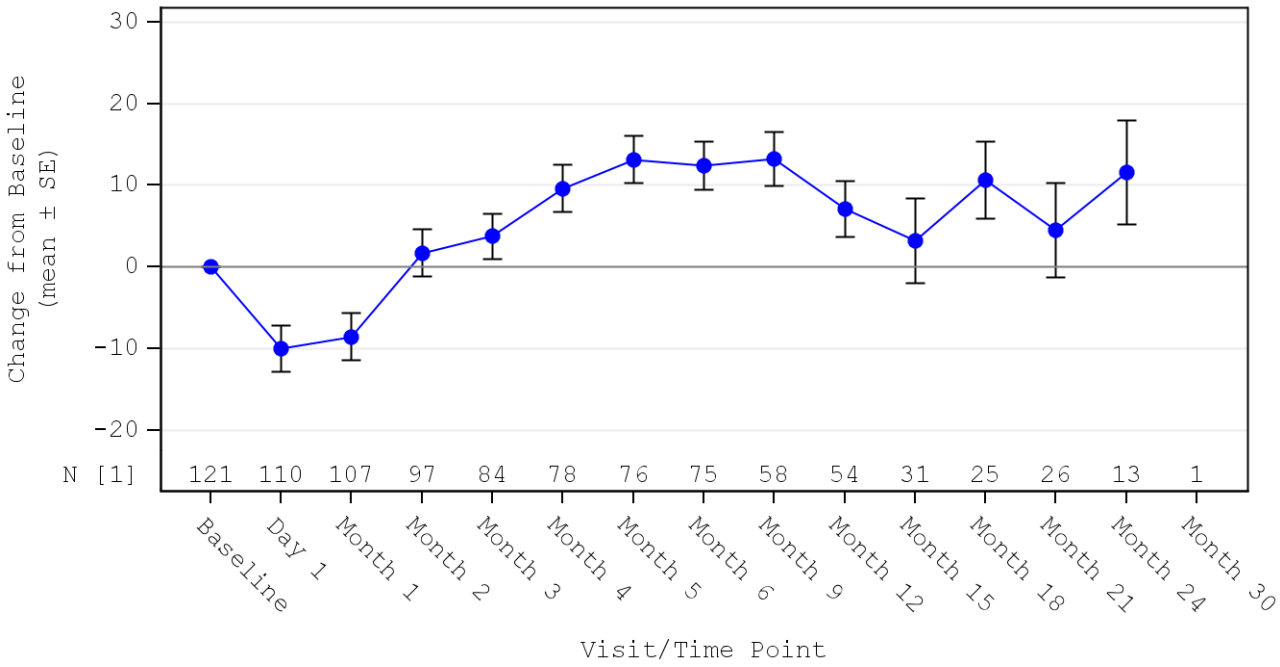
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Social Functioning




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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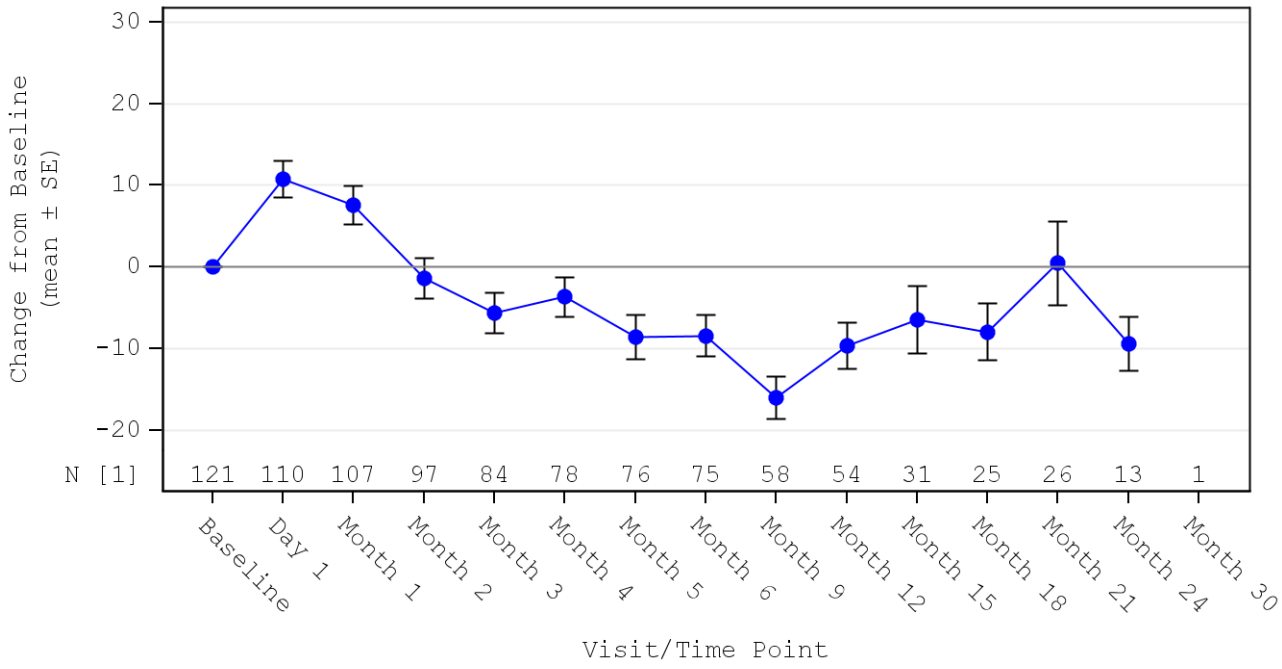
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Fatigue




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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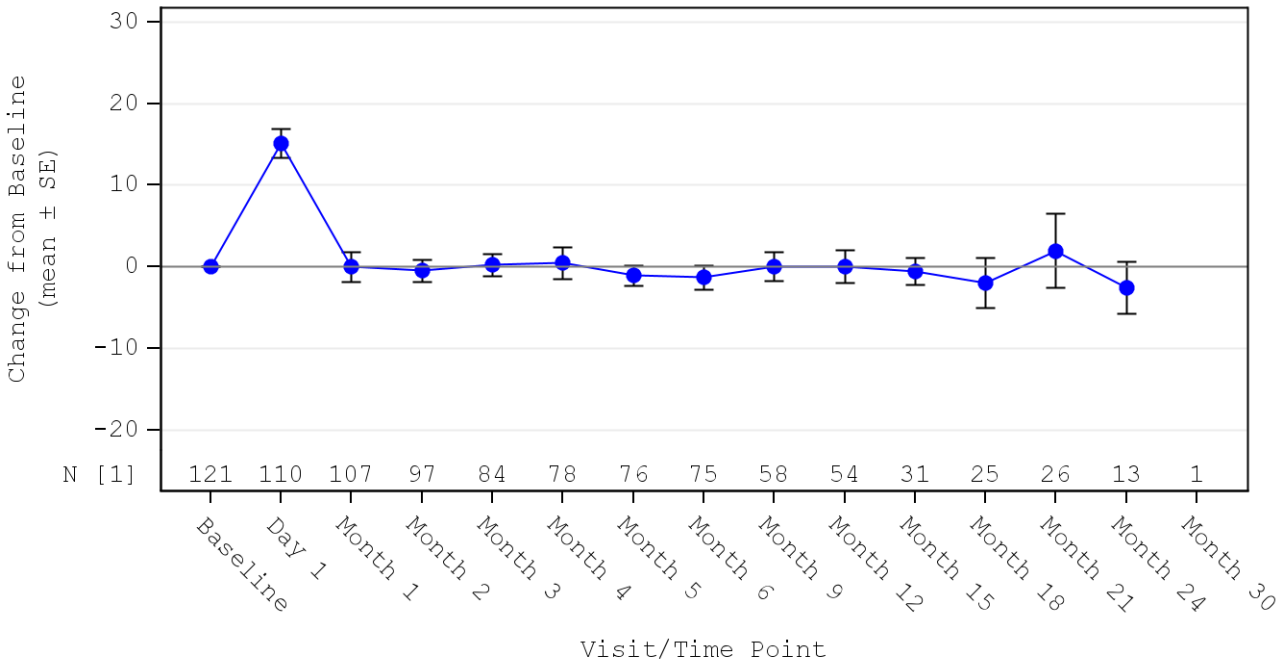
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Nausea/Vomiting




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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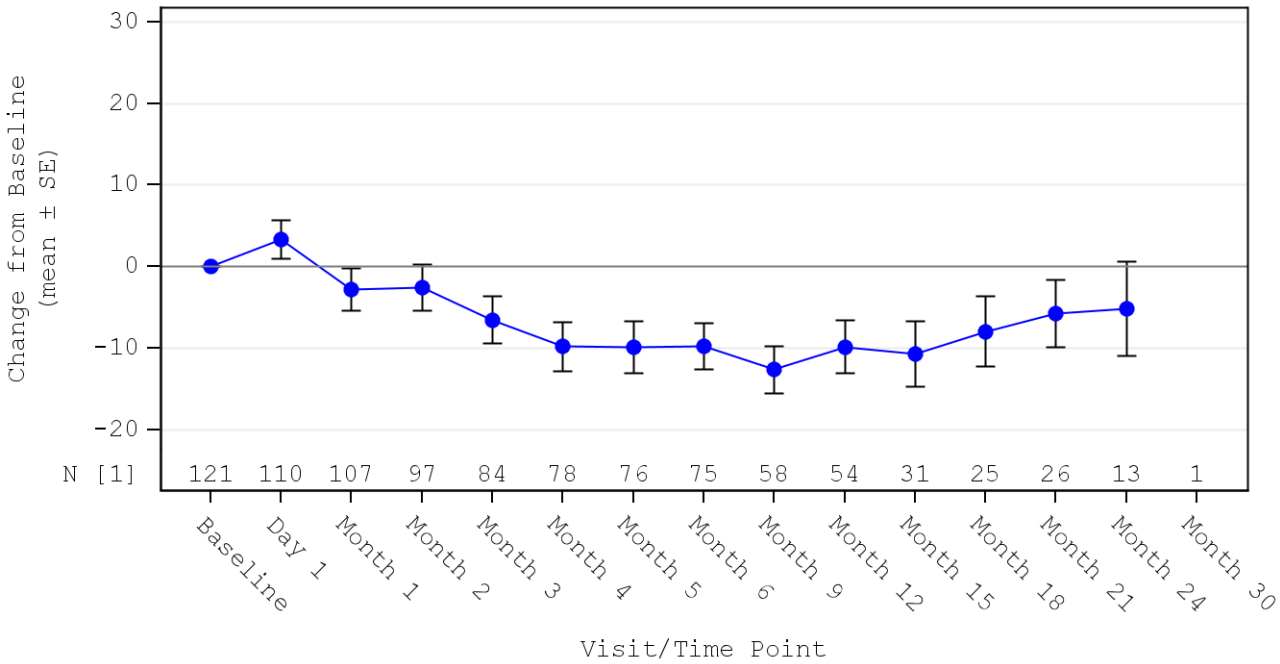
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Pain




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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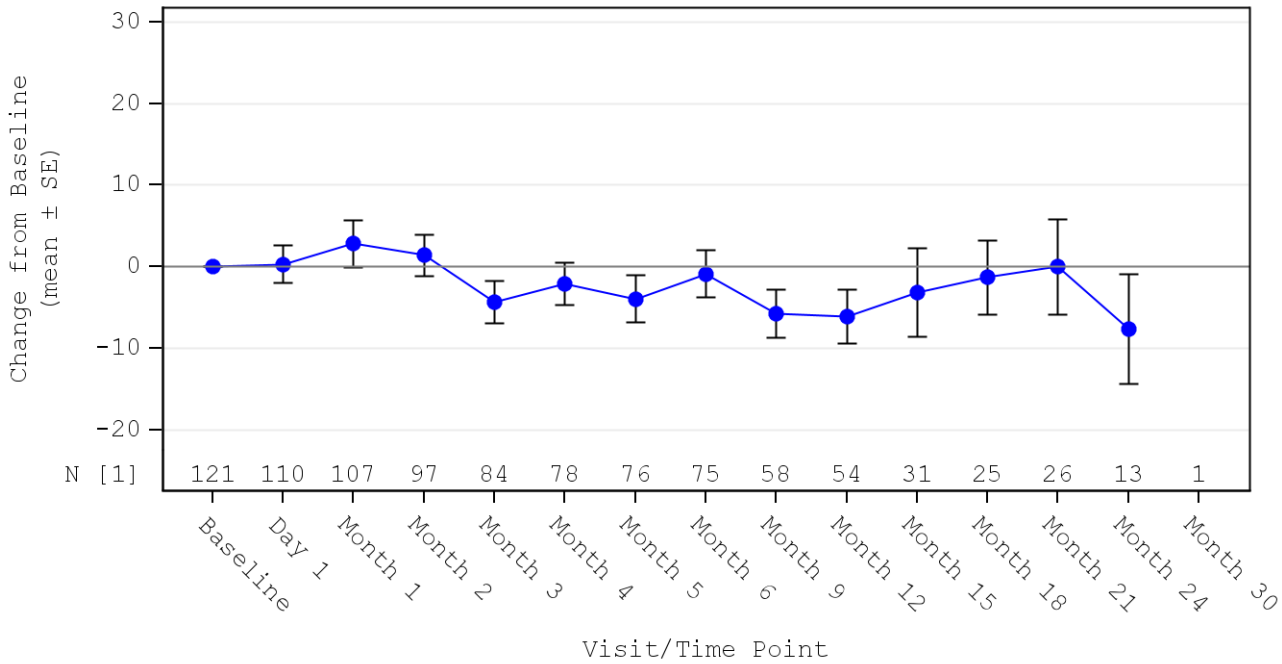
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Dyspnea




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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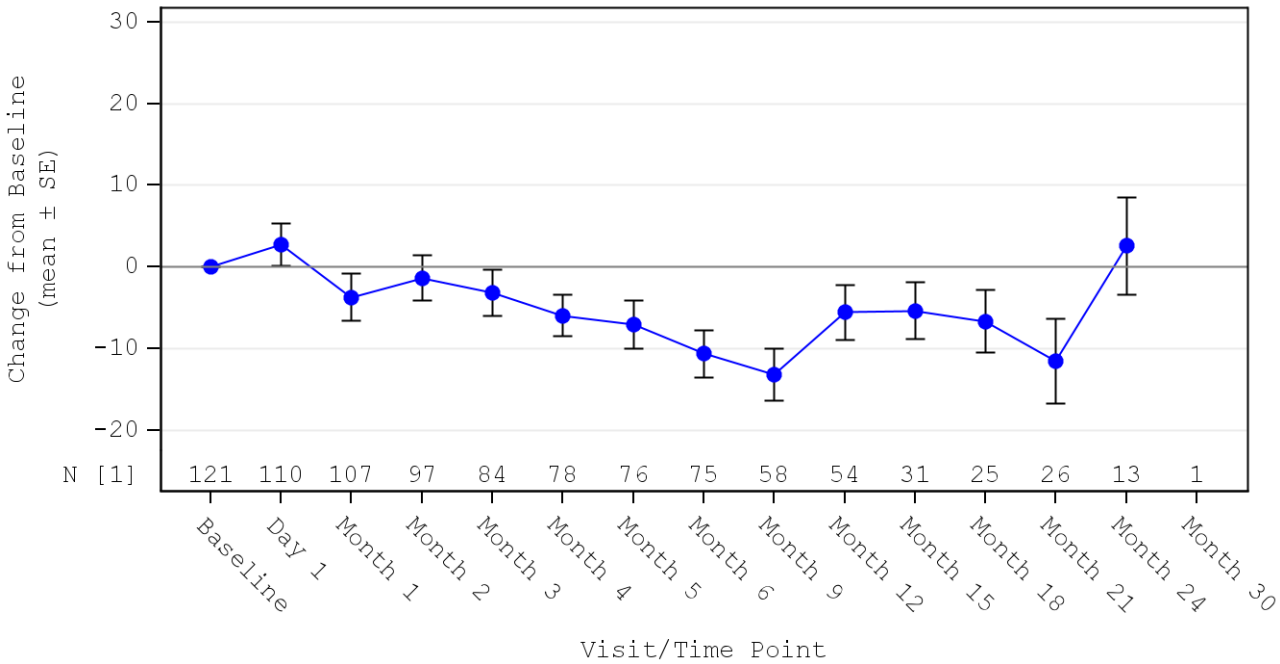
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Insomnia




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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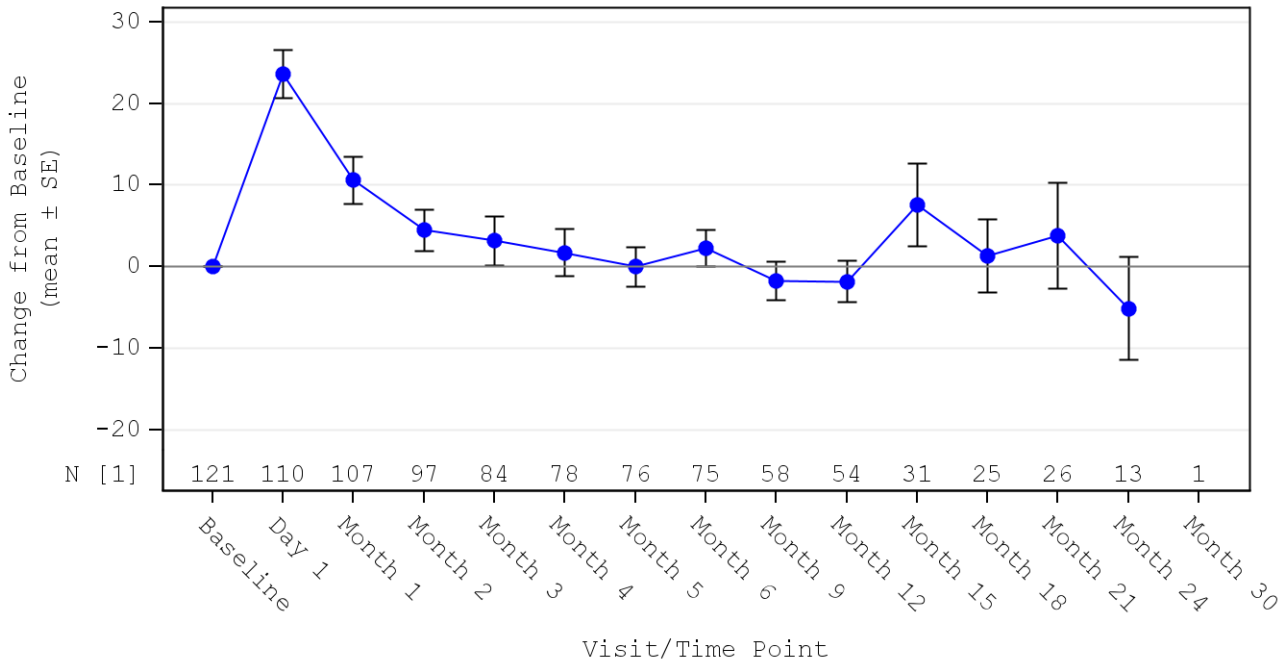
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Appetite




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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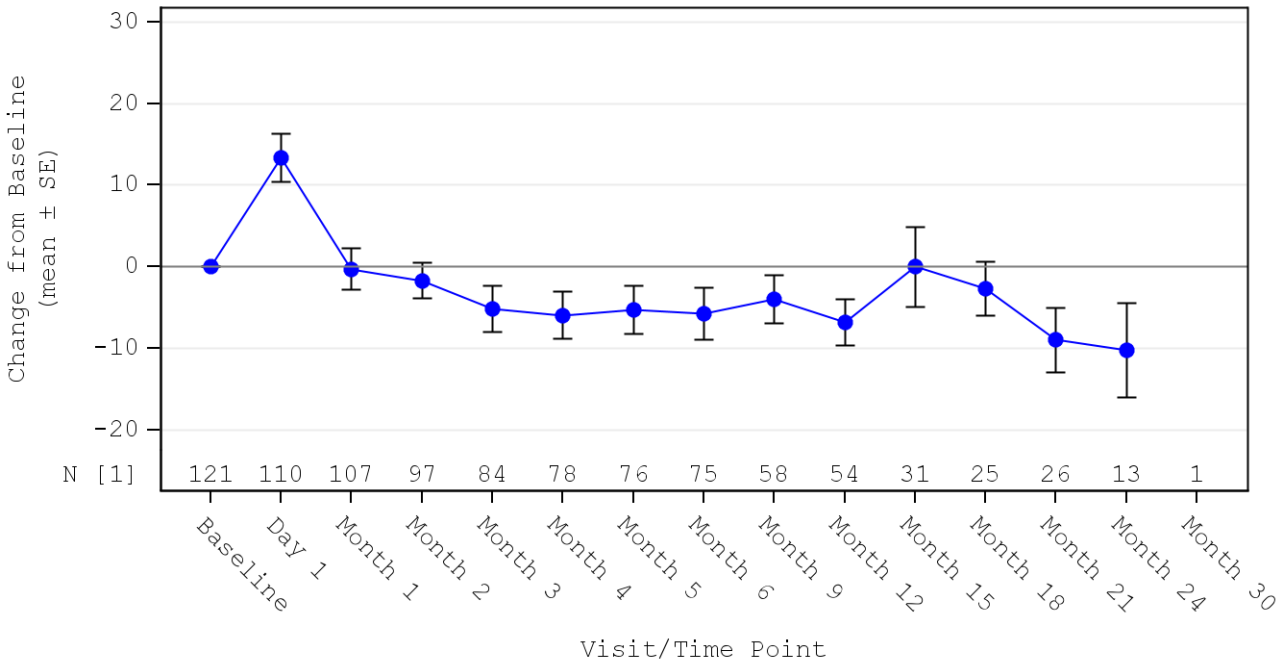
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Constipation




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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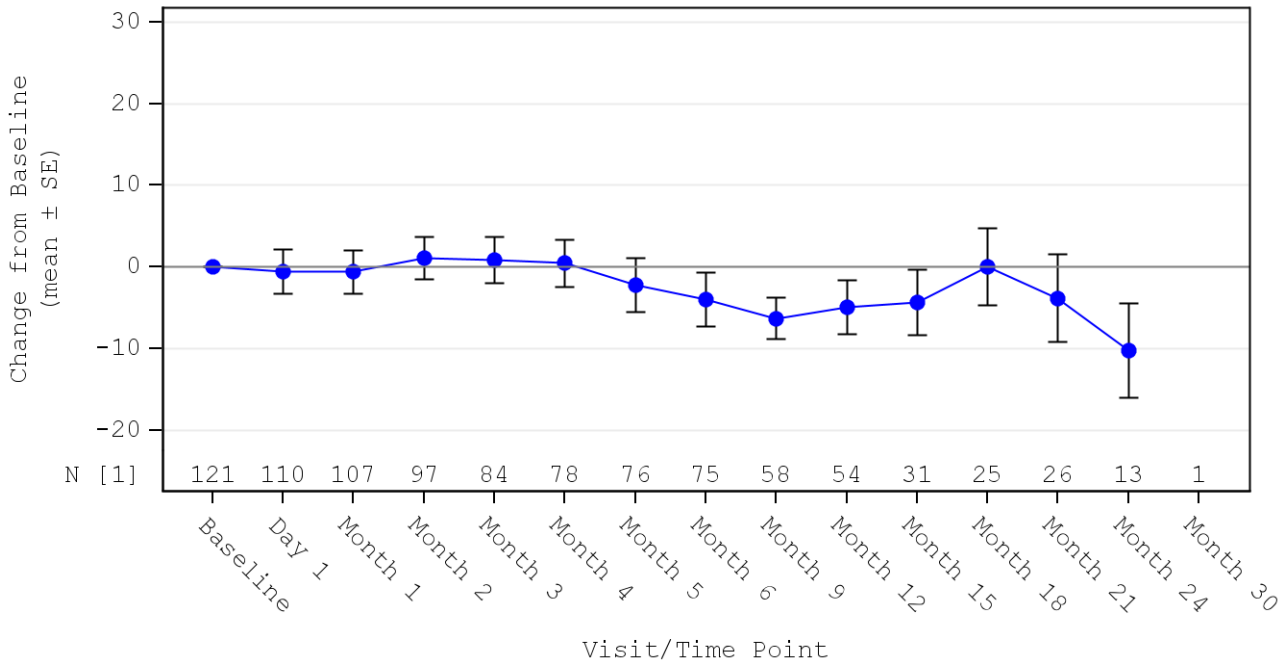
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Diarrhea




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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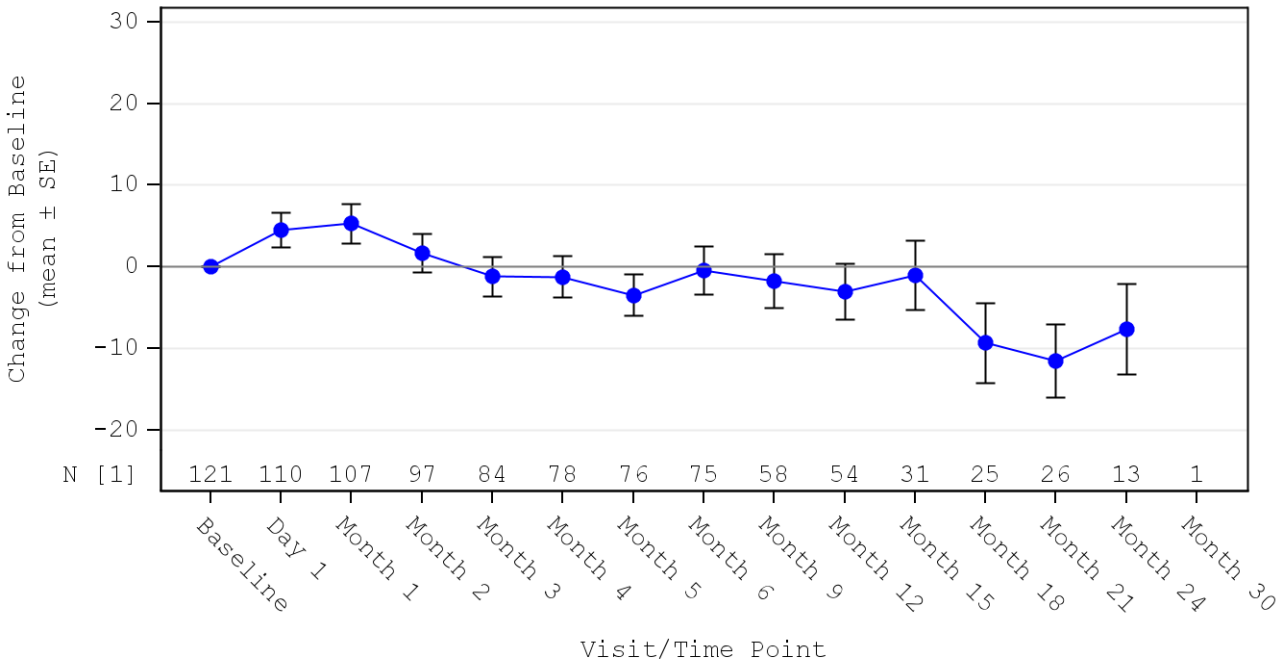
Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Financial




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.

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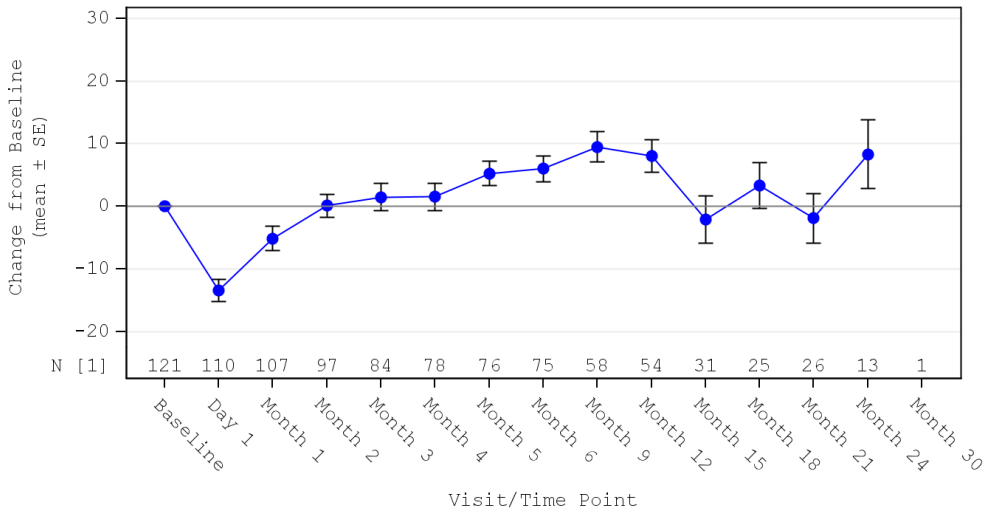
Celgene Corporation
Protocol: BB2121-MM-001

Cut-off date: 21DEC2020

Figure 12.1.1d
Change in Scores from Baseline on the QLQ-C30 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells
PRO Instrument/Scale: QLQ-C30 / Global Qol




[1] Number of subjects with data. Mean and SE only presented for visits with N>=10.
Baseline is defined as the screening visit (or baseline if screening is missing).
Source Tables: Tab_4_2_1d, Tab_4_5_1d, Tab_5_2_1d.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_12_1.SAS
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## 6.2 Gesundheitsbezogene Lebensqualität gemessen anhand der Funktionsskalen des EORTC QLQ-MY20 (Datenschnitt vom 21.12.2020)

- Exploratory Responder Definition MCID = 15
- Responder definition MCID = 33 (body image) and MCID =11 (future perspective)
- Exploratory Responder Definition MCID = 10 (with baseline defined as the screening visit)
- Exploratory Responder Definition MCID = 15 (with baseline defined as the screening visit)
- Responder Definition MCID = 33 (body image) and MCID =11 (with baseline defined as the screening visit)
- Scores by timepoint
- Change of scores from baseline (with baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy)
- Change of scores from baseline (with baseline defined as the screening visit)

Table 6.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 13 ( 11.8) | 15 ( 13.6) |
| | No Change - n(%) | 80 ( 72.7) | 79 ( 71.8) |
| | Deterioration - n(%) | 17 ( 15.5) | 16 ( 14.5) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 18 ( 16.8) | 31 ( 29.0) |
| | No Change - n(%) | 71 ( 66.4) | 69 ( 64.5) |
| | Deterioration - n(%) | 18 ( 16.8) | 7 ( 6.5) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
Date/time of run: 12JUL2021 16:20
Analysis Plan: 12MAY2021 Confidential

Table 6.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 2 | n | 96 | 96 |
| | Improvement - n(%) | 20 ( 20.8) | 38 ( 39.6) |
| | No Change - n(%) | 68 ( 70.8) | 53 ( 55.2) |
| | Deterioration - n(%) | 8 ( 8.3) | 5 ( 5.2) |
| | Missing | 26 | 26 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 20 ( 23.8) | 31 ( 36.9) |
| | No Change - n(%) | 54 ( 64.3) | 46 ( 54.8) |
| | Deterioration - n(%) | 10 ( 11.9) | 7 ( 8.3) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 6.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 20 ( 25.6) | 32 ( 41.0) |
| | No Change - n(%) | 50 ( 64.1) | 40 ( 51.3) |
| | Deterioration - n(%) | 8 ( 10.3) | 6 ( 7.7) |
| | Missing | 44 | 44 |
| Month 5 | n | 75 | 75 |
| | Improvement - n(%) | 24 ( 32.0) | 31 ( 41.3) |
| | No Change - n(%) | 45 ( 60.0) | 41 ( 54.7) |
| | Deterioration - n(%) | 6 ( 8.0) | 3 ( 4.0) |
| | Missing | 47 | 47 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 6.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 6 | n | 74 | 74 |
| | Improvement - n(%) | 23 ( 31.1) | 28 ( 37.8) |
| | No Change - n(%) | 44 ( 59.5) | 42 ( 56.8) |
| | Deterioration - n(%) | 7 ( 9.5) | 4 ( 5.4) |
| | Missing | 48 | 48 |
| Month 9 | n | 57 | 57 |
| | Improvement - n(%) | 17 ( 29.8) | 25 ( 43.9) |
| | No Change - n(%) | 36 ( 63.2) | 30 ( 52.6) |
| | Deterioration - n(%) | 4 ( 7.0) | 2 ( 3.5) |
| | Missing | 65 | 65 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 6.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 13 ( 24.1) | 26 ( 48.1) |
| | No Change - n(%) | 35 ( 64.8) | 26 ( 48.1) |
| | Deterioration - n(%) | 6 ( 11.1) | 2 ( 3.7) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 7 ( 22.6) | 13 ( 41.9) |
| | No Change - n(%) | 20 ( 64.5) | 15 ( 48.4) |
| | Deterioration - n(%) | 4 ( 12.9) | 3 ( 9.7) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 6.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 8 ( 32.0) | 9 ( 36.0) |
| | No Change - n(%) | 14 ( 56.0) | 16 ( 64.0) |
| | Deterioration - n(%) | 3 ( 12.0) | 0 |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 6 ( 23.1) | 6 ( 23.1) |
| | No Change - n(%) | 17 ( 65.4) | 19 ( 73.1) |
| | Deterioration - n(%) | 3 ( 11.5) | 1 ( 3.8) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.

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Table 6.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 4 ( 30.8) | 5 ( 38.5) |
| | No Change - n(%) | 9 ( 69.2) | 7 ( 53.8) |
| | Deterioration - n(%) | 0 | 1 ( 7.7) |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.

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Table 6.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 8 ( 27.6) | 8 ( 27.6) |
| | No Change - n(%) | 20 ( 69.0) | 17 ( 58.6) |
| | Deterioration - n(%) | 1 ( 3.4) | 4 ( 13.8) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 0 |
| | No Change - n(%) | 0 | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.3d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 2 ( 22.2) | 0 |
| | No Change - n(%) | 6 ( 66.7) | 8 ( 88.9) |
| | Deterioration - n(%) | 1 ( 11.1) | 1 ( 11.1) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.

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Table 6.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 13 ( 11.8) | 32 ( 29.1) |
| | No Change - n(%) | 80 ( 72.7) | 39 ( 35.5) |
| | Deterioration - n(%) | 17 ( 15.5) | 39 ( 35.5) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 18 ( 16.8) | 53 ( 49.5) |
| | No Change - n(%) | 71 ( 66.4) | 37 ( 34.6) |
| | Deterioration - n(%) | 18 ( 16.8) | 17 ( 15.9) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 2 | n | 96 | 96 |
| | Improvement - n(%) | 20 ( 20.8) | 54 ( 56.3) |
| | No Change - n(%) | 68 ( 70.8) | 28 ( 29.2) |
| | Deterioration - n(%) | 8 ( 8.3) | 14 ( 14.6) |
| | Missing | 26 | 26 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 20 ( 23.8) | 46 ( 54.8) |
| | No Change - n(%) | 54 ( 64.3) | 21 ( 25.0) |
| | Deterioration - n(%) | 10 ( 11.9) | 17 ( 20.2) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.

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Table 6.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 20 ( 25.6) | 47 ( 60.3) |
| | No Change - n(%) | 50 ( 64.1) | 19 ( 24.4) |
| | Deterioration - n(%) | 8 ( 10.3) | 12 ( 15.4) |
| | Missing | 44 | 44 |
| Month 5 | n | 75 | 75 |
| | Improvement - n(%) | 24 ( 32.0) | 49 ( 65.3) |
| | No Change - n(%) | 45 ( 60.0) | 20 ( 26.7) |
| | Deterioration - n(%) | 6 ( 8.0) | 6 ( 8.0) |
| | Missing | 47 | 47 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.

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Table 6.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 6 | n | 74 | 74 |
| | Improvement - n(%) | 23 ( 31.1) | 46 ( 62.2) |
| | No Change - n(%) | 44 ( 59.5) | 18 ( 24.3) |
| | Deterioration - n(%) | 7 ( 9.5) | 10 ( 13.5) |
| | Missing | 48 | 48 |
| Month 9 | n | 57 | 57 |
| | Improvement - n(%) | 17 ( 29.8) | 35 ( 61.4) |
| | No Change - n(%) | 36 ( 63.2) | 14 ( 24.6) |
| | Deterioration - n(%) | 4 ( 7.0) | 8 ( 14.0) |
| | Missing | 65 | 65 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.

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Table 6.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 13 ( 24.1) | 37 ( 68.5) |
| | No Change - n(%) | 35 ( 64.8) | 14 ( 25.9) |
| | Deterioration - n(%) | 6 ( 11.1) | 3 ( 5.6) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 7 ( 22.6) | 17 ( 54.8) |
| | No Change - n(%) | 20 ( 64.5) | 9 ( 29.0) |
| | Deterioration - n(%) | 4 ( 12.9) | 5 ( 16.1) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 8 ( 32.0) | 15 ( 60.0) |
| | No Change - n(%) | 14 ( 56.0) | 6 ( 24.0) |
| | Deterioration - n(%) | 3 ( 12.0) | 4 ( 16.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 6 ( 23.1) | 13 ( 50.0) |
| | No Change - n(%) | 17 ( 65.4) | 10 ( 38.5) |
| | Deterioration - n(%) | 3 ( 11.5) | 3 ( 11.5) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 4 ( 30.8) | 9 ( 69.2) |
| | No Change - n(%) | 9 ( 69.2) | 3 ( 23.1) |
| | Deterioration - n(%) | 0 | 1 ( 7.7) |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 8 ( 27.6) | 14 ( 48.3) |
| | No Change - n(%) | 20 ( 69.0) | 8 ( 27.6) |
| | Deterioration - n(%) | 1 ( 3.4) | 7 ( 24.1) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 0 |
| | No Change - n(%) | 0 | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 2 ( 22.2) | 3 ( 33.3) |
| | No Change - n(%) | 6 ( 66.7) | 3 ( 33.3) |
| | Deterioration - n(%) | 1 ( 11.1) | 3 ( 33.3) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the EORTC QLQ-MY20 population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.

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Celgene Corporation
Protocol: BB2121-MM-001 Cut-off date: 21DEC2020

Table 6.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 13 ( 11.8) | 37 ( 33.6) |
| | No Change - n(%) | 70 ( 63.6) | 35 ( 31.8) |
| | Deterioration - n(%) | 27 ( 24.5) | 38 ( 34.5) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 13 ( 12.1) | 46 ( 43.0) |
| | No Change - n(%) | 66 ( 61.7) | 37 ( 34.6) |
| | Deterioration - n(%) | 28 ( 26.2) | 24 ( 22.4) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Celgene Corporation
Protocol: BB2121-MM-001 Cut-off date: 21DEC2020

Table 6.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 2 | n | 96 | 96 |
| | Improvement - n(%) | 17 ( 17.7) | 57 ( 59.4) |
| | No Change - n(%) | 62 ( 64.6) | 21 ( 21.9) |
| | Deterioration - n(%) | 17 ( 17.7) | 18 ( 18.8) |
| | Missing | 26 | 26 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 16 ( 19.0) | 47 ( 56.0) |
| | No Change - n(%) | 56 ( 66.7) | 23 ( 27.4) |
| | Deterioration - n(%) | 12 ( 14.3) | 14 ( 16.7) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 16 ( 20.5) | 44 ( 56.4) |
| | No Change - n(%) | 51 ( 65.4) | 21 ( 26.9) |
| | Deterioration - n(%) | 11 ( 14.1) | 13 ( 16.7) |
| | Missing | 44 | 44 |
| Month 5 | n | 75 | 75 |
| | Improvement - n(%) | 13 ( 17.3) | 47 ( 62.7) |
| | No Change - n(%) | 55 ( 73.3) | 23 ( 30.7) |
| | Deterioration - n(%) | 7 ( 9.3) | 5 ( 6.7) |
| | Missing | 47 | 47 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 6 | n | 74 | 74 |
| | Improvement - n(%) | 13 ( 17.6) | 45 ( 60.8) |
| | No Change - n(%) | 52 ( 70.3) | 18 ( 24.3) |
| | Deterioration - n(%) | 9 ( 12.2) | 11 ( 14.9) |
| | Missing | 48 | 48 |
| Month 9 | n | 57 | 57 |
| | Improvement - n(%) | 10 ( 17.5) | 33 ( 57.9) |
| | No Change - n(%) | 42 ( 73.7) | 16 ( 28.1) |
| | Deterioration - n(%) | 5 ( 8.8) | 8 ( 14.0) |
| | Missing | 65 | 65 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 8 ( 14.8) | 40 ( 74.1) |
| | No Change - n(%) | 39 ( 72.2) | 8 ( 14.8) |
| | Deterioration - n(%) | 7 ( 13.0) | 6 ( 11.1) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 7 ( 22.6) | 21 ( 67.7) |
| | No Change - n(%) | 21 ( 67.7) | 5 ( 16.1) |
| | Deterioration - n(%) | 3 ( 9.7) | 5 ( 16.1) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 6 ( 24.0) | 14 ( 56.0) |
| | No Change - n(%) | 16 ( 64.0) | 9 ( 36.0) |
| | Deterioration - n(%) | 3 ( 12.0) | 2 ( 8.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 7 ( 26.9) | 16 ( 61.5) |
| | No Change - n(%) | 17 ( 65.4) | 8 ( 30.8) |
| | Deterioration - n(%) | 2 ( 7.7) | 2 ( 7.7) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 3 ( 23.1) | 11 ( 84.6) |
| | No Change - n(%) | 10 ( 76.9) | 1 ( 7.7) |
| | Deterioration - n(%) | 0 | 1 ( 7.7) |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 6 ( 20.7) | 12 ( 41.4) |
| | No Change - n(%) | 21 ( 72.4) | 7 ( 24.1) |
| | Deterioration - n(%) | 2 ( 6.9) | 10 ( 34.5) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.2.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 10) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 0 | 3 ( 33.3) |
| | No Change - n(%) | 8 ( 88.9) | 3 ( 33.3) |
| | Deterioration - n(%) | 1 ( 11.1) | 3 ( 33.3) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+10 for improvement and <=-10 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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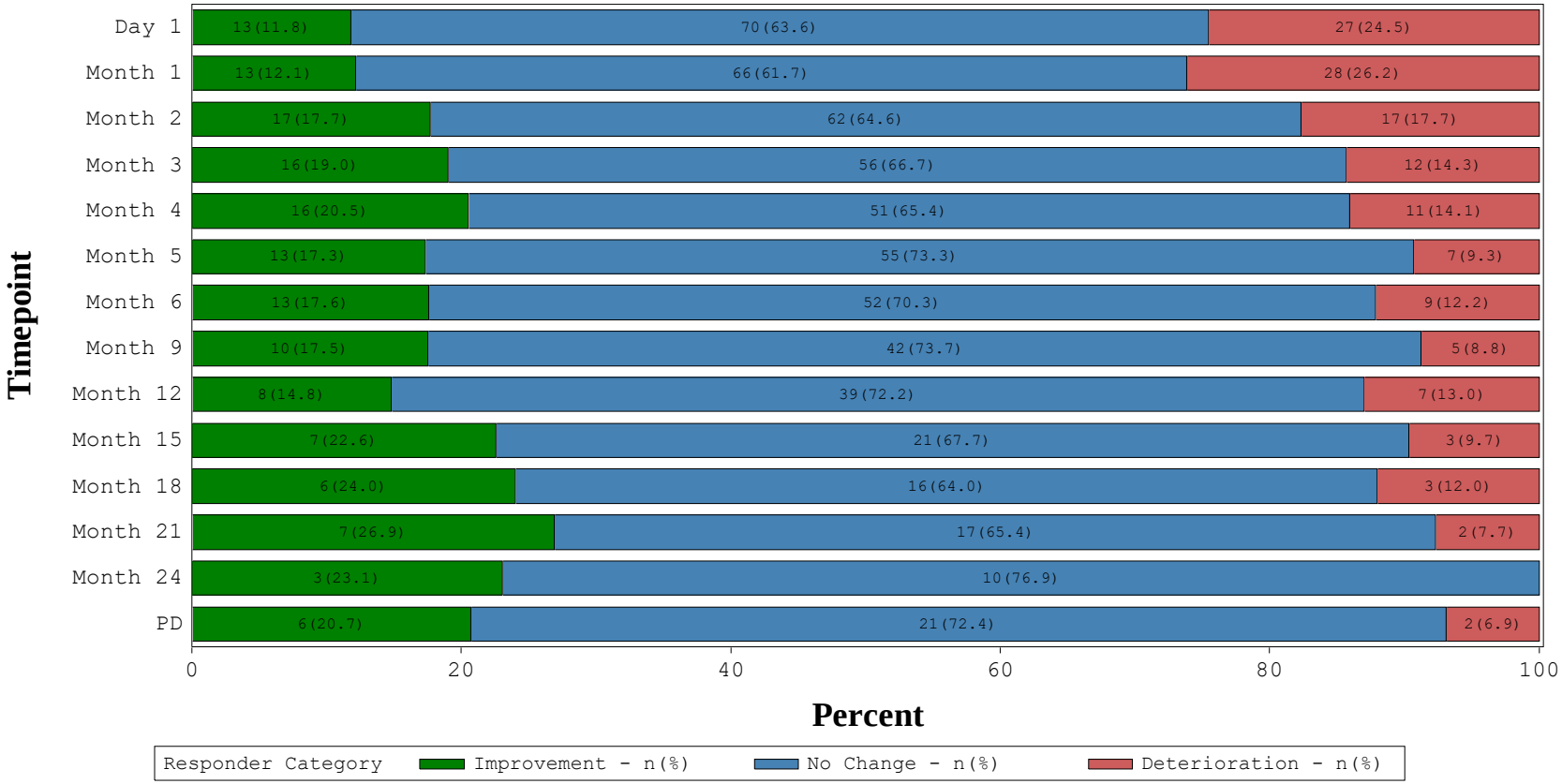
Figure 6.1.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-MY20 Body Image Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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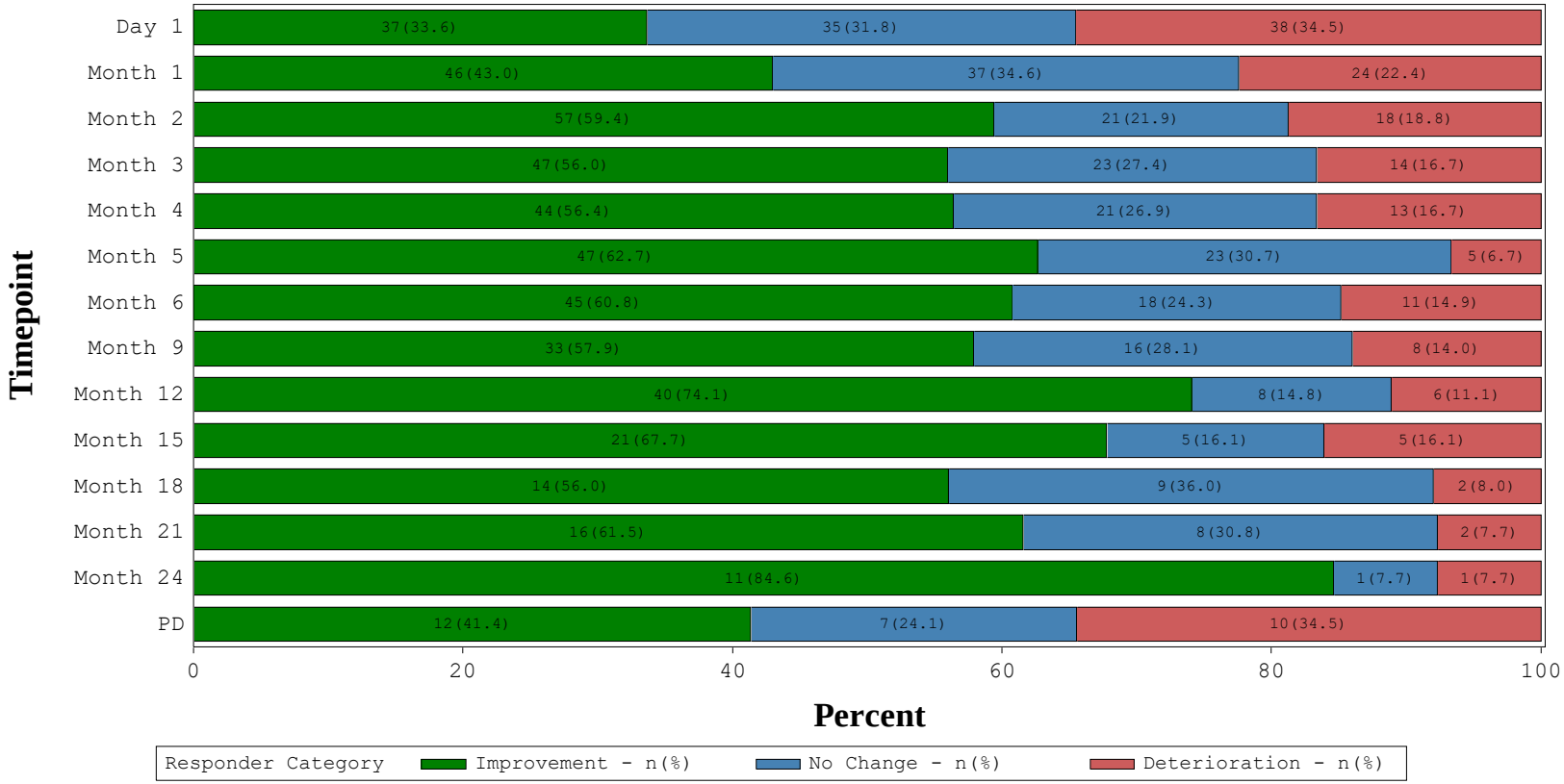
Figure 6.2.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-MY20 Future Perspective Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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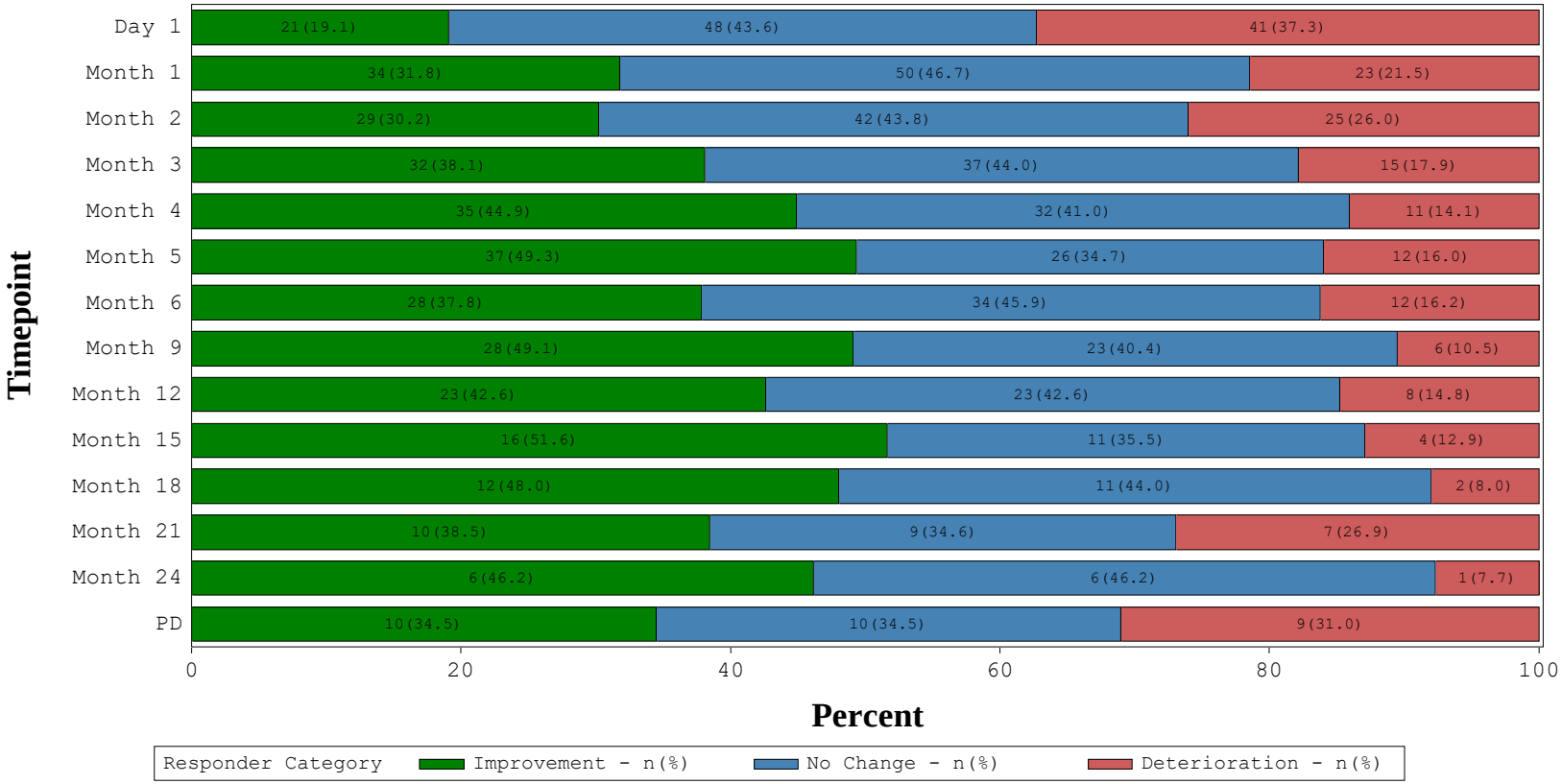
Figure 6.3.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-MY20 Disease Symptoms Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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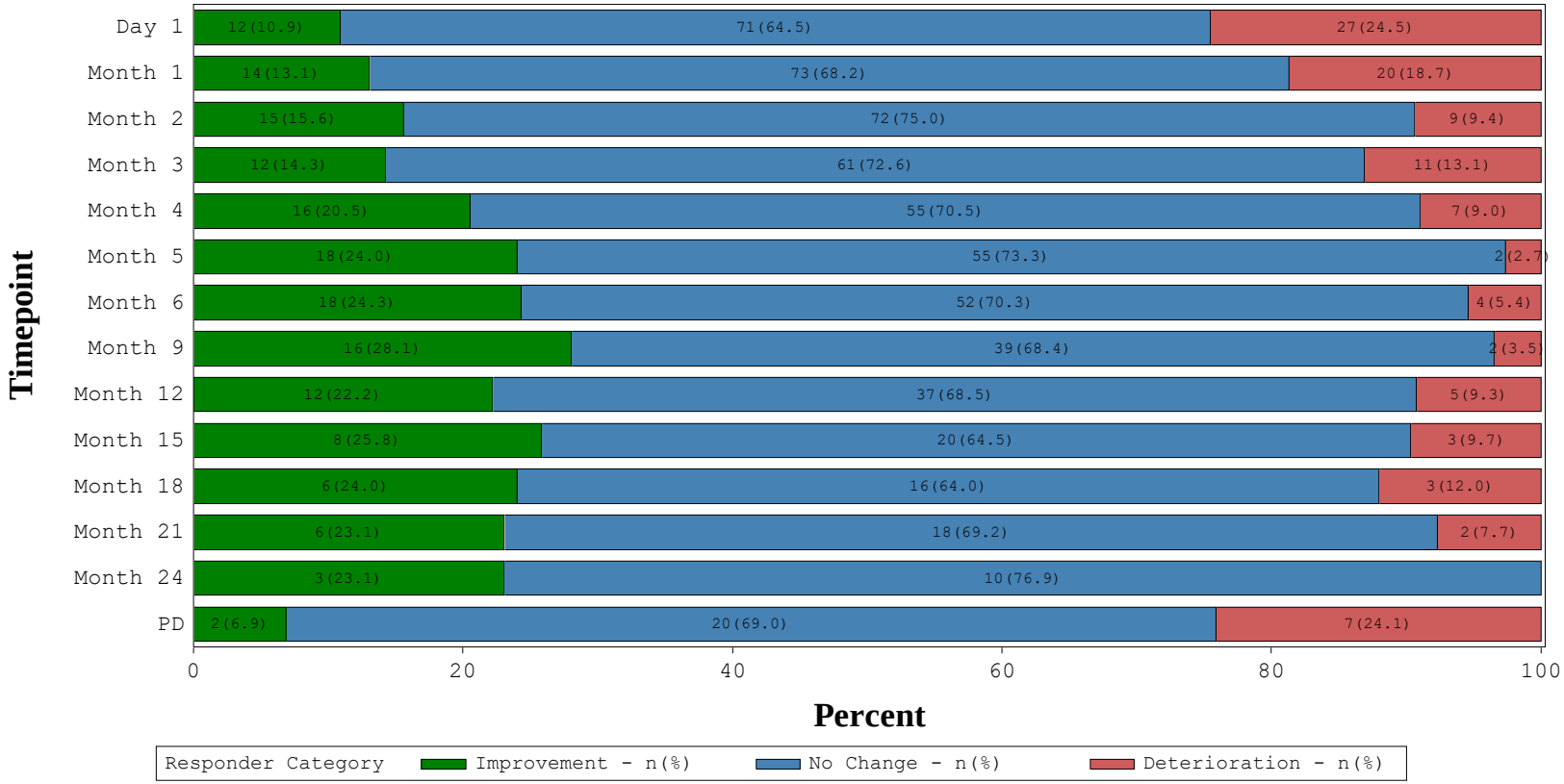
Figure 6.4.1d (Sensitivity analysis)
Bar Graph of Subjects Reaching the RD on the EORTC QLQ-MY20 Side Effects Subscale by Timepoint, Overall and by Subgroup
PRO Analysis Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall




Based on the exploratory responder definition for change in score from baseline: >=+10 for improvement and <=-10 for worsening.
RD=Responder Definition; PD=Progressive Disease. Baseline is defined as the screening visit (or baseline if screening is missing).
Subjects with missing data are not included.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_4_1.SAS
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Table 6.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 13 ( 11.8) | 20 ( 18.2) |
| | No Change - n(%) | 70 ( 63.6) | 68 ( 61.8) |
| | Deterioration - n(%) | 27 ( 24.5) | 22 ( 20.0) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 13 ( 12.1) | 27 ( 25.2) |
| | No Change - n(%) | 66 ( 61.7) | 71 ( 66.4) |
| | Deterioration - n(%) | 28 ( 26.2) | 9 ( 8.4) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 2 | n | 96 | 96 |
| | Improvement - n(%) | 17 ( 17.7) | 34 ( 35.4) |
| | No Change - n(%) | 62 ( 64.6) | 56 ( 58.3) |
| | Deterioration - n(%) | 17 ( 17.7) | 6 ( 6.3) |
| | Missing | 26 | 26 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 16 ( 19.0) | 33 ( 39.3) |
| | No Change - n(%) | 56 ( 66.7) | 45 ( 53.6) |
| | Deterioration - n(%) | 12 ( 14.3) | 6 ( 7.1) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 16 ( 20.5) | 32 ( 41.0) |
| | No Change - n(%) | 51 ( 65.4) | 40 ( 51.3) |
| | Deterioration - n(%) | 11 ( 14.1) | 6 ( 7.7) |
| | Missing | 44 | 44 |
| Month 5 | n | 75 | 75 |
| | Improvement - n(%) | 13 ( 17.3) | 31 ( 41.3) |
| | No Change - n(%) | 55 ( 73.3) | 43 ( 57.3) |
| | Deterioration - n(%) | 7 ( 9.3) | 1 ( 1.3) |
| | Missing | 47 | 47 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 6 | n | 74 | 74 |
| | Improvement - n(%) | 13 ( 17.6) | 33 ( 44.6) |
| | No Change - n(%) | 52 ( 70.3) | 36 ( 48.6) |
| | Deterioration - n(%) | 9 ( 12.2) | 5 ( 6.8) |
| | Missing | 48 | 48 |
| Month 9 | n | 57 | 57 |
| | Improvement - n(%) | 10 ( 17.5) | 22 ( 38.6) |
| | No Change - n(%) | 42 ( 73.7) | 32 ( 56.1) |
| | Deterioration - n(%) | 5 ( 8.8) | 3 ( 5.3) |
| | Missing | 65 | 65 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 8 ( 14.8) | 27 ( 50.0) |
| | No Change - n(%) | 39 ( 72.2) | 25 ( 46.3) |
| | Deterioration - n(%) | 7 ( 13.0) | 2 ( 3.7) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 7 ( 22.6) | 15 ( 48.4) |
| | No Change - n(%) | 21 ( 67.7) | 12 ( 38.7) |
| | Deterioration - n(%) | 3 ( 9.7) | 4 ( 12.9) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 6 ( 24.0) | 10 ( 40.0) |
| | No Change - n(%) | 16 ( 64.0) | 14 ( 56.0) |
| | Deterioration - n(%) | 3 ( 12.0) | 1 ( 4.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 7 ( 26.9) | 11 ( 42.3) |
| | No Change - n(%) | 17 ( 65.4) | 14 ( 53.8) |
| | Deterioration - n(%) | 2 ( 7.7) | 1 ( 3.8) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 3 ( 23.1) | 8 ( 61.5) |
| | No Change - n(%) | 10 ( 76.9) | 4 ( 30.8) |
| | Deterioration - n(%) | 0 | 1 ( 7.7) |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 6 ( 20.7) | 7 ( 24.1) |
| | No Change - n(%) | 21 ( 72.4) | 17 ( 58.6) |
| | Deterioration - n(%) | 2 ( 6.9) | 5 ( 17.2) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.3.3.1d
Proportion of Subjects Reaching the Exploratory Responder Definition (MCID = 15) for the EORTC QLQ-MY20 Subscales by Timepoint
(Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 0 | 2 ( 22.2) |
| | No Change - n(%) | 8 ( 88.9) | 6 ( 66.7) |
| | Deterioration - n(%) | 1 ( 11.1) | 1 ( 11.1) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the exploratory responder definition (RD) for change in score from baseline for each subscale: >=+15 for improvement and <=-15 for worsening.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Responder Category [a] | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Day 1 | n | 110 | 110 |
| | Improvement - n(%) | 13 ( 11.8) | 37 ( 33.6) |
| | No Change - n(%) | 70 ( 63.6) | 35 ( 31.8) |
| | Deterioration - n(%) | 27 ( 24.5) | 38 ( 34.5) |
| | Missing | 12 | 12 |
| Month 1 | n | 107 | 107 |
| | Improvement - n(%) | 13 ( 12.1) | 46 ( 43.0) |
| | No Change - n(%) | 66 ( 61.7) | 37 ( 34.6) |
| | Deterioration - n(%) | 28 ( 26.2) | 24 ( 22.4) |
| | Missing | 15 | 15 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 2 | n | 96 | 96 |
| | Improvement - n(%) | 17 ( 17.7) | 57 ( 59.4) |
| | No Change - n(%) | 62 ( 64.6) | 21 ( 21.9) |
| | Deterioration - n(%) | 17 ( 17.7) | 18 ( 18.8) |
| | Missing | 26 | 26 |
| Month 3 | n | 84 | 84 |
| | Improvement - n(%) | 16 ( 19.0) | 47 ( 56.0) |
| | No Change - n(%) | 56 ( 66.7) | 23 ( 27.4) |
| | Deterioration - n(%) | 12 ( 14.3) | 14 ( 16.7) |
| | Missing | 38 | 38 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 4 | n | 78 | 78 |
| | Improvement - n(%) | 16 ( 20.5) | 44 ( 56.4) |
| | No Change - n(%) | 51 ( 65.4) | 21 ( 26.9) |
| | Deterioration - n(%) | 11 ( 14.1) | 13 ( 16.7) |
| | Missing | 44 | 44 |
| Month 5 | n | 75 | 75 |
| | Improvement - n(%) | 13 ( 17.3) | 47 ( 62.7) |
| | No Change - n(%) | 55 ( 73.3) | 23 ( 30.7) |
| | Deterioration - n(%) | 7 ( 9.3) | 5 ( 6.7) |
| | Missing | 47 | 47 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 6 | n | 74 | 74 |
| | Improvement - n(%) | 13 ( 17.6) | 45 ( 60.8) |
| | No Change - n(%) | 52 ( 70.3) | 18 ( 24.3) |
| | Deterioration - n(%) | 9 ( 12.2) | 11 ( 14.9) |
| | Missing | 48 | 48 |
| Month 9 | n | 57 | 57 |
| | Improvement - n(%) | 10 ( 17.5) | 33 ( 57.9) |
| | No Change - n(%) | 42 ( 73.7) | 16 ( 28.1) |
| | Deterioration - n(%) | 5 ( 8.8) | 8 ( 14.0) |
| | Missing | 65 | 65 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_3_1.SAS
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Table 6.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 12 | n | 54 | 54 |
| | Improvement - n(%) | 8 ( 14.8) | 40 ( 74.1) |
| | No Change - n(%) | 39 ( 72.2) | 8 ( 14.8) |
| | Deterioration - n(%) | 7 ( 13.0) | 6 ( 11.1) |
| | Missing | 68 | 68 |
| Month 15 | n | 31 | 31 |
| | Improvement - n(%) | 7 ( 22.6) | 21 ( 67.7) |
| | No Change - n(%) | 21 ( 67.7) | 5 ( 16.1) |
| | Deterioration - n(%) | 3 ( 9.7) | 5 ( 16.1) |
| | Missing | 91 | 91 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 18 | n | 25 | 25 |
| | Improvement - n(%) | 6 ( 24.0) | 14 ( 56.0) |
| | No Change - n(%) | 16 ( 64.0) | 9 ( 36.0) |
| | Deterioration - n(%) | 3 ( 12.0) | 2 ( 8.0) |
| | Missing | 97 | 97 |
| Month 21 | n | 26 | 26 |
| | Improvement - n(%) | 7 ( 26.9) | 16 ( 61.5) |
| | No Change - n(%) | 17 ( 65.4) | 8 ( 30.8) |
| | Deterioration - n(%) | 2 ( 7.7) | 2 ( 7.7) |
| | Missing | 96 | 96 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| Month 24 | n | 13 | 13 |
| | Improvement - n(%) | 3 ( 23.1) | 11 ( 84.6) |
| | No Change - n(%) | 10 ( 76.9) | 1 ( 7.7) |
| | Deterioration - n(%) | 0 | 1 ( 7.7) |
| | Missing | 109 | 109 |
| Month 30 | n | 1 | 1 |
| | Improvement - n(%) | 1 (100.0) | 1 (100.0) |
| | No Change - n(%) | 0 | 0 |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| PD | n | 29 | 29 |
| | Improvement - n(%) | 6 ( 20.7) | 12 ( 41.4) |
| | No Change - n(%) | 21 ( 72.4) | 7 ( 24.1) |
| | Deterioration - n(%) | 2 ( 6.9) | 10 ( 34.5) |
| | Missing | 93 | 93 |
| CR | n | 1 | 1 |
| | Improvement - n(%) | 0 | 0 |
| | No Change - n(%) | 1 (100.0) | 1 (100.0) |
| | Deterioration - n(%) | 0 | 0 |
| | Missing | 121 | 121 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.3.1.1d
Proportion of Subjects Reaching the Responder Definition (RD) for the EORTC QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| Visit/Time Point | Responder Category [a] | Body Image | Future Perspective |
| End of Study | n | 9 | 9 |
| | Improvement - n(%) | 0 | 3 ( 33.3) |
| | No Change - n(%) | 8 ( 88.9) | 3 ( 33.3) |
| | Deterioration - n(%) | 1 ( 11.1) | 3 ( 33.3) |
| | Missing | 113 | 113 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
N: Number of patients in the population.
n: Number of patients assessed at the respective timepoint.
[a] Based on the responder definition (RD) for change in score from baseline for each subscale: >=+33 for improvement and <=-33 for worsening on Body Image; >=+11 for improvement and <=-11 for worsening on Future Perspective.
Baseline is defined as the screening visit (or the baseline evaluation if screening is missing).

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Table 6.1d
Scores on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score (N=122) Body Image | Future Perspective |
|---|---|---|---|
| Screening | n | 117 | 117 |
| | Mean | 78.3 | 60.5 |
| | SD | 30.74 | 24.69 |
| | Median | 100.0 | 66.7 |
| | Q1, Q3 | 66.7,100.0 | 44.4, 77.8 |
| | Min, Max | 0,100 | 0,100 |
| Baseline Evaluations | n | 122 | 122 |
| | Mean | 75.1 | 60.4 |
| | SD | 26.26 | 25.55 |
| | Median | 66.7 | 66.7 |
| | Q1, Q3 | 66.7,100.0 | 44.4, 77.8 |
| | Min, Max | 0,100 | 0,100 |
| Day 1 | n | 110 | 110 |
| | Mean | 73.6 | 60.6 |
| | SD | 30.32 | 24.11 |
| | Median | 66.7 | 66.7 |
| | Q1, Q3 | 66.7,100.0 | 44.4, 66.7 |
| | Min, Max | 0,100 | 0,100 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
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Table 6.1d
Scores on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 1 | n | 107 | 107 |
| | Mean | 75.4 | 68.1 |
| | SD | 27.98 | 23.84 |
| | Median | 66.7 | 66.7 |
| | Q1, Q3 | 66.7,100.0 | 55.6, 88.9 |
| | Min, Max | 0,100 | 0,100 |
| Month 2 | n | 96 | 96 |
| | Mean | 80.6 | 72.6 |
| | SD | 25.90 | 23.25 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 66.7,100.0 | 66.7, 88.9 |
| | Min, Max | 0,100 | 0,100 |
| Month 3 | n | 84 | 84 |
| | Mean | 81.7 | 72.5 |
| | SD | 26.59 | 21.44 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 66.7,100.0 | 61.1, 88.9 |
| | Min, Max | 0,100 | 11,100 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.1d
Scores on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 4 | n | 78 | 78 |
| | Mean | 82.9 | 73.4 |
| | SD | 26.18 | 21.14 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 66.7,100.0 | 66.7, 88.9 |
| | Min, Max | 0,100 | 22,100 |
| Month 5 | n | 75 | 75 |
| | Mean | 85.3 | 77.9 |
| | SD | 22.75 | 19.46 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 66.7,100.0 | 66.7, 88.9 |
| | Min, Max | 0,100 | 0,100 |
| Month 6 | n | 74 | 74 |
| | Mean | 84.2 | 74.8 |
| | SD | 23.55 | 22.17 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 66.7,100.0 | 66.7,100.0 |
| | Min, Max | 0,100 | 0,100 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Scores on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 9 | n | 57 | 57 |
| | Mean | 88.9 | 76.4 |
| | SD | 23.00 | 21.83 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 100.0,100.0 | 66.7,100.0 |
| | Min, Max | 0,100 | 0,100 |
| Month 12 | n | 54 | 54 |
| | Mean | 87.0 | 78.0 |
| | SD | 23.72 | 20.07 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 66.7,100.0 | 66.7,100.0 |
| | Min, Max | 0,100 | 22,100 |
| Month 15 | n | 31 | 31 |
| | Mean | 88.2 | 72.8 |
| | SD | 25.16 | 25.95 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 100.0,100.0 | 66.7,100.0 |
| | Min, Max | 0,100 | 0,100 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.1d
Scores on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 18 | n | 25 | 25 |
| | Mean | 89.3 | 77.3 |
| | SD | 20.91 | 26.54 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 100.0,100.0 | 66.7,100.0 |
| | Min, Max | 33,100 | 0,100 |
| Month 21 | n | 26 | 26 |
| | Mean | 87.2 | 70.5 |
| | SD | 25.08 | 30.62 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 66.7,100.0 | 55.6,100.0 |
| | Min, Max | 0,100 | 0,100 |
| Month 24 | n | 13 | 13 |
| | Mean | 92.3 | 81.2 |
| | SD | 14.62 | 20.98 |
| | Median | 100.0 | 77.8 |
| | Q1, Q3 | 100.0,100.0 | 66.7,100.0 |
| | Min, Max | 67,100 | 33,100 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.1d
Scores on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 30 | n | 1 | 1 |
| | Mean | 100.0 | 66.7 |
| | SD | | |
| | Median | 100.0 | 66.7 |
| | Q1, Q3 | 100.0,100.0 | 66.7, 66.7 |
| | Min, Max | 100,100 | 67, 67 |
| PD | n | 29 | 29 |
| | Mean | 86.2 | 64.8 |
| | SD | 24.43 | 24.50 |
| | Median | 100.0 | 66.7 |
| | Q1, Q3 | 66.7,100.0 | 44.4, 77.8 |
| | Min, Max | 0,100 | 11,100 |
| CR | n | 1 | 1 |
| | Mean | 100.0 | 66.7 |
| | SD | | |
| | Median | 100.0 | 66.7 |
| | Q1, Q3 | 100.0,100.0 | 66.7, 66.7 |
| | Min, Max | 100,100 | 67, 67 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.1d
Scores on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| End of Study | n | 9 | 9 |
| | Mean | 88.9 | 67.9 |
| | SD | 16.67 | 23.86 |
| | Median | 100.0 | 66.7 |
| | Q1, Q3 | 66.7,100.0 | 55.6, 88.9 |
| | Min, Max | 67,100 | 33,100 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Day 1 | n | 110 | 110 |
| | Mean | -2.7 | -0.9 |
| | SD | 21.24 | 18.07 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -11.1, 11.1 |
| | Min, Max | -67, 33 | -44, 56 |
| | p-value for Comparison to Zero [b] | 0.055 | 0.993 |
| Month 1 | n | 107 | 107 |
| | Mean | -0.3 | 7.9 |
| | SD | 21.72 | 17.60 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -67, 67 | -44, 56 |
| | p-value for Comparison to Zero [b] | 0.740 | <0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 6.2d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 2 | n | 96 | 96 |
| | Mean | 3.8 | 12.4 |
| | SD | 20.45 | 20.51 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -67, 67 | -33, 78 |
| | p-value for Comparison to Zero [b] | 0.132 | <0.001 |
| Month 3 | n | 84 | 84 |
| | Mean | 3.2 | 10.6 |
| | SD | 21.72 | 22.42 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -67, 33 | -56, 78 |
| | p-value for Comparison to Zero [b] | 0.780 | <0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 4 | n | 78 | 78 |
| | Mean | 4.7 | 12.0 |
| | SD | 25.04 | 22.13 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 22.2 |
| | Min, Max | -100, 67 | -56, 78 |
| | p-value for Comparison to Zero [b] | 0.349 | <0.001 |
| Month 5 | n | 75 | 75 |
| | Mean | 7.6 | 14.8 |
| | SD | 23.62 | 19.70 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | Min, Max | -100, 67 | -44, 78 |
| | p-value for Comparison to Zero [b] | 0.008 | <0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 6 | n | 74 | 74 |
| | Mean | 7.7 | 12.8 |
| | SD | 21.04 | 21.10 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 22.2 |
| | Min, Max | -33, 67 | -56, 67 |
| | p-value for Comparison to Zero [b] | 0.023 | <0.001 |
| Month 9 | n | 57 | 57 |
| | Mean | 6.4 | 13.8 |
| | SD | 25.54 | 19.16 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 22.2 |
| | Min, Max | -100, 67 | -22, 67 |
| | p-value for Comparison to Zero [b] | 0.031 | <0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 12 | n | 54 | 54 |
| | Mean | 2.5 | 15.4 |
| | SD | 24.10 | 17.32 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | -67, 33 | -33, 67 |
| | p-value for Comparison to Zero [b] | 0.893 | <0.001 |
| Month 15 | n | 31 | 31 |
| | Mean | 2.2 | 9.7 |
| | SD | 22.67 | 18.54 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -67, 33 | -33, 44 |
| | p-value for Comparison to Zero [b] | 0.836 | 0.004 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 18 | n | 25 | 25 |
| | Mean | 8.0 | 16.4 |
| | SD | 24.11 | 22.71 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | Min, Max | -33, 67 | -11, 67 |
| | p-value for Comparison to Zero [b] | 0.442 | <0.001 |
| Month 21 | n | 26 | 26 |
| | Mean | 2.6 | 9.0 |
| | SD | 22.95 | 16.64 |
| | Median | 0.0 | 5.6 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 11.1 |
| | Min, Max | -67, 33 | -22, 56 |
| | p-value for Comparison to Zero [b] | 1.000 | 0.007 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Body Image | Future Perspective |
| Month 24 | n | 13 | 13 |
| | Mean | 12.8 | 12.8 |
| | SD | 21.68 | 24.78 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 22.2 |
| | Min, Max | 0, 67 | -44, 67 |
| | p-value for Comparison to Zero [b] | 0.125 | 0.063 |
| Month 30 | n | 1 | 1 |
| | Mean | 100.0 | 66.7 |
| | SD | | |
| | Median | 100.0 | 66.7 |
| | Q1, Q3 | 100.0,100.0 | 66.7, 66.7 |
| | Min, Max | 100,100 | 67, 67 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Body Image | Future Perspective |
| PD | n | 29 | 29 |
| | Mean | 6.9 | 6.1 |
| | SD | 27.28 | 17.96 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 22.2 |
| | Min, Max | -100, 67 | -22, 33 |
| | p-value for Comparison to Zero [b] | 0.098 | 0.050 |
| CR | n | 1 | 1 |
| | Mean | 33.3 | 0.0 |
| | SD | | |
| | Median | 33.3 | 0.0 |
| | Q1, Q3 | 33.3, 33.3 | 0.0, 0.0 |
| | Min, Max | 33, 33 | 0, 0 |
| | p-value for Comparison to Zero [b] | 1.000 | N/A |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Body Image | Future Perspective |
| End of Study | n | 9 | 9 |
| | Mean | 3.7 | -1.2 |
| | SD | 20.03 | 11.71 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -11.1, 11.1 |
| | Min, Max | -33, 33 | -22, 11 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
[b] p-value based on two-sided Wilcoxon signed rank test.

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Table 6.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Day 1 | n | 110 | 110 |
| | Mean | -4.5 | 0.6 |
| | SD | 28.73 | 22.21 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -11.1, 11.1 |
| | Min, Max | -100,100 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.244 | 0.737 |
| Month 1 | n | 107 | 107 |
| | Mean | -4.0 | 6.5 |
| | SD | 26.19 | 21.04 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | -33.3, 0.0 | 0.0, 22.2 |
| | Min, Max | -67,100 | -44, 78 |
| | p-value for Comparison to Zero [b] | 0.286 | 0.002 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Body Image | Future Perspective |
| Month 2 | n | 96 | 96 |
| | Mean | 2.8 | 11.7 |
| | SD | 26.34 | 22.65 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -33,100 | -56, 89 |
| | p-value for Comparison to Zero [b] | 0.392 | <0.001 |
| Month 3 | n | 84 | 84 |
| | Mean | 1.2 | 11.9 |
| | SD | 26.10 | 23.70 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -67,100 | -56, 67 |
| | p-value for Comparison to Zero [b] | 0.643 | <0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Body Image | Future Perspective |
| Month 4 | n | 78 | 78 |
| | Mean | 3.4 | 12.5 |
| | SD | 26.64 | 22.39 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -67,100 | -44, 67 |
| | p-value for Comparison to Zero [b] | 0.497 | <0.001 |
| Month 5 | n | 75 | 75 |
| | Mean | 4.4 | 15.3 |
| | SD | 22.15 | 19.31 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -33,100 | -33, 67 |
| | p-value for Comparison to Zero [b] | 0.164 | <0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Body Image | Future Perspective |
| Month 6 | n | 74 | 74 |
| | Mean | 3.2 | 13.1 |
| | SD | 24.16 | 22.92 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -67,100 | -67, 67 |
| | p-value for Comparison to Zero [b] | 0.385 | <0.001 |
| Month 9 | n | 57 | 57 |
| | Mean | 4.1 | 12.9 |
| | SD | 19.99 | 20.01 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -33, 67 | -22, 67 |
| | p-value for Comparison to Zero [b] | 0.192 | <0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Body Image | Future Perspective |
| Month 12 | n | 54 | 54 |
| | Mean | 1.2 | 15.8 |
| | SD | 25.05 | 20.54 |
| | Median | 0.0 | 16.7 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -67, 67 | -44, 67 |
| | p-value for Comparison to Zero [b] | 0.763 | <0.001 |
| Month 15 | n | 31 | 31 |
| | Mean | 3.2 | 8.6 |
| | SD | 27.70 | 23.95 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 22.2 |
| | Min, Max | -100, 67 | -56, 33 |
| | p-value for Comparison to Zero [b] | 0.426 | 0.041 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| Visit/Time Point | Parameter | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| | | Body Image | Future Perspective |
| Month 18 | n | 25 | 25 |
| | Mean | 6.7 | 15.1 |
| | SD | 30.43 | 22.43 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | Min, Max | -67, 67 | -33, 56 |
| | p-value for Comparison to Zero [b] | 0.320 | 0.002 |
| Month 21 | n | 26 | 26 |
| | Mean | 6.4 | 13.7 |
| | SD | 31.30 | 20.20 |
| | Median | 0.0 | 11.1 |
| | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | Min, Max | -100, 67 | -44, 44 |
| | p-value for Comparison to Zero [b] | 0.211 | 0.001 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Body Image | Future Perspective |
| Month 24 | n | 13 | 13 |
| | Mean | 10.3 | 15.4 |
| | SD | 21.01 | 20.56 |
| | Median | 0.0 | 22.2 |
| | Q1, Q3 | 0.0, 0.0 | 11.1, 22.2 |
| | Min, Max | 0, 67 | -44, 33 |
| | p-value for Comparison to Zero [b] | 0.250 | 0.032 |
| Month 30 | n | 1 | 1 |
| | Mean | 66.7 | 33.3 |
| | SD | | |
| | Median | 66.7 | 33.3 |
| | Q1, Q3 | 66.7, 66.7 | 33.3, 33.3 |
| | Min, Max | 67, 67 | 33, 33 |
| | p-value for Comparison to Zero [b] | 1.000 | 1.000 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
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Table 6.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Body Image | Future Perspective |
| PD | n | 29 | 29 |
| | Mean | 6.9 | 4.2 |
| | SD | 22.50 | 23.08 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -11.1, 11.1 |
| | Min, Max | -33, 67 | -33, 56 |
| | p-value for Comparison to Zero [b] | 0.164 | 0.365 |
| CR | n | 1 | 1 |
| | Mean | 0.0 | 0.0 |
| | SD | | |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | Min, Max | 0, 0 | 0, 0 |
| | p-value for Comparison to Zero [b] | N/A | N/A |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUL2021 14:20
Analysis Plan: 12MAY2021 Confidential

Table 6.2.1d
Change in Scores from Baseline on the QLQ-MY20 Subscales by Timepoint (Sensitivity Analysis)
PRO Analysis Population excluding subjects receiving 150 x $10^6$ CAR T cells

| | | EORTC QLQ-MY20 Subscale Score - Change in Score from Baseline [a] (N=122) | |
|---|---|---|---|
| Visit/Time Point | Parameter | Body Image | Future Perspective |
| End of Study | n | 9 | 9 |
| | Mean | -3.7 | 6.2 |
| | SD | 11.11 | 26.12 |
| | Median | 0.0 | 0.0 |
| | Q1, Q3 | 0.0, 0.0 | -11.1, 11.1 |
| | Min, Max | -33, 0 | -22, 67 |
| | p-value for Comparison to Zero [b] | 1.000 | 0.813 |

CR = Complete response; EORTC QLQ-MY20 = European Organisation for Research and Treatment of Cancer – Quality of Life Multiple Myeloma Module; PD = Progressive disease; PRO = Patient-reported outcome; N/A = Not available.
[a] Baseline defined as the screening visit (or the baseline evaluation if screening is missing).
[b] p-value based on two-sided Wilcoxon signed rank test.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 30JUL2021 14:20
Analysis Plan: 12MAY2021 Confidential

# 7. Verträglichkeit (Datenschnitt vom 21.12.2020)

## 7.1 UE Gesamtraten

Table 8.2.2d
Adverse Events (AEs) Summary (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) |
| Subjects with at least one AE | 72 ( 52.9) | 111 ( 81.6) | 124 ( 91.2) | 128 ( 94.1) |
| Subjects with at least one AE related to LD-Chemotherapy | 2 ( 1.5) | 93 ( 68.4) | 119 ( 87.5) | 123 ( 90.4) |
| Subjects with at least one AE related to bb2121 | 0 | 6 ( 4.4) | 121 ( 89.0) | 121 ( 89.0) |
| Subjects with at least one SAE | 30 ( 22.1) | 11 ( 8.1) | 86 ( 63.2) | 89 ( 65.4) |
| Subjects with at least one SAE related to LD-Chemotherapy | 0 | 3 ( 2.2) | 21 ( 15.4) | 22 ( 16.2) |
| Subjects with at least one SAE related to bb2121 | 0 | 1 ( 0.7) | 43 ( 31.6) | 43 ( 31.6) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE | 57 ( 41.9) | 104 ( 76.5) | 124 ( 91.2) | 128 ( 94.1) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to LD-Chemotherapy | 2 ( 1.5) | 81 ( 59.6) | 106 ( 77.9) | 120 ( 88.2) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to bb2121 | 0 | 1 ( 0.7) | 120 ( 88.2) | 120 ( 88.2) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE | 48 ( 35.3) | 71 ( 52.2) | 123 ( 90.4) | 127 ( 93.4) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to LD-Chemotherapy | 0 | 65 ( 47.8) | 111 ( 81.6) | 115 ( 84.6) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to bb2121 | 0 | 5 ( 3.7) | 82 ( 60.3) | 82 ( 60.3) |

[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_8_1_2.SAS
Date/time of run: 29JUN2021 09:18
Analysis Plan: 12MAY2021 Confidential

Table 8.1.2d
Adverse Events (AEs) Summary (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) |
| Subjects with at least one AE | 62 ( 50.0) | 107 ( 86.3) | 124 (100.0) | 124 (100.0) |
| Subjects with at least one AE related to LD-Chemotherapy | 2 ( 1.6) | 91 ( 73.4) | 119 ( 96.0) | 121 ( 97.6) |
| Subjects with at least one AE related to bb2121 | 0 | 6 ( 4.8) | 121 ( 97.6) | 121 ( 97.6) |
| Subjects with at least one SAE | 22 ( 17.7) | 8 ( 6.5) | 86 ( 69.4) | 86 ( 69.4) |
| Subjects with at least one SAE related to LD-Chemotherapy | 0 | 2 ( 1.6) | 21 ( 16.9) | 21 ( 16.9) |
| Subjects with at least one SAE related to bb2121 | 0 | 1 ( 0.8) | 43 ( 34.7) | 43 ( 34.7) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE | 50 ( 40.3) | 100 ( 80.6) | 124 (100.0) | 124 (100.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to LD-Chemotherapy | 2 ( 1.6) | 79 ( 63.7) | 106 ( 85.5) | 118 ( 95.2) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to bb2121 | 0 | 1 ( 0.8) | 120 ( 96.8) | 120 ( 96.8) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE | 39 ( 31.5) | 67 ( 54.0) | 123 ( 99.2) | 123 ( 99.2) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to LD-Chemotherapy | 0 | 63 ( 50.8) | 111 ( 89.5) | 113 ( 91.1) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to bb2121 | 0 | 5 ( 4.0) | 82 ( 66.1) | 82 ( 66.1) |

[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_8_1_2.SAS
Date/time of run: 29JUN2021 09:18
Analysis Plan: 12MAY2021 Confidential

## 7.2 UESI



Table 10.5.2d
Adverse Events of Special Interest (AESI)/Selected Adverse Events Summary, Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) | Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI/Selected AEs | 54 ( 39.7) | 82 ( 60.3) | 123 ( 90.4) | 127 ( 93.4) | 132 ( 97.1) |
| Subjects with at least one serious AESI/Selected AEs | 14 ( 10.3) | 6 ( 4.4) | 69 ( 50.7) | 72 ( 52.9) | 80 ( 58.8) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI/Selected AEs | 39 ( 28.7) | 62 ( 45.6) | 122 ( 89.7) | 124 ( 91.2) | 128 ( 94.1) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI/Selected AEs | 39 ( 28.7) | 69 ( 50.7) | 122 ( 89.7) | 127 ( 93.4) | 132 ( 97.1) |

AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms.
[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_5_1.SAS
Date/time of run: 29JUN2021 10:12
Analysis Plan: 12MAY2021 Confidential

Table 10.5.1d
Adverse Events of Special Interest (AESI)/Selected Adverse Events Summary, Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) | Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI/Selected AEs | 47 ( 37.9) | 78 ( 62.9) | 123 ( 99.2) | 123 ( 99.2) | 123 ( 99.2) |
| Subjects with at least one serious AESI/Selected AEs | 10 ( 8.1) | 3 ( 2.4) | 69 ( 55.6) | 69 ( 55.6) | 73 ( 58.9) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI/Selected AEs | 34 ( 27.4) | 60 ( 48.4) | 122 ( 98.4) | 122 ( 98.4) | 122 ( 98.4) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI/Selected AEs | 32 ( 25.8) | 65 ( 52.4) | 122 ( 98.4) | 123 ( 99.2) | 123 ( 99.2) |

AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms.
[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_5_1.SAS
Date/time of run: 29JUN2021 10:12
Analysis Plan: 12MAY2021 Confidential

## 7.3UE nach SOC und PT

### 7.3.1 UE Grad 1 und 2 nach SOC und PT

Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one Grade 1 or 2 AE | 57 ( 41.9) | 104 ( 76.5) | 124 ( 91.2) | 128 ( 94.1) |
| Immune system disorders | 0 | 1 ( 0.7) | 107 ( 78.7) | 107 ( 78.7) |
| Cytokine release syndrome | 0 | 0 | 104 ( 76.5) | 104 ( 76.5) |
| Hypogammaglobulinaemia | 0 | 1 ( 0.7) | 23 ( 16.9) | 24 ( 17.6) |
| Gastrointestinal disorders | 15 ( 11.0) | 69 ( 50.7) | 94 ( 69.1) | 113 ( 83.1) |
| Diarrhoea | 2 ( 1.5) | 11 ( 8.1) | 43 ( 31.6) | 51 ( 37.5) |
| Nausea | 7 ( 5.1) | 45 ( 33.1) | 36 ( 26.5) | 71 ( 52.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Constipation | 2 ( 1.5) | 19 ( 14.0) | 21 ( 15.4) | 36 ( 26.5) |
| Vomiting | 2 ( 1.5) | 9 ( 6.6) | 20 ( 14.7) | 28 ( 20.6) |
| Dry mouth | 0 | 1 ( 0.7) | 9 ( 6.6) | 9 ( 6.6) |
| Dyspepsia | 0 | 2 ( 1.5) | 9 ( 6.6) | 11 ( 8.1) |
| Blood and lymphatic system disorders | 29 ( 21.3) | 40 ( 29.4) | 93 ( 68.4) | 95 ( 69.9) |
| Neutropenia | 7 ( 5.1) | 15 ( 11.0) | 65 ( 47.8) | 66 ( 48.5) |
| Anaemia | 17 ( 12.5) | 17 ( 12.5) | 55 ( 40.4) | 55 ( 40.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Thrombocytopenia | 15 ( 11.0) | 16 ( 11.8) | 42 ( 30.9) | 47 ( 34.6) |
| Leukopenia | 3 ( 2.2) | 18 ( 13.2) | 31 ( 22.8) | 32 ( 23.5) |
| Lymphopenia | 1 ( 0.7) | 3 ( 2.2) | 20 ( 14.7) | 20 ( 14.7) |
| General disorders and administration site conditions | 13 ( 9.6) | 26 ( 19.1) | 93 ( 68.4) | 99 ( 72.8) |
| Fatigue | 6 ( 4.4) | 13 ( 9.6) | 40 ( 29.4) | 48 ( 35.3) |
| Pyrexia | 4 ( 2.9) | 6 ( 4.4) | 30 ( 22.1) | 34 ( 25.0) |
| Oedema peripheral | 4 ( 2.9) | 4 ( 2.9) | 18 ( 13.2) | 19 ( 14.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Asthenia | 1 ( 0.7) | 4 ( 2.9) | 17 ( 12.5) | 21 ( 15.4) |
| Chills | 1 ( 0.7) | 2 ( 1.5) | 13 ( 9.6) | 15 ( 11.0) |
| Metabolism and nutrition disorders | 14 ( 10.3) | 34 ( 25.0) | 93 ( 68.4) | 99 ( 72.8) |
| Hypokalaemia | 3 ( 2.2) | 10 ( 7.4) | 44 ( 32.4) | 50 ( 36.8) |
| Hypocalcaemia | 3 ( 2.2) | 6 ( 4.4) | 30 ( 22.1) | 32 ( 23.5) |
| Hypomagnesaemia | 2 ( 1.5) | 5 ( 3.7) | 29 ( 21.3) | 30 ( 22.1) |
| Decreased appetite | 1 ( 0.7) | 10 ( 7.4) | 27 ( 19.9) | 33 ( 24.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Hypophosphataemia | 3 ( 2.2) | 2 ( 1.5) | 27 ( 19.9) | 29 ( 21.3) |
| Hyponatraemia | 3 ( 2.2) | 4 ( 2.9) | 21 ( 15.4) | 22 ( 16.2) |
| Hypoalbuminaemia | 2 ( 1.5) | 7 ( 5.1) | 18 ( 13.2) | 20 ( 14.7) |
| Hypercalcaemia | 2 ( 1.5) | 0 | 8 ( 5.9) | 8 ( 5.9) |
| Hyperglycaemia | 1 ( 0.7) | 2 ( 1.5) | 6 ( 4.4) | 8 ( 5.9) |
| Hyperuricaemia | 5 ( 3.7) | 4 ( 2.9) | 4 ( 2.9) | 8 ( 5.9) |
| Infections and infestations | 9 ( 6.6) | 6 ( 4.4) | 79 ( 58.1) | 81 ( 59.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Upper respiratory tract infection | 1 ( 0.7) | 0 | 19 ( 14.0) | 19 ( 14.0) |
| Pneumonia | 1 ( 0.7) | 0 | 10 ( 7.4) | 10 ( 7.4) |
| Nasopharyngitis | 0 | 0 | 7 ( 5.1) | 7 ( 5.1) |
| Musculoskeletal and connective tissue disorders | 11 ( 8.1) | 14 ( 10.3) | 71 ( 52.2) | 75 ( 55.1) |
| Back pain | 3 ( 2.2) | 5 ( 3.7) | 17 ( 12.5) | 21 ( 15.4) |
| Arthralgia | 2 ( 1.5) | 3 ( 2.2) | 16 ( 11.8) | 19 ( 14.0) |
| Bone pain | 1 ( 0.7) | 0 | 13 ( 9.6) | 13 ( 9.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Musculoskeletal chest pain | 2 ( 1.5) | 1 ( 0.7) | 9 ( 6.6) | 9 ( 6.6) |
| Musculoskeletal pain | 0 | 2 ( 1.5) | 8 ( 5.9) | 9 ( 6.6) |
| Myalgia | 0 | 0 | 8 ( 5.9) | 8 ( 5.9) |
| Pain in extremity | 2 ( 1.5) | 3 ( 2.2) | 7 ( 5.1) | 10 ( 7.4) |
| Investigations | 12 ( 8.8) | 17 ( 12.5) | 67 ( 49.3) | 70 ( 51.5) |
| Aspartate aminotransferase increased | 4 ( 2.9) | 3 ( 2.2) | 21 ( 15.4) | 23 ( 16.9) |
| Weight decreased | 1 ( 0.7) | 1 ( 0.7) | 17 ( 12.5) | 17 ( 12.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

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Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Alanine aminotransferase increased | 2 ( 1.5) | 2 ( 1.5) | 16 ( 11.8) | 17 ( 12.5) |
| Blood alkaline phosphatase increased | 3 ( 2.2) | 1 ( 0.7) | 15 ( 11.0) | 15 ( 11.0) |
| C-reactive protein increased | 0 | 1 ( 0.7) | 13 ( 9.6) | 13 ( 9.6) |
| Weight increased | 0 | 1 ( 0.7) | 8 ( 5.9) | 8 ( 5.9) |
| Blood creatinine increased | 2 ( 1.5) | 6 ( 4.4) | 5 ( 3.7) | 8 ( 5.9) |
| Nervous system disorders | 5 ( 3.7) | 23 ( 16.9) | 65 ( 47.8) | 71 ( 52.2) |
| Headache | 2 ( 1.5) | 14 ( 10.3) | 26 ( 19.1) | 38 ( 27.9) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

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Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Dizziness | 0 | 3 ( 2.2) | 17 ( 12.5) | 20 ( 14.7) |
| Tremor | 0 | 1 ( 0.7) | 9 ( 6.6) | 10 ( 7.4) |
| Aphasia | 0 | 0 | 7 ( 5.1) | 7 ( 5.1) |
| Somnolence | 0 | 1 ( 0.7) | 7 ( 5.1) | 8 ( 5.9) |
| Respiratory, thoracic and mediastinal disorders | 4 ( 2.9) | 8 ( 5.9) | 60 ( 44.1) | 64 ( 47.1) |
| Cough | 2 ( 1.5) | 2 ( 1.5) | 23 ( 16.9) | 24 ( 17.6) |
| Nasal congestion | 0 | 1 ( 0.7) | 10 ( 7.4) | 11 ( 8.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

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Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dyspnoea | 1 ( 0.7) | 2 ( 1.5) | 9 ( 6.6) | 10 ( 7.4) |
| Oropharyngeal pain | 0 | 0 | 9 ( 6.6) | 9 ( 6.6) |
| Epistaxis | 1 ( 0.7) | 1 ( 0.7) | 7 ( 5.1) | 8 ( 5.9) |
| Psychiatric disorders | 3 ( 2.2) | 10 ( 7.4) | 44 ( 32.4) | 51 ( 37.5) |
| Confusional state | 0 | 0 | 16 ( 11.8) | 16 ( 11.8) |
| Anxiety | 1 ( 0.7) | 5 ( 3.7) | 12 ( 8.8) | 17 ( 12.5) |
| Insomnia | 0 | 4 ( 2.9) | 11 ( 8.1) | 14 ( 10.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

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Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Skin and subcutaneous tissue disorders | 2 ( 1.5) | 4 ( 2.9) | 42 ( 30.9) | 46 ( 33.8) |
| Alopecia | 0 | 0 | 10 ( 7.4) | 10 ( 7.4) |
| Rash | 0 | 0 | 8 ( 5.9) | 8 ( 5.9) |
| Vascular disorders | 2 ( 1.5) | 5 ( 3.7) | 34 ( 25.0) | 36 ( 26.5) |
| Hypotension | 0 | 4 ( 2.9) | 20 ( 14.7) | 23 ( 16.9) |
| Hypertension | 0 | 1 ( 0.7) | 11 ( 8.1) | 11 ( 8.1) |
| Cardiac disorders | 5 ( 3.7) | 7 ( 5.1) | 31 ( 22.8) | 33 ( 24.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

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Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Tachycardia | 0 | 4 ( 2.9) | 18 ( 13.2) | 20 ( 14.7) |
| Renal and urinary disorders | 4 ( 2.9) | 7 ( 5.1) | 25 ( 18.4) | 30 ( 22.1) |
| Acute kidney injury | 0 | 5 ( 3.7) | 5 ( 3.7) | 9 ( 6.6) |
| Injury, poisoning and procedural complications | 3 ( 2.2) | 2 ( 1.5) | 22 ( 16.2) | 24 ( 17.6) |
| Infusion related reaction | 0 | 0 | 8 ( 5.9) | 8 ( 5.9) |
| Eye disorders | 1 ( 0.7) | 3 ( 2.2) | 18 ( 13.2) | 21 ( 15.4) |
| Diplopia | 0 | 2 ( 1.5) | 5 ( 3.7) | 7 ( 5.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

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Table 9.4.2.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Target Dose Level
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 0.7) | 1 ( 0.7) | 12 ( 8.8) | 12 ( 8.8) |
| Reproductive system and breast disorders | 0 | 0 | 10 ( 7.4) | 10 ( 7.4) |
| Hepatobiliary disorders | 1 ( 0.7) | 1 ( 0.7) | 7 ( 5.1) | 8 ( 5.9) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one Grade 1 or 2 AE | 50 ( 40.3) | 100 ( 80.6) | 124 (100.0) | 124 (100.0) |
| Immune system disorders | 0 | 1 ( 0.8) | 107 ( 86.3) | 107 ( 86.3) |
| Cytokine release syndrome | 0 | 0 | 104 ( 83.9) | 104 ( 83.9) |
| Hypogammaglobulinaemia | 0 | 1 ( 0.8) | 23 ( 18.5) | 24 ( 19.4) |
| Gastrointestinal disorders | 13 ( 10.5) | 67 ( 54.0) | 94 ( 75.8) | 111 ( 89.5) |
| Diarrhoea | 2 ( 1.6) | 11 ( 8.9) | 43 ( 34.7) | 51 ( 41.1) |
| Nausea | 6 ( 4.8) | 44 ( 35.5) | 36 ( 29.0) | 70 ( 56.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Constipation | 2 ( 1.6) | 19 ( 15.3) | 21 ( 16.9) | 36 ( 29.0) |
| Vomiting | 2 ( 1.6) | 7 ( 5.6) | 20 ( 16.1) | 26 ( 21.0) |
| Dry mouth | 0 | 1 ( 0.8) | 9 ( 7.3) | 9 ( 7.3) |
| Dyspepsia | 0 | 2 ( 1.6) | 9 ( 7.3) | 11 ( 8.9) |
| Blood and lymphatic system disorders | 25 ( 20.2) | 39 ( 31.5) | 93 ( 75.0) | 94 ( 75.8) |
| Neutropenia | 6 ( 4.8) | 15 ( 12.1) | 65 ( 52.4) | 66 ( 53.2) |
| Anaemia | 14 ( 11.3) | 17 ( 13.7) | 55 ( 44.4) | 55 ( 44.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Thrombocytopenia | 12 ( 9.7) | 15 ( 12.1) | 42 ( 33.9) | 46 ( 37.1) |
| Leukopenia | 1 ( 0.8) | 17 ( 13.7) | 31 ( 25.0) | 31 ( 25.0) |
| Lymphopenia | 1 ( 0.8) | 3 ( 2.4) | 20 ( 16.1) | 20 ( 16.1) |
| General disorders and administration site conditions | 12 ( 9.7) | 24 ( 19.4) | 93 ( 75.0) | 97 ( 78.2) |
| Fatigue | 5 ( 4.0) | 11 ( 8.9) | 40 ( 32.3) | 46 ( 37.1) |
| Pyrexia | 4 ( 3.2) | 6 ( 4.8) | 30 ( 24.2) | 34 ( 27.4) |
| Oedema peripheral | 4 ( 3.2) | 4 ( 3.2) | 18 ( 14.5) | 19 ( 15.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Asthenia | 1 ( 0.8) | 4 ( 3.2) | 17 ( 13.7) | 21 ( 16.9) |
| Chills | 1 ( 0.8) | 2 ( 1.6) | 13 ( 10.5) | 15 ( 12.1) |
| Metabolism and nutrition disorders | 12 ( 9.7) | 32 ( 25.8) | 93 ( 75.0) | 97 ( 78.2) |
| Hypokalaemia | 2 ( 1.6) | 9 ( 7.3) | 44 ( 35.5) | 49 ( 39.5) |
| Hypocalcaemia | 3 ( 2.4) | 5 ( 4.0) | 30 ( 24.2) | 31 ( 25.0) |
| Hypomagnesaemia | 1 ( 0.8) | 5 ( 4.0) | 29 ( 23.4) | 30 ( 24.2) |
| Decreased appetite | 1 ( 0.8) | 10 ( 8.1) | 27 ( 21.8) | 33 ( 26.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypophosphataemia | 3 ( 2.4) | 2 ( 1.6) | 27 ( 21.8) | 29 ( 23.4) |
| Hyponatraemia | 2 ( 1.6) | 4 ( 3.2) | 21 ( 16.9) | 22 ( 17.7) |
| Hypoalbuminaemia | 2 ( 1.6) | 7 ( 5.6) | 18 ( 14.5) | 20 ( 16.1) |
| Hypercalcaemia | 1 ( 0.8) | 0 | 8 ( 6.5) | 8 ( 6.5) |
| Hyperglycaemia | 1 ( 0.8) | 2 ( 1.6) | 6 ( 4.8) | 8 ( 6.5) |
| Hyperuricaemia | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) | 8 ( 6.5) |
| Infections and infestations | 7 ( 5.6) | 5 ( 4.0) | 79 ( 63.7) | 80 ( 64.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Upper respiratory tract infection | 1 ( 0.8) | 0 | 19 ( 15.3) | 19 ( 15.3) |
| Pneumonia | 0 | 0 | 10 ( 8.1) | 10 ( 8.1) |
| Nasopharyngitis | 0 | 0 | 7 ( 5.6) | 7 ( 5.6) |
| Musculoskeletal and connective tissue disorders | 11 ( 8.9) | 14 ( 11.3) | 71 ( 57.3) | 75 ( 60.5) |
| Back pain | 3 ( 2.4) | 5 ( 4.0) | 17 ( 13.7) | 21 ( 16.9) |
| Arthralgia | 2 ( 1.6) | 3 ( 2.4) | 16 ( 12.9) | 19 ( 15.3) |
| Bone pain | 1 ( 0.8) | 0 | 13 ( 10.5) | 13 ( 10.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Musculoskeletal chest pain | 2 ( 1.6) | 1 ( 0.8) | 9 ( 7.3) | 9 ( 7.3) |
| Musculoskeletal pain | 0 | 2 ( 1.6) | 8 ( 6.5) | 9 ( 7.3) |
| Myalgia | 0 | 0 | 8 ( 6.5) | 8 ( 6.5) |
| Pain in extremity | 2 ( 1.6) | 3 ( 2.4) | 7 ( 5.6) | 10 ( 8.1) |
| Investigations | 10 ( 8.1) | 15 ( 12.1) | 67 ( 54.0) | 68 ( 54.8) |
| Aspartate aminotransferase increased | 2 ( 1.6) | 2 ( 1.6) | 21 ( 16.9) | 22 ( 17.7) |
| Weight decreased | 1 ( 0.8) | 1 ( 0.8) | 17 ( 13.7) | 17 ( 13.7) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Alanine aminotransferase increased | 1 ( 0.8) | 1 ( 0.8) | 16 ( 12.9) | 16 ( 12.9) |
| Blood alkaline phosphatase increased | 2 ( 1.6) | 1 ( 0.8) | 15 ( 12.1) | 15 ( 12.1) |
| C-reactive protein increased | 0 | 1 ( 0.8) | 13 ( 10.5) | 13 ( 10.5) |
| Weight increased | 0 | 1 ( 0.8) | 8 ( 6.5) | 8 ( 6.5) |
| Blood creatinine increased | 1 ( 0.8) | 5 ( 4.0) | 5 ( 4.0) | 7 ( 5.6) |
| Nervous system disorders | 5 ( 4.0) | 23 ( 18.5) | 65 ( 52.4) | 71 ( 57.3) |
| Headache | 2 ( 1.6) | 14 ( 11.3) | 26 ( 21.0) | 38 ( 30.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dizziness | 0 | 3 ( 2.4) | 17 ( 13.7) | 20 ( 16.1) |
| Tremor | 0 | 1 ( 0.8) | 9 ( 7.3) | 10 ( 8.1) |
| Aphasia | 0 | 0 | 7 ( 5.6) | 7 ( 5.6) |
| Somnolence | 0 | 1 ( 0.8) | 7 ( 5.6) | 8 ( 6.5) |
| Respiratory, thoracic and mediastinal disorders | 4 ( 3.2) | 6 ( 4.8) | 60 ( 48.4) | 62 ( 50.0) |
| Cough | 2 ( 1.6) | 2 ( 1.6) | 23 ( 18.5) | 24 ( 19.4) |
| Nasal congestion | 0 | 0 | 10 ( 8.1) | 10 ( 8.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dyspnoea | 1 ( 0.8) | 2 ( 1.6) | 9 ( 7.3) | 10 ( 8.1) |
| Oropharyngeal pain | 0 | 0 | 9 ( 7.3) | 9 ( 7.3) |
| Epistaxis | 1 ( 0.8) | 0 | 7 ( 5.6) | 7 ( 5.6) |
| Psychiatric disorders | 3 ( 2.4) | 9 ( 7.3) | 44 ( 35.5) | 50 ( 40.3) |
| Confusional state | 0 | 0 | 16 ( 12.9) | 16 ( 12.9) |
| Anxiety | 1 ( 0.8) | 5 ( 4.0) | 12 ( 9.7) | 17 ( 13.7) |
| Insomnia | 0 | 3 ( 2.4) | 11 ( 8.9) | 13 ( 10.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Skin and subcutaneous tissue disorders | 1 ( 0.8) | 4 ( 3.2) | 42 ( 33.9) | 46 ( 37.1) |
| Alopecia | 0 | 0 | 10 ( 8.1) | 10 ( 8.1) |
| Rash | 0 | 0 | 8 ( 6.5) | 8 ( 6.5) |
| Vascular disorders | 2 ( 1.6) | 5 ( 4.0) | 34 ( 27.4) | 36 ( 29.0) |
| Hypotension | 0 | 4 ( 3.2) | 20 ( 16.1) | 23 ( 18.5) |
| Hypertension | 0 | 1 ( 0.8) | 11 ( 8.9) | 11 ( 8.9) |
| Cardiac disorders | 4 ( 3.2) | 6 ( 4.8) | 31 ( 25.0) | 32 ( 25.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Tachycardia | 0 | 3 ( 2.4) | 18 ( 14.5) | 19 ( 15.3) |
| Renal and urinary disorders | 3 ( 2.4) | 5 ( 4.0) | 25 ( 20.2) | 28 ( 22.6) |
| Acute kidney injury | 0 | 3 ( 2.4) | 5 ( 4.0) | 7 ( 5.6) |
| Injury, poisoning and procedural complications | 2 ( 1.6) | 1 ( 0.8) | 22 ( 17.7) | 23 ( 18.5) |
| Infusion related reaction | 0 | 0 | 8 ( 6.5) | 8 ( 6.5) |
| Eye disorders | 1 ( 0.8) | 3 ( 2.4) | 18 ( 14.5) | 21 ( 16.9) |
| Diplopia | 0 | 2 ( 1.6) | 5 ( 4.0) | 7 ( 5.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 0.8) | 1 ( 0.8) | 12 ( 9.7) | 12 ( 9.7) |
| Reproductive system and breast disorders | 0 | 0 | 10 ( 8.1) | 10 ( 8.1) |
| Hepatobiliary disorders | 1 ( 0.8) | 0 | 7 ( 5.6) | 7 ( 5.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Number of subjects with at least one grade 1 or 2 AESI/Selected AEs | 39 ( 28.7) | 62 ( 45.6) | 122 ( 89.7) | 124 ( 91.2) | 128 ( 94.1) |
| Cytokine Release Syndrome | 0 | 0 | 104 ( 76.5) | 104 ( 76.5) | 104 ( 76.5) |
| Cytokine release syndrome | 0 | 0 | 104 ( 76.5) | 104 ( 76.5) | 104 ( 76.5) |
| Cytopenia-Overall | 29 ( 21.3) | 42 ( 30.9) | 93 ( 68.4) | 95 ( 69.9) | 98 ( 72.1) |
| Neutropenia | 7 ( 5.1) | 15 ( 11.0) | 65 ( 47.8) | 66 ( 48.5) | 68 ( 50.0) |
| Anaemia | 17 ( 12.5) | 17 ( 12.5) | 55 ( 40.4) | 55 ( 40.4) | 60 ( 44.1) |
| Thrombocytopenia | 15 ( 11.0) | 16 ( 11.8) | 42 ( 30.9) | 47 ( 34.6) | 52 ( 38.2) |
| Leukopenia | 3 ( 2.2) | 18 ( 13.2) | 31 ( 22.8) | 32 ( 23.5) | 34 ( 25.0) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
Date/time of run: 15JUL2021 10:34
Analysis Plan: 12MAY2021 Confidential

### 7.3.2 UESI Grad 1 und 2 nach SOC und PT

Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Lymphopenia | 1 ( 0.7) | 3 ( 2.2) | 20 ( 14.7) | 20 ( 14.7) | 21 ( 15.4) |
| Neutrophil count decreased | 0 | 1 ( 0.7) | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| CD4 lymphocytes decreased | 1 ( 0.7) | 0 | 2 ( 1.5) | 2 ( 1.5) | 3 ( 2.2) |
| Pancytopenia | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Platelet count decreased | 0 | 2 ( 1.5) | 2 ( 1.5) | 3 ( 2.2) | 3 ( 2.2) |
| Febrile neutropenia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Cytopenia-Neutropenia | 8 ( 5.9) | 26 ( 19.1) | 74 ( 54.4) | 76 ( 55.9) | 77 ( 56.6) |
| Neutropenia | 7 ( 5.1) | 15 ( 11.0) | 65 ( 47.8) | 66 ( 48.5) | 68 ( 50.0) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
Date/time of run: 15JUL2021 10:34
Analysis Plan: 12MAY2021 Confidential

Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Leukopenia | 3 ( 2.2) | 18 ( 13.2) | 31 ( 22.8) | 32 ( 23.5) | 34 ( 25.0) |
| Neutrophil count decreased | 0 | 1 ( 0.7) | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| Febrile neutropenia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Cytopenia-Anaemia | 17 ( 12.5) | 17 ( 12.5) | 55 ( 40.4) | 55 ( 40.4) | 60 ( 44.1) |
| Anaemia | 17 ( 12.5) | 17 ( 12.5) | 55 ( 40.4) | 55 ( 40.4) | 60 ( 44.1) |
| Cytopenia-Thrombocytopenia | 15 ( 11.0) | 18 ( 13.2) | 44 ( 32.4) | 50 ( 36.8) | 54 ( 39.7) |
| Thrombocytopenia | 15 ( 11.0) | 16 ( 11.8) | 42 ( 30.9) | 47 ( 34.6) | 52 ( 38.2) |
| Platelet count decreased | 0 | 2 ( 1.5) | 2 ( 1.5) | 3 ( 2.2) | 3 ( 2.2) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
Date/time of run: 15JUL2021 10:34
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Cytopenia-Lymphopenia | 2 ( 1.5) | 3 ( 2.2) | 22 ( 16.2) | 22 ( 16.2) | 24 ( 17.6) |
| Lymphopenia | 1 ( 0.7) | 3 ( 2.2) | 20 ( 14.7) | 20 ( 14.7) | 21 ( 15.4) |
| CD4 lymphocytes decreased | 1 ( 0.7) | 0 | 2 ( 1.5) | 2 ( 1.5) | 3 ( 2.2) |
| Cytopenia-Pancytopenia | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Pancytopenia | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Neurologic Toxicity- Broad | 7 ( 5.1) | 32 ( 23.5) | 84 ( 61.8) | 90 ( 66.2) | 91 ( 66.9) |
| Headache | 2 ( 1.5) | 14 ( 10.3) | 26 ( 19.1) | 38 ( 27.9) | 39 ( 28.7) |
| Dizziness | 0 | 3 ( 2.2) | 17 ( 12.5) | 20 ( 14.7) | 20 ( 14.7) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
Date/time of run: 15JUL2021 10:34
Analysis Plan: 12MAY2021 Confidential

Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Confusional state | 0 | 0 | 16 ( 11.8) | 16 ( 11.8) | 16 ( 11.8) |
| Anxiety | 1 ( 0.7) | 5 ( 3.7) | 12 ( 8.8) | 17 ( 12.5) | 18 ( 13.2) |
| Insomnia | 0 | 4 ( 2.9) | 11 ( 8.1) | 14 ( 10.3) | 14 ( 10.3) |
| Tremor | 0 | 1 ( 0.7) | 9 ( 6.6) | 10 ( 7.4) | 10 ( 7.4) |
| Aphasia | 0 | 0 | 7 ( 5.1) | 7 ( 5.1) | 7 ( 5.1) |
| Somnolence | 0 | 1 ( 0.7) | 7 ( 5.1) | 8 ( 5.9) | 8 ( 5.9) |
| Encephalopathy | 1 ( 0.7) | 0 | 6 ( 4.4) | 6 ( 4.4) | 7 ( 5.1) |
| Diplopia | 0 | 2 ( 1.5) | 5 ( 3.7) | 7 ( 5.1) | 7 ( 5.1) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Mental status changes | 0 | 1 ( 0.7) | 5 ( 3.7) | 6 ( 4.4) | 6 ( 4.4) |
| Sleep disorder | 0 | 0 | 5 ( 3.7) | 5 ( 3.7) | 5 ( 3.7) |
| Urinary incontinence | 0 | 0 | 5 ( 3.7) | 5 ( 3.7) | 5 ( 3.7) |
| Vision blurred | 0 | 0 | 5 ( 3.7) | 5 ( 3.7) | 5 ( 3.7) |
| Hallucination | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Herpes zoster | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Peripheral sensory neuropathy | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Cognitive disorder | 0 | 0 | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
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Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
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| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Delirium | 1 ( 0.7) | 0 | 3 ( 2.2) | 3 ( 2.2) | 4 ( 2.9) |
| Lethargy | 0 | 0 | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| Muscular weakness | 0 | 0 | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| Neuralgia | 0 | 0 | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| Paraesthesia | 0 | 0 | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| Restless legs syndrome | 0 | 0 | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| Sciatica | 0 | 1 ( 0.7) | 3 ( 2.2) | 4 ( 2.9) | 4 ( 2.9) |
| Amnesia | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Asterixis | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Carpal tunnel syndrome | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Disorientation | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Disturbance in attention | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Dysarthria | 0 | 1 ( 0.7) | 2 ( 1.5) | 3 ( 2.2) | 3 ( 2.2) |
| Dysgraphia | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Gait disturbance | 0 | 1 ( 0.7) | 2 ( 1.5) | 3 ( 2.2) | 3 ( 2.2) |
| Head discomfort | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
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Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Hypoaesthesia oral | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Neuropathy peripheral | 1 ( 0.7) | 0 | 2 ( 1.5) | 2 ( 1.5) | 3 ( 2.2) |
| Peripheral sensorimotor neuropathy | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Seizure | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Spinal pain | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Syncope | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Vertigo | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Abnormal dreams | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

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|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Anal incontinence | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Ataxia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Bradyphrenia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Cranial nerve disorder | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Dyscalculia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Dysphonia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Eyelid ptosis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Hemiparesis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

A preferred term may be seen in multiple AESI/Selected AE categories.
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Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
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Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Hypoaesthesia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Hypophagia | 0 | 1 ( 0.7) | 1 ( 0.7) | 2 ( 1.5) | 2 ( 1.5) |
| Hypotonia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Libido decreased | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Memory impairment | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Migraine | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Motion sickness | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Motor dysfunction | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

A preferred term may be seen in multiple AESI/Selected AE categories.
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
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Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Narcolepsy | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Nervousness | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Orthostatic hypotension | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Presyncope | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Pupillary reflex impaired | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Sinus headache | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Sleep deficit | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Taste disorder | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Temporomandibular joint syndrome | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Toxic encephalopathy | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Adult failure to thrive | 1 ( 0.7) | 0 | 0 | 0 | 1 ( 0.7) |
| Aphonia | 1 ( 0.7) | 0 | 0 | 0 | 1 ( 0.7) |
| Dizziness postural | 0 | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) |
| Mood altered | 1 ( 0.7) | 0 | 0 | 0 | 1 ( 0.7) |
| Post herpetic neuralgia | 0 | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) |
| Spinal cord compression | 1 ( 0.7) | 0 | 0 | 0 | 1 ( 0.7) |

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| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Neurologic Toxicity - Focused | 1 ( 0.7) | 8 ( 5.9) | 48 ( 35.3) | 53 ( 39.0) | 53 ( 39.0) |
| Confusional state | 0 | 0 | 16 ( 11.8) | 16 ( 11.8) | 16 ( 11.8) |
| Insomnia | 0 | 4 ( 2.9) | 11 ( 8.1) | 14 ( 10.3) | 14 ( 10.3) |
| Tremor | 0 | 1 ( 0.7) | 9 ( 6.6) | 10 ( 7.4) | 10 ( 7.4) |
| Aphasia | 0 | 0 | 7 ( 5.1) | 7 ( 5.1) | 7 ( 5.1) |
| Somnolence | 0 | 1 ( 0.7) | 7 ( 5.1) | 8 ( 5.9) | 8 ( 5.9) |
| Encephalopathy | 1 ( 0.7) | 0 | 6 ( 4.4) | 6 ( 4.4) | 7 ( 5.1) |
| Mental status changes | 0 | 1 ( 0.7) | 5 ( 3.7) | 6 ( 4.4) | 6 ( 4.4) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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| Sleep disorder | 0 | 0 | 5 ( 3.7) | 5 ( 3.7) | 5 ( 3.7) |
| Hallucination | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Cognitive disorder | 0 | 0 | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| Delirium | 1 ( 0.7) | 0 | 3 ( 2.2) | 3 ( 2.2) | 4 ( 2.9) |
| Lethargy | 0 | 0 | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| Amnesia | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Asterixis | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Disorientation | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Disturbance in attention | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Dysarthria | 0 | 1 ( 0.7) | 2 ( 1.5) | 3 ( 2.2) | 3 ( 2.2) |
| Dysgraphia | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Gait disturbance | 0 | 1 ( 0.7) | 2 ( 1.5) | 3 ( 2.2) | 3 ( 2.2) |
| Seizure | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Ataxia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Bradyphrenia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Dyscalculia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Hemiparesis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Hypotonia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Memory impairment | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Motor dysfunction | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Sleep deficit | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Infections-Overall | 9 ( 6.6) | 7 ( 5.1) | 79 ( 58.1) | 82 ( 60.3) | 87 ( 64.0) |
| Upper respiratory tract infection | 1 ( 0.7) | 0 | 19 ( 14.0) | 19 ( 14.0) | 19 ( 14.0) |
| Pneumonia | 1 ( 0.7) | 0 | 10 ( 7.4) | 10 ( 7.4) | 11 ( 8.1) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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| Nasopharyngitis | 0 | 0 | 7 ( 5.1) | 7 ( 5.1) | 7 ( 5.1) |
| Influenza | 0 | 0 | 6 ( 4.4) | 6 ( 4.4) | 6 ( 4.4) |
| Sinusitis | 0 | 0 | 6 ( 4.4) | 6 ( 4.4) | 6 ( 4.4) |
| Urinary tract infection | 1 ( 0.7) | 0 | 6 ( 4.4) | 6 ( 4.4) | 7 ( 5.1) |
| Candida infection | 0 | 0 | 5 ( 3.7) | 5 ( 3.7) | 5 ( 3.7) |
| Respiratory tract infection | 1 ( 0.7) | 1 ( 0.7) | 5 ( 3.7) | 5 ( 3.7) | 6 ( 4.4) |
| Rhinovirus infection | 1 ( 0.7) | 0 | 5 ( 3.7) | 5 ( 3.7) | 6 ( 4.4) |
| Bronchitis | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |

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|---|---|---|---|---|---|
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| Clostridium difficile infection | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Corona virus infection | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Gastroenteritis | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Herpes zoster | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Respiratory syncytial virus infection | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Oral candidiasis | 0 | 2 ( 1.5) | 3 ( 2.2) | 5 ( 3.7) | 5 ( 3.7) |
| Oral herpes | 0 | 0 | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| Clostridium difficile colitis | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |

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[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
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| Conjunctivitis | 1 ( 0.7) | 0 | 2 ( 1.5) | 2 ( 1.5) | 3 ( 2.2) |
| Parainfluenzae virus infection | 1 ( 0.7) | 0 | 2 ( 1.5) | 2 ( 1.5) | 3 ( 2.2) |
| Skin papilloma | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Urinary tract infection bacterial | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Bronchitis haemophilus | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Bronchopulmonary aspergillosis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Cellulitis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Device related infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

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[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Diverticulitis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Ear infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Enterococcal infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Escherichia bacteraemia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Escherichia urinary tract infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Gastroenteritis salmonella | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| H1N1 influenza | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Impetigo | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

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| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Laryngitis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Lung infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Onychomycosis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Pharyngitis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Pseudomonas infection | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) | 2 ( 1.5) |
| Rhinitis | 0 | 1 ( 0.7) | 1 ( 0.7) | 2 ( 1.5) | 2 ( 1.5) |
| Sepsis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

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| Skin candida | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Staphylococcal infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Streptococcal bacteraemia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Tracheitis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Upper respiratory tract infection bacterial | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) | 2 ( 1.5) |
| Vascular device infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Bacteraemia | 0 | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) |
| Herpes simplex | 0 | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) |

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| Post herpetic neuralgia | 0 | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) |
| Tinea infection | 1 ( 0.7) | 0 | 0 | 0 | 1 ( 0.7) |
| Typhoid fever | 1 ( 0.7) | 0 | 0 | 0 | 1 ( 0.7) |
| Infections-Pathogen Unspecified | 5 ( 3.7) | 3 ( 2.2) | 54 ( 39.7) | 56 ( 41.2) | 59 ( 43.4) |
| Upper respiratory tract infection | 1 ( 0.7) | 0 | 19 ( 14.0) | 19 ( 14.0) | 19 ( 14.0) |
| Pneumonia | 1 ( 0.7) | 0 | 10 ( 7.4) | 10 ( 7.4) | 11 ( 8.1) |
| Nasopharyngitis | 0 | 0 | 7 ( 5.1) | 7 ( 5.1) | 7 ( 5.1) |
| Sinusitis | 0 | 0 | 6 ( 4.4) | 6 ( 4.4) | 6 ( 4.4) |

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| Urinary tract infection | 1 ( 0.7) | 0 | 6 ( 4.4) | 6 ( 4.4) | 7 ( 5.1) |
| Respiratory tract infection | 1 ( 0.7) | 1 ( 0.7) | 5 ( 3.7) | 5 ( 3.7) | 6 ( 4.4) |
| Bronchitis | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Gastroenteritis | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Conjunctivitis | 1 ( 0.7) | 0 | 2 ( 1.5) | 2 ( 1.5) | 3 ( 2.2) |
| Device related infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Diverticulitis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Ear infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

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| Impetigo | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Laryngitis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Lung infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Pharyngitis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Rhinitis | 0 | 1 ( 0.7) | 1 ( 0.7) | 2 ( 1.5) | 2 ( 1.5) |
| Sepsis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Tracheitis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Vascular device infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Bacteraemia | 0 | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) |
| Infections-Viral | 2 ( 1.5) | 1 ( 0.7) | 27 ( 19.9) | 28 ( 20.6) | 30 ( 22.1) |
| Influenza | 0 | 0 | 6 ( 4.4) | 6 ( 4.4) | 6 ( 4.4) |
| Rhinovirus infection | 1 ( 0.7) | 0 | 5 ( 3.7) | 5 ( 3.7) | 6 ( 4.4) |
| Corona virus infection | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Herpes zoster | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Respiratory syncytial virus infection | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Oral herpes | 0 | 0 | 3 ( 2.2) | 3 ( 2.2) | 3 ( 2.2) |
| Parainfluenzae virus infection | 1 ( 0.7) | 0 | 2 ( 1.5) | 2 ( 1.5) | 3 ( 2.2) |
| Skin papilloma | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| H1N1 influenza | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Herpes simplex | 0 | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) |
| Infections-Bacterial | 3 ( 2.2) | 0 | 17 ( 12.5) | 17 ( 12.5) | 20 ( 14.7) |
| Clostridium difficile infection | 0 | 0 | 4 ( 2.9) | 4 ( 2.9) | 4 ( 2.9) |
| Clostridium difficile colitis | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Urinary tract infection bacterial | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Bronchitis haemophilus | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Cellulitis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Enterococcal infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Escherichia bacteraemia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Escherichia urinary tract infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Gastroenteritis salmonella | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Pseudomonas infection | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) | 2 ( 1.5) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Staphylococcal infection | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Streptococcal bacteraemia | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Upper respiratory tract infection bacterial | 1 ( 0.7) | 0 | 1 ( 0.7) | 1 ( 0.7) | 2 ( 1.5) |
| Typhoid fever | 1 ( 0.7) | 0 | 0 | 0 | 1 ( 0.7) |
| Infections-Fungal | 1 ( 0.7) | 2 ( 1.5) | 9 ( 6.6) | 11 ( 8.1) | 12 ( 8.8) |
| Candida infection | 0 | 0 | 5 ( 3.7) | 5 ( 3.7) | 5 ( 3.7) |
| Oral candidiasis | 0 | 2 ( 1.5) | 3 ( 2.2) | 5 ( 3.7) | 5 ( 3.7) |
| Bronchopulmonary aspergillosis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 10.4.2d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells (N=136) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Onychomycosis | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Skin candida | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Tinea infection | 1 ( 0.7) | 0 | 0 | 0 | 1 ( 0.7) |
| New Malignancy | 0 | 0 | 6 ( 4.4) | 6 ( 4.4) | 6 ( 4.4) |
| Basal cell carcinoma | 0 | 0 | 5 ( 3.7) | 5 ( 3.7) | 5 ( 3.7) |
| Squamous cell carcinoma | 0 | 0 | 1 ( 0.7) | 1 ( 0.7) | 1 ( 0.7) |
| Macrophage Activation Syndrome (MAS) | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |
| Haemophagocytic lymphohistiocytosis | 0 | 0 | 2 ( 1.5) | 2 ( 1.5) | 2 ( 1.5) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Number of subjects with at least one grade 1 or 2 AESI/Selected AEs | 34 ( 27.4) | 60 ( 48.4) | 122 ( 98.4) | 122 ( 98.4) | 122 ( 98.4) |
| Cytokine Release Syndrome | 0 | 0 | 104 ( 83.9) | 104 ( 83.9) | 104 ( 83.9) |
| Cytokine release syndrome | 0 | 0 | 104 ( 83.9) | 104 ( 83.9) | 104 ( 83.9) |
| Cytopenia-Overall | 25 ( 20.2) | 41 ( 33.1) | 93 ( 75.0) | 94 ( 75.8) | 94 ( 75.8) |
| Neutropenia | 6 ( 4.8) | 15 ( 12.1) | 65 ( 52.4) | 66 ( 53.2) | 67 ( 54.0) |
| Anaemia | 14 ( 11.3) | 17 ( 13.7) | 55 ( 44.4) | 55 ( 44.4) | 57 ( 46.0) |
| Thrombocytopenia | 12 ( 9.7) | 15 ( 12.1) | 42 ( 33.9) | 46 ( 37.1) | 49 ( 39.5) |
| Leukopenia | 1 ( 0.8) | 17 ( 13.7) | 31 ( 25.0) | 31 ( 25.0) | 32 ( 25.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Lymphopenia | 1 ( 0.8) | 3 ( 2.4) | 20 ( 16.1) | 20 ( 16.1) | 21 ( 16.9) |
| Neutrophil count decreased | 0 | 1 ( 0.8) | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| CD4 lymphocytes decreased | 1 ( 0.8) | 0 | 2 ( 1.6) | 2 ( 1.6) | 3 ( 2.4) |
| Pancytopenia | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Platelet count decreased | 0 | 2 ( 1.6) | 2 ( 1.6) | 3 ( 2.4) | 3 ( 2.4) |
| Febrile neutropenia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Cytopenia-Neutropenia | 6 ( 4.8) | 25 ( 20.2) | 74 ( 59.7) | 75 ( 60.5) | 75 ( 60.5) |
| Neutropenia | 6 ( 4.8) | 15 ( 12.1) | 65 ( 52.4) | 66 ( 53.2) | 67 ( 54.0) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
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Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Leukopenia | 1 ( 0.8) | 17 ( 13.7) | 31 ( 25.0) | 31 ( 25.0) | 32 ( 25.8) |
| Neutrophil count decreased | 0 | 1 ( 0.8) | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| Febrile neutropenia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Cytopenia-Anaemia | 14 ( 11.3) | 17 ( 13.7) | 55 ( 44.4) | 55 ( 44.4) | 57 ( 46.0) |
| Anaemia | 14 ( 11.3) | 17 ( 13.7) | 55 ( 44.4) | 55 ( 44.4) | 57 ( 46.0) |
| Cytopenia-Thrombocytopenia | 12 ( 9.7) | 17 ( 13.7) | 44 ( 35.5) | 49 ( 39.5) | 51 ( 41.1) |
| Thrombocytopenia | 12 ( 9.7) | 15 ( 12.1) | 42 ( 33.9) | 46 ( 37.1) | 49 ( 39.5) |
| Platelet count decreased | 0 | 2 ( 1.6) | 2 ( 1.6) | 3 ( 2.4) | 3 ( 2.4) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Cytopenia-Lymphopenia | 2 ( 1.6) | 3 ( 2.4) | 22 ( 17.7) | 22 ( 17.7) | 24 ( 19.4) |
| Lymphopenia | 1 ( 0.8) | 3 ( 2.4) | 20 ( 16.1) | 20 ( 16.1) | 21 ( 16.9) |
| CD4 lymphocytes decreased | 1 ( 0.8) | 0 | 2 ( 1.6) | 2 ( 1.6) | 3 ( 2.4) |
| Cytopenia-Pancytopenia | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Pancytopenia | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Neurologic Toxicity- Broad | 7 ( 5.6) | 31 ( 25.0) | 84 ( 67.7) | 89 ( 71.8) | 90 ( 72.6) |
| Headache | 2 ( 1.6) | 14 ( 11.3) | 26 ( 21.0) | 38 ( 30.6) | 39 ( 31.5) |
| Dizziness | 0 | 3 ( 2.4) | 17 ( 13.7) | 20 ( 16.1) | 20 ( 16.1) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Confusional state | 0 | 0 | 16 ( 12.9) | 16 ( 12.9) | 16 ( 12.9) |
| Anxiety | 1 ( 0.8) | 5 ( 4.0) | 12 ( 9.7) | 17 ( 13.7) | 18 ( 14.5) |
| Insomnia | 0 | 3 ( 2.4) | 11 ( 8.9) | 13 ( 10.5) | 13 ( 10.5) |
| Tremor | 0 | 1 ( 0.8) | 9 ( 7.3) | 10 ( 8.1) | 10 ( 8.1) |
| Aphasia | 0 | 0 | 7 ( 5.6) | 7 ( 5.6) | 7 ( 5.6) |
| Somnolence | 0 | 1 ( 0.8) | 7 ( 5.6) | 8 ( 6.5) | 8 ( 6.5) |
| Encephalopathy | 1 ( 0.8) | 0 | 6 ( 4.8) | 6 ( 4.8) | 7 ( 5.6) |
| Diplopia | 0 | 2 ( 1.6) | 5 ( 4.0) | 7 ( 5.6) | 7 ( 5.6) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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or MedDRA SOC and PT definitions, and medical judgment.
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[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
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bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Mental status changes | 0 | 1 ( 0.8) | 5 ( 4.0) | 6 ( 4.8) | 6 ( 4.8) |
| Sleep disorder | 0 | 0 | 5 ( 4.0) | 5 ( 4.0) | 5 ( 4.0) |
| Urinary incontinence | 0 | 0 | 5 ( 4.0) | 5 ( 4.0) | 5 ( 4.0) |
| Vision blurred | 0 | 0 | 5 ( 4.0) | 5 ( 4.0) | 5 ( 4.0) |
| Hallucination | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Herpes zoster | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Peripheral sensory neuropathy | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Cognitive disorder | 0 | 0 | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
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Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Delirium | 1 ( 0.8) | 0 | 3 ( 2.4) | 3 ( 2.4) | 4 ( 3.2) |
| Lethargy | 0 | 0 | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| Muscular weakness | 0 | 0 | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| Neuralgia | 0 | 0 | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| Paraesthesia | 0 | 0 | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| Restless legs syndrome | 0 | 0 | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| Sciatica | 0 | 1 ( 0.8) | 3 ( 2.4) | 4 ( 3.2) | 4 ( 3.2) |
| Amnesia | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
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Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
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bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Asterixis | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Carpal tunnel syndrome | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Disorientation | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Disturbance in attention | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Dysarthria | 0 | 1 ( 0.8) | 2 ( 1.6) | 3 ( 2.4) | 3 ( 2.4) |
| Dysgraphia | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Gait disturbance | 0 | 1 ( 0.8) | 2 ( 1.6) | 3 ( 2.4) | 3 ( 2.4) |
| Head discomfort | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

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Table 10.4.1d
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Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Hypoaesthesia oral | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Neuropathy peripheral | 1 ( 0.8) | 0 | 2 ( 1.6) | 2 ( 1.6) | 3 ( 2.4) |
| Peripheral sensorimotor neuropathy | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Seizure | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Spinal pain | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Syncope | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Vertigo | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Abnormal dreams | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

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Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Anal incontinence | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Ataxia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Bradyphrenia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Cranial nerve disorder | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Dyscalculia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Dysphonia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Eyelid ptosis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Hemiparesis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

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Table 10.4.1d
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| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Hypoaesthesia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Hypophagia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Hypotonia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Libido decreased | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Memory impairment | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Migraine | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Motion sickness | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Motor dysfunction | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
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| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Narcolepsy | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Nervousness | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Orthostatic hypotension | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Presyncope | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Pupillary reflex impaired | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Sinus headache | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Sleep deficit | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Taste disorder | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
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The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
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| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Temporomandibular joint syndrome | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Toxic encephalopathy | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Adult failure to thrive | 1 ( 0.8) | 0 | 0 | 0 | 1 ( 0.8) |
| Aphonia | 1 ( 0.8) | 0 | 0 | 0 | 1 ( 0.8) |
| Dizziness postural | 0 | 1 ( 0.8) | 0 | 1 ( 0.8) | 1 ( 0.8) |
| Mood altered | 1 ( 0.8) | 0 | 0 | 0 | 1 ( 0.8) |
| Post herpetic neuralgia | 0 | 1 ( 0.8) | 0 | 1 ( 0.8) | 1 ( 0.8) |
| Spinal cord compression | 1 ( 0.8) | 0 | 0 | 0 | 1 ( 0.8) |

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|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Neurologic Toxicity - Focused | 1 ( 0.8) | 7 ( 5.6) | 48 ( 38.7) | 52 ( 41.9) | 52 ( 41.9) |
| Confusional state | 0 | 0 | 16 ( 12.9) | 16 ( 12.9) | 16 ( 12.9) |
| Insomnia | 0 | 3 ( 2.4) | 11 ( 8.9) | 13 ( 10.5) | 13 ( 10.5) |
| Tremor | 0 | 1 ( 0.8) | 9 ( 7.3) | 10 ( 8.1) | 10 ( 8.1) |
| Aphasia | 0 | 0 | 7 ( 5.6) | 7 ( 5.6) | 7 ( 5.6) |
| Somnolence | 0 | 1 ( 0.8) | 7 ( 5.6) | 8 ( 6.5) | 8 ( 6.5) |
| Encephalopathy | 1 ( 0.8) | 0 | 6 ( 4.8) | 6 ( 4.8) | 7 ( 5.6) |
| Mental status changes | 0 | 1 ( 0.8) | 5 ( 4.0) | 6 ( 4.8) | 6 ( 4.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Sleep disorder | 0 | 0 | 5 ( 4.0) | 5 ( 4.0) | 5 ( 4.0) |
| Hallucination | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Cognitive disorder | 0 | 0 | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| Delirium | 1 ( 0.8) | 0 | 3 ( 2.4) | 3 ( 2.4) | 4 ( 3.2) |
| Lethargy | 0 | 0 | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| Amnesia | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Asterixis | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Disorientation | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |

A preferred term may be seen in multiple AESI/Selected AE categories.
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| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Disturbance in attention | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Dysarthria | 0 | 1 ( 0.8) | 2 ( 1.6) | 3 ( 2.4) | 3 ( 2.4) |
| Dysgraphia | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Gait disturbance | 0 | 1 ( 0.8) | 2 ( 1.6) | 3 ( 2.4) | 3 ( 2.4) |
| Seizure | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Ataxia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Bradyphrenia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Dyscalculia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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or MedDRA SOC and PT definitions, and medical judgment.
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[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

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Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Hemiparesis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Hypotonia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Memory impairment | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Motor dysfunction | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Sleep deficit | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Infections-Overall | 7 ( 5.6) | 6 ( 4.8) | 79 ( 63.7) | 81 ( 65.3) | 84 ( 67.7) |
| Upper respiratory tract infection | 1 ( 0.8) | 0 | 19 ( 15.3) | 19 ( 15.3) | 19 ( 15.3) |
| Pneumonia | 0 | 0 | 10 ( 8.1) | 10 ( 8.1) | 10 ( 8.1) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
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[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
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Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
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bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Nasopharyngitis | 0 | 0 | 7 ( 5.6) | 7 ( 5.6) | 7 ( 5.6) |
| Influenza | 0 | 0 | 6 ( 4.8) | 6 ( 4.8) | 6 ( 4.8) |
| Sinusitis | 0 | 0 | 6 ( 4.8) | 6 ( 4.8) | 6 ( 4.8) |
| Urinary tract infection | 1 ( 0.8) | 0 | 6 ( 4.8) | 6 ( 4.8) | 7 ( 5.6) |
| Candida infection | 0 | 0 | 5 ( 4.0) | 5 ( 4.0) | 5 ( 4.0) |
| Respiratory tract infection | 1 ( 0.8) | 1 ( 0.8) | 5 ( 4.0) | 5 ( 4.0) | 6 ( 4.8) |
| Rhinovirus infection | 0 | 0 | 5 ( 4.0) | 5 ( 4.0) | 5 ( 4.0) |
| Bronchitis | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |

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| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Clostridium difficile infection | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Corona virus infection | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Gastroenteritis | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Herpes zoster | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Respiratory syncytial virus infection | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Oral candidiasis | 0 | 1 ( 0.8) | 3 ( 2.4) | 4 ( 3.2) | 4 ( 3.2) |
| Oral herpes | 0 | 0 | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| Clostridium difficile colitis | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |

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[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

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|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Conjunctivitis | 1 ( 0.8) | 0 | 2 ( 1.6) | 2 ( 1.6) | 3 ( 2.4) |
| Parainfluenzae virus infection | 1 ( 0.8) | 0 | 2 ( 1.6) | 2 ( 1.6) | 3 ( 2.4) |
| Skin papilloma | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Urinary tract infection bacterial | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Bronchitis haemophilus | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Bronchopulmonary aspergillosis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Cellulitis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Device related infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Diverticulitis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Ear infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Enterococcal infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Escherichia bacteraemia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Escherichia urinary tract infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Gastroenteritis salmonella | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| H1N1 influenza | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Impetigo | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
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| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Laryngitis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Lung infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Onychomycosis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Pharyngitis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Pseudomonas infection | 1 ( 0.8) | 0 | 1 ( 0.8) | 1 ( 0.8) | 2 ( 1.6) |
| Rhinitis | 0 | 1 ( 0.8) | 1 ( 0.8) | 2 ( 1.6) | 2 ( 1.6) |
| Sepsis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
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|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Skin candida | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Staphylococcal infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Streptococcal bacteraemia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Tracheitis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Upper respiratory tract infection bacterial | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Vascular device infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Bacteraemia | 0 | 1 ( 0.8) | 0 | 1 ( 0.8) | 1 ( 0.8) |
| Herpes simplex | 0 | 1 ( 0.8) | 0 | 1 ( 0.8) | 1 ( 0.8) |

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| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Post herpetic neuralgia | 0 | 1 ( 0.8) | 0 | 1 ( 0.8) | 1 ( 0.8) |
| Tinea infection | 1 ( 0.8) | 0 | 0 | 0 | 1 ( 0.8) |
| Typhoid fever | 1 ( 0.8) | 0 | 0 | 0 | 1 ( 0.8) |
| Infections-Pathogen Unspecified | 4 ( 3.2) | 3 ( 2.4) | 54 ( 43.5) | 56 ( 45.2) | 58 ( 46.8) |
| Upper respiratory tract infection | 1 ( 0.8) | 0 | 19 ( 15.3) | 19 ( 15.3) | 19 ( 15.3) |
| Pneumonia | 0 | 0 | 10 ( 8.1) | 10 ( 8.1) | 10 ( 8.1) |
| Nasopharyngitis | 0 | 0 | 7 ( 5.6) | 7 ( 5.6) | 7 ( 5.6) |
| Sinusitis | 0 | 0 | 6 ( 4.8) | 6 ( 4.8) | 6 ( 4.8) |

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| Urinary tract infection | 1 ( 0.8) | 0 | 6 ( 4.8) | 6 ( 4.8) | 7 ( 5.6) |
| Respiratory tract infection | 1 ( 0.8) | 1 ( 0.8) | 5 ( 4.0) | 5 ( 4.0) | 6 ( 4.8) |
| Bronchitis | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Gastroenteritis | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Conjunctivitis | 1 ( 0.8) | 0 | 2 ( 1.6) | 2 ( 1.6) | 3 ( 2.4) |
| Device related infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Diverticulitis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Ear infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

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| Impetigo | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Laryngitis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Lung infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Pharyngitis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Rhinitis | 0 | 1 ( 0.8) | 1 ( 0.8) | 2 ( 1.6) | 2 ( 1.6) |
| Sepsis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Tracheitis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

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| Vascular device infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Bacteraemia | 0 | 1 ( 0.8) | 0 | 1 ( 0.8) | 1 ( 0.8) |
| Infections-Viral | 1 ( 0.8) | 1 ( 0.8) | 27 ( 21.8) | 28 ( 22.6) | 29 ( 23.4) |
| Influenza | 0 | 0 | 6 ( 4.8) | 6 ( 4.8) | 6 ( 4.8) |
| Rhinovirus infection | 0 | 0 | 5 ( 4.0) | 5 ( 4.0) | 5 ( 4.0) |
| Corona virus infection | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Herpes zoster | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Respiratory syncytial virus infection | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
Date/time of run: 15JUL2021 10:34
Analysis Plan: 12MAY2021 Confidential

Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Oral herpes | 0 | 0 | 3 ( 2.4) | 3 ( 2.4) | 3 ( 2.4) |
| Parainfluenzae virus infection | 1 ( 0.8) | 0 | 2 ( 1.6) | 2 ( 1.6) | 3 ( 2.4) |
| Skin papilloma | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| H1N1 influenza | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Herpes simplex | 0 | 1 ( 0.8) | 0 | 1 ( 0.8) | 1 ( 0.8) |
| Infections-Bacterial | 2 ( 1.6) | 0 | 17 ( 13.7) | 17 ( 13.7) | 19 ( 15.3) |
| Clostridium difficile infection | 0 | 0 | 4 ( 3.2) | 4 ( 3.2) | 4 ( 3.2) |
| Clostridium difficile colitis | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
Date/time of run: 15JUL2021 10:34
Analysis Plan: 12MAY2021 Confidential

Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Urinary tract infection bacterial | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Bronchitis haemophilus | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Cellulitis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Enterococcal infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Escherichia bacteraemia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Escherichia urinary tract infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Gastroenteritis salmonella | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Pseudomonas infection | 1 ( 0.8) | 0 | 1 ( 0.8) | 1 ( 0.8) | 2 ( 1.6) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
Date/time of run: 15JUL2021 10:34
Analysis Plan: 12MAY2021 Confidential

Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Staphylococcal infection | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Streptococcal bacteraemia | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Upper respiratory tract infection bacterial | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Typhoid fever | 1 ( 0.8) | 0 | 0 | 0 | 1 ( 0.8) |
| Infections-Fungal | 1 ( 0.8) | 1 ( 0.8) | 9 ( 7.3) | 10 ( 8.1) | 11 ( 8.9) |
| Candida infection | 0 | 0 | 5 ( 4.0) | 5 ( 4.0) | 5 ( 4.0) |
| Oral candidiasis | 0 | 1 ( 0.8) | 3 ( 2.4) | 4 ( 3.2) | 4 ( 3.2) |
| Bronchopulmonary aspergillosis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
Date/time of run: 15JUL2021 10:34
Analysis Plan: 12MAY2021 Confidential

Table 10.4.1d
Grade 1 or 2 Adverse Events of Special Interest (AESI)/Selected Adverse Events by AESI/Selected Adverse Events by Category and Preferred
Term (Including Neurotoxicity Signs or Symptoms)
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Overall

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=124) | | | | |
|---|---|---|---|---|---|
| AESI/Selected AEs Category [a]<br>Preferred Term [b] | Leukapheresis to LD-Chemo [c]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) | Leukapheresis to End of Follow-up<br>n (%) |
| Onychomycosis | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Skin candida | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Tinea infection | 1 ( 0.8) | 0 | 0 | 0 | 1 ( 0.8) |
| New Malignancy | 0 | 0 | 6 ( 4.8) | 6 ( 4.8) | 6 ( 4.8) |
| Basal cell carcinoma | 0 | 0 | 5 ( 4.0) | 5 ( 4.0) | 5 ( 4.0) |
| Squamous cell carcinoma | 0 | 0 | 1 ( 0.8) | 1 ( 0.8) | 1 ( 0.8) |
| Macrophage Activation Syndrome (MAS) | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |
| Haemophagocytic lymphohistiocytosis | 0 | 0 | 2 ( 1.6) | 2 ( 1.6) | 2 ( 1.6) |

A preferred term may be seen in multiple AESI/Selected AE categories.
[a] AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms. A subject is counted
only once for multiple events within each AESI/Selected AEs category. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgment.
[b] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term.
[c] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_1_1.SAS
Date/time of run: 15JUL2021 10:34
Analysis Plan: 12MAY2021 Confidential

# 8. Subgruppenanalysen (Datenschnitt vom 21.12.2020)

## 8.1 Gesamtüberleben

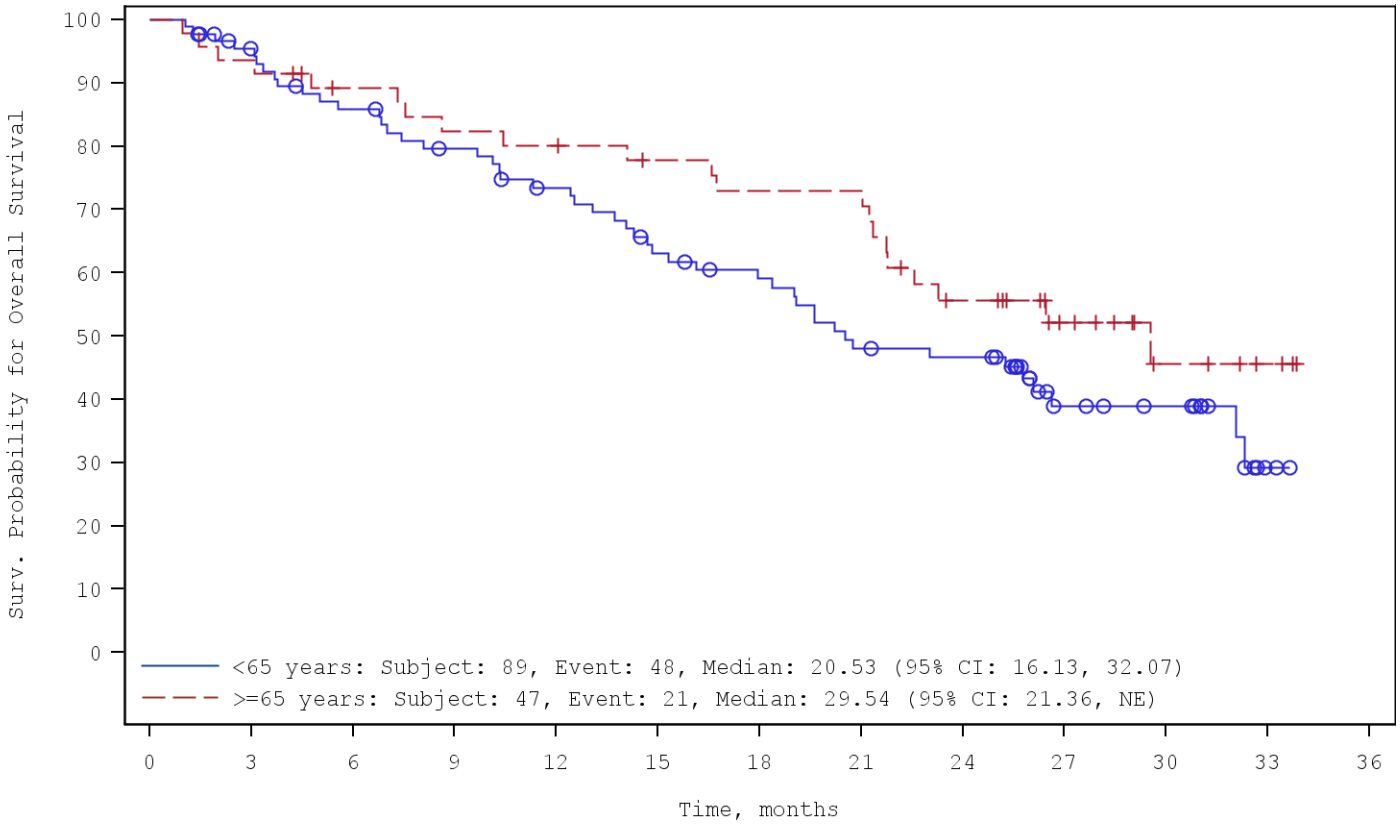
Table 1.2d
Summary of Overall Survival by Age Group 1
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | <65 years (N=89) | >=65 years (N=47) |
|---|---|---|---|
| Overall Survival (OS) | N | 89 | 47 |
| Censored | n (%) | 41 ( 46.1) | 26 ( 55.3) |
| Died | n (%) | 48 ( 53.9) | 21 ( 44.7) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | 10.35 (6.77,14.29) | 16.72 (7.33,21.78) |
| | Median (95% CI) | 20.53 (16.13,32.07) | 29.54 (21.36, NE) |
| | 75th Pcnt. (95% CI) | NE (32.07, NE) | NE ( NE , NE) |
| 3 Months Event-Free | % (SE) | 95.4 ( 2.24) | 93.6 ( 3.57) |
| 6 Months Event-Free | % (SE) | 85.8 ( 3.80) | 89.3 ( 4.54) |
| 9 Months Event-Free | % (SE) | 79.7 ( 4.41) | 82.4 ( 5.66) |
| 12 Months Event-Free | % (SE) | 73.4 ( 4.87) | 80.1 ( 5.95) |
| 15 Months Event-Free | % (SE) | 63.1 ( 5.39) | 77.7 ( 6.22) |
| 18 Months Event-Free | % (SE) | 59.1 ( 5.52) | 72.9 ( 6.72) |
| 21 Months Event-Free | % (SE) | 48.1 ( 5.70) | 72.9 ( 6.72) |
| 24 Months Event-Free | % (SE) | 46.7 ( 5.70) | 55.7 ( 7.66) |
| 27 Months Event-Free | % (SE) | 38.9 ( 5.96) | 52.2 ( 7.94) |
| 30 Months Event-Free | % (SE) | 38.9 ( 5.96) | 45.7 ( 9.25) |
| 33 Months Event-Free | % (SE) | 29.2 ( 7.45) | 45.7 ( 9.25) |
| 36 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) |

Note: CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_1_1.SAS
Date/time of run: 18JUN2021 13:11
Analysis Plan: 12MAY2021 Confidential

Figure 1.2d
Kaplan-Meier Curve of Overall Survival by Age Group 1
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells




| No. of Subjects at Risk | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| <65 years: | 89 | 80 | 71 | 64 | 57 | 48 | 43 | 35 | 33 | 16 | 13 | 2 | 0 |
| >=65 years: | 47 | 44 | 39 | 36 | 35 | 32 | 30 | 30 | 21 | 13 | 6 | 3 | 0 |

NE=Not Estimable. Missing categories are not presented. Source Table: Table 1.2d.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_1_1.SAS
Date/time of run: 18JUN2021 13:49
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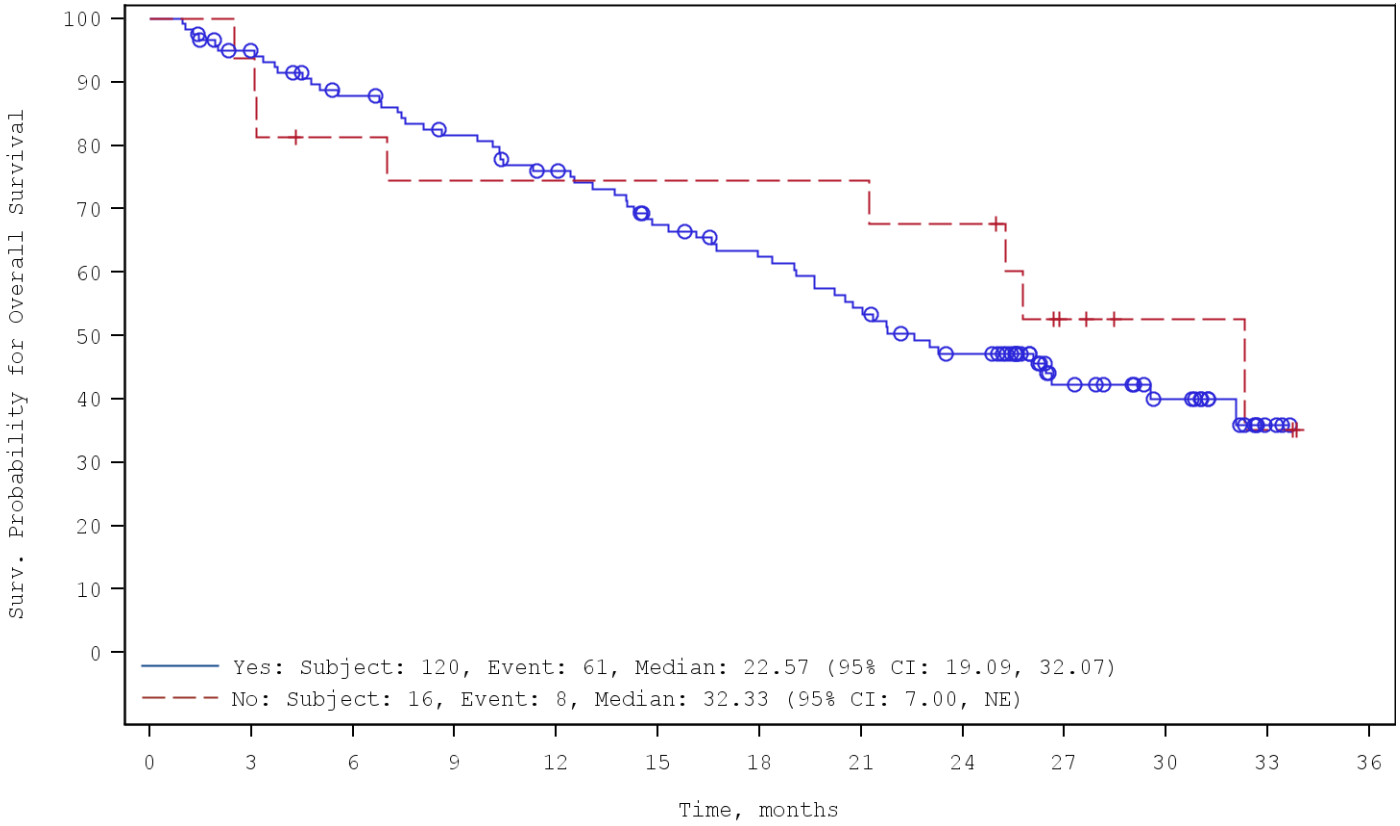
Table 1.2d
Summary of Overall Survival by Double Refractory
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Yes (N=120) | No (N=16) |
|---|---|---|---|
| Overall Survival (OS) | N | 120 | 16 |
| Censored | n (%) | 59 ( 49.2) | 8 ( 50.0) |
| Died | n (%) | 61 ( 50.8) | 8 ( 50.0) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | 12.52 (8.08,15.31) | 7.00 (2.50,25.76) |
| | Median (95% CI) | 22.57 (19.09,32.07) | 32.33 ( 7.00, NE ) |
| | 75th Pcnt. (95% CI) | NE (32.07, NE ) | NE (32.33, NE ) |
| 3 Months Event-Free | % (SE) | 94.9 ( 2.01) | 93.8 ( 6.05) |
| 6 Months Event-Free | % (SE) | 87.9 ( 3.03) | 81.3 ( 9.76) |
| 9 Months Event-Free | % (SE) | 81.5 ( 3.64) | 74.5 (11.05) |
| 12 Months Event-Free | % (SE) | 76.0 ( 4.03) | 74.5 (11.05) |
| 15 Months Event-Free | % (SE) | 67.4 ( 4.48) | 74.5 (11.05) |
| 18 Months Event-Free | % (SE) | 62.4 ( 4.67) | 74.5 (11.05) |
| 21 Months Event-Free | % (SE) | 54.4 ( 4.86) | 74.5 (11.05) |
| 24 Months Event-Free | % (SE) | 47.1 ( 4.92) | 67.7 (11.94) |
| 27 Months Event-Free | % (SE) | 42.3 ( 5.16) | 52.7 (13.20) |
| 30 Months Event-Free | % (SE) | 39.9 ( 5.38) | 52.7 (13.20) |
| 33 Months Event-Free | % (SE) | 35.9 ( 6.15) | 35.1 (16.82) |
| 36 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) |

Note: CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_1_1.SAS
Date/time of run: 18JUN2021 13:11
Analysis Plan: 12MAY2021 Confidential

Figure 1.2d
Kaplan-Meier Curve of Overall Survival by Double Refractory
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells




| No. of Subjects at Risk | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Yes: | 120 | 109 | 98 | 89 | 81 | 69 | 62 | 54 | 44 | 24 | 16 | 3 | 0 |
| No: | 16 | 15 | 12 | 11 | 11 | 11 | 11 | 11 | 10 | 5 | 3 | 2 | 0 |

NE=Not Estimable. Missing categories are not presented. Source Table: Table 1.2d.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_1_1.SAS
Date/time of run: 18JUN2021 13:49
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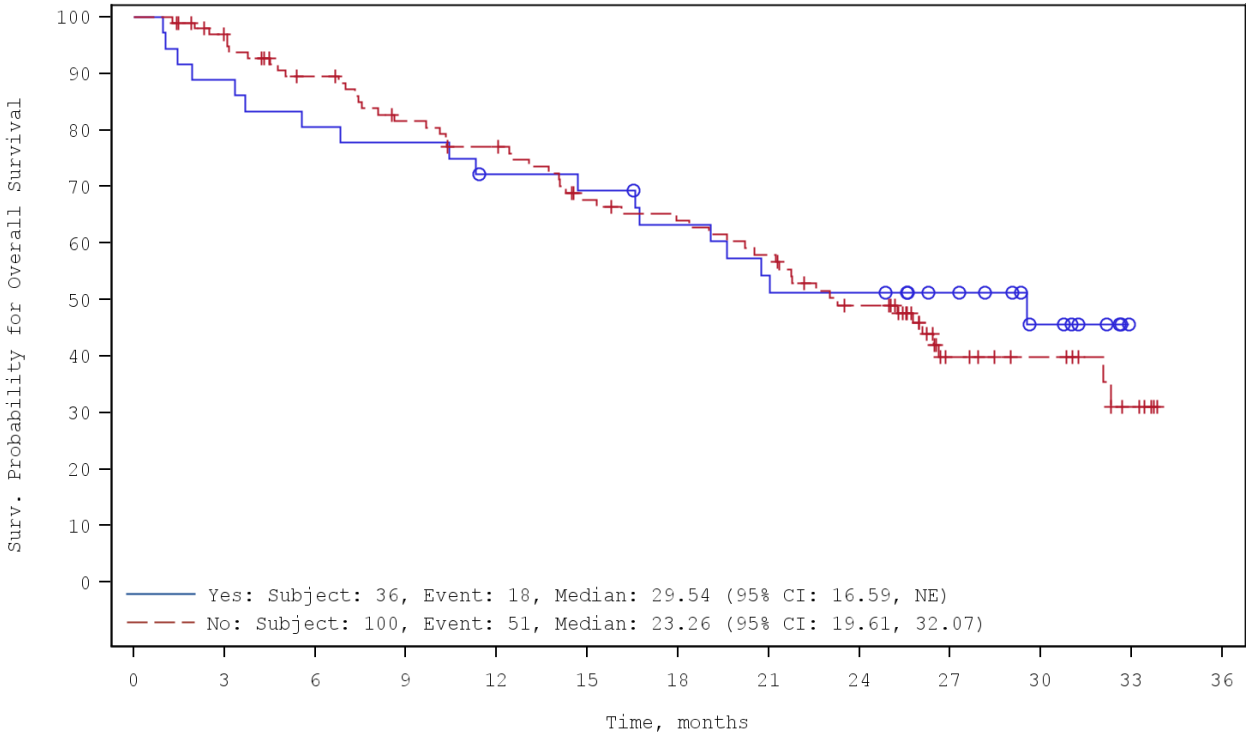
Table 1.2d
Summary of Overall Survival by Penta-refractory
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Yes (N=36) | No (N=100) |
|---|---|---|---|
| Overall Survival (OS) | N | 36 | 100 |
| Censored | n (%) | 18 ( 50.0) | 49 ( 49.0) |
| Died | n (%) | 18 ( 50.0) | 51 ( 51.0) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | 10.87 (1.94,19.09) | 12.52 (7.56,16.13) |
| | Median (95% CI) | 29.54 (16.59, NE) | 23.26 (19.61,32.07) |
| | 75th Pcnt. (95% CI) | NE ( NE , NE) | NE (32.07, NE) |
| 3 Months Event-Free | % (SE) | 88.9 ( 5.24) | 96.9 ( 1.75) |
| 6 Months Event-Free | % (SE) | 80.6 ( 6.60) | 89.4 ( 3.16) |
| 9 Months Event-Free | % (SE) | 77.8 ( 6.93) | 81.6 ( 4.04) |
| 12 Months Event-Free | % (SE) | 72.2 ( 7.47) | 77.1 ( 4.41) |
| 15 Months Event-Free | % (SE) | 69.3 ( 7.71) | 67.7 ( 4.97) |
| 18 Months Event-Free | % (SE) | 63.3 ( 8.13) | 64.0 ( 5.13) |
| 21 Months Event-Free | % (SE) | 54.3 ( 8.48) | 57.9 ( 5.32) |
| 24 Months Event-Free | % (SE) | 51.2 ( 8.53) | 49.0 ( 5.46) |
| 27 Months Event-Free | % (SE) | 51.2 ( 8.53) | 39.8 ( 5.82) |
| 30 Months Event-Free | % (SE) | 45.6 ( 9.29) | 39.8 ( 5.82) |
| 33 Months Event-Free | % (SE) | NE ( NE ) | 31.0 ( 7.14) |
| 36 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) |

Note: CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_1_1.SAS
Date/time of run: 18JUN2021 13:11
Analysis Plan: 12MAY2021 Confidential

Figure 1.2d
Kaplan-Meier Curve of Overall Survival by Penta-refractory
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells




No. of Subjects at Risk

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Yes: | 36 | 32 | 29 | 28 | 25 | 24 | 21 | 18 | 17 | 13 | 7 | 0 | 0 |
| No: | 100 | 92 | 81 | 72 | 67 | 56 | 52 | 47 | 37 | 16 | 12 | 5 | 0 |

NE=Not Estimable. Missing categories are not presented. Source Table: Table 1.2d.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_1_1.SAS
Date/time of run: 18JUN2021 13:49
Analysis Plan: 12MAY2021 Confidential

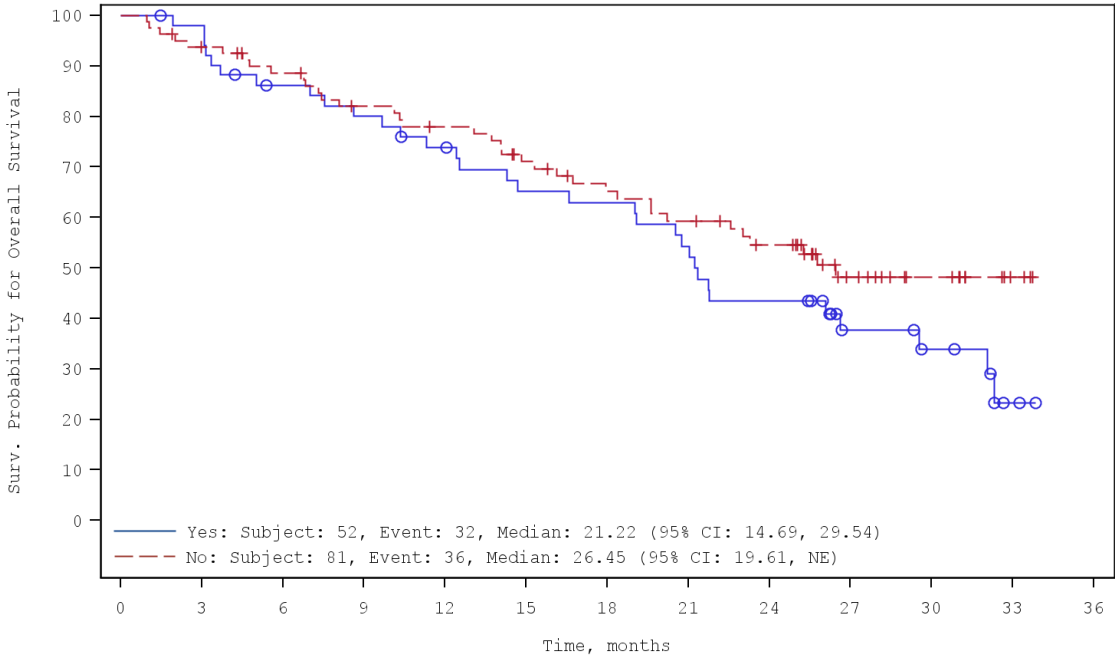
Table 1.2d
Summary of Overall Survival by Presence of Extramedullary Plasmacytoma
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Yes (N=52) | No (N=81) | Missing (N=3) |
|---|---|---|---|---|
| Overall Survival (OS) | N | 52 | 81 | 3 |
| Censored | n (%) | 20 ( 38.5) | 45 ( 55.6) | 2 ( 66.7) |
| Died | n (%) | 32 ( 61.5) | 36 ( 44.4) | 1 ( 33.3) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | 11.30 (5.03,16.59) | 14.06 (7.33,17.94) | NE* |
| | Median (95% CI) | 21.22 (14.69,29.54) | 26.45 (19.61, NE) | NE* |
| | 75th Pcnt. (95% CI) | 32.33 (26.61, NE) | NE ( NE , NE) | NE* |
| 3 Months Event-Free | % (SE) | 98.0 ( 1.94) | 93.8 ( 2.69) | NE* |
| 6 Months Event-Free | % (SE) | 86.2 ( 4.83) | 88.6 ( 3.58) | NE* |
| 9 Months Event-Free | % (SE) | 80.1 ( 5.65) | 82.0 ( 4.36) | NE* |
| 12 Months Event-Free | % (SE) | 73.9 ( 6.25) | 78.0 ( 4.73) | NE* |
| 15 Months Event-Free | % (SE) | 65.2 ( 6.86) | 71.1 ( 5.22) | NE* |
| 18 Months Event-Free | % (SE) | 63.0 ( 6.96) | 65.2 ( 5.55) | NE* |
| 21 Months Event-Free | % (SE) | 54.3 ( 7.23) | 59.3 ( 5.78) | NE* |
| 24 Months Event-Free | % (SE) | 43.4 ( 7.24) | 54.6 ( 5.92) | NE* |
| 27 Months Event-Free | % (SE) | 37.7 ( 7.34) | 48.2 ( 6.30) | NE* |
| 30 Months Event-Free | % (SE) | 34.0 ( 7.51) | 48.2 ( 6.30) | NE* |
| 33 Months Event-Free | % (SE) | 23.3 ( 8.16) | 48.2 ( 6.30) | NE* |
| 36 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) | NE* |

Note: CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_1_1.SAS
Date/time of run: 18JUN2021 13:11
Analysis Plan: 12MAY2021 Confidential

Figure 1.2d
Kaplan-Meier Curve of Overall Survival by Presence of Extramedullary Plasmacytoma
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells




No. of Subjects at Risk

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Yes: | 52 | 50 | 42 | 39 | 35 | 30 | 29 | 25 | 20 | 11 | 8 | 2 | 0 |
| No: | 81 | 74 | 68 | 61 | 57 | 50 | 44 | 40 | 34 | 18 | 11 | 3 | 0 |

NE=Not Estimable. Missing categories are not presented. Source Table: Table 1.2d.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Fig_1_1.SAS
Date/time of run: 18JUN2021 13:49
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## 8.2 Ansprechen

Table 12.1d
Summary of ORR and CR based on IMWG Criteria - IRC Review, by Age Group 1
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | <65 years (N=89) | >=65 years (N=47) |
|---|---|---|
| Overall Response Rate - n (%) [a] | 55 ( 61.8) | 37 ( 78.7) |
| 95% CI [b] | 50.9, 71.9 | 64.3, 89.3 |
| Complete Response Rate - n (%) [a] | 27 ( 30.3) | 14 ( 29.8) |
| 95% CI [b] | 21.0, 41.0 | 17.3, 44.9 |

IMWG = International Myeloma Working Group; IRC = Independent Response Committee; CI = Confidence Interval.
[a] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR);
Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR).
The denominator used for rate calculation is the number of subjects in the designated study population.
[b] Clopper-Pearson exact confidence interval (CI).

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Table 12.1d
Summary of ORR and CR based on IMWG Criteria - IRC Review, by Double Refractory
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Yes (N=120) | No (N=16) |
|---|---|---|
| Overall Response Rate - n (%) [a] | 81 ( 67.5) | 11 ( 68.8) |
| 95% CI [b] | 58.3, 75.8 | 41.3, 89.0 |
| Complete Response Rate - n (%) [a] | 36 ( 30.0) | 5 ( 31.3) |
| 95% CI [b] | 22.0, 39.0 | 11.0, 58.7 |

IMWG = International Myeloma Working Group; IRC = Independent Response Committee; CI = Confidence Interval.
[a] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR);
Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR).
The denominator used for rate calculation is the number of subjects in the designated study population.
[b] Clopper-Pearson exact confidence interval (CI).

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Table 12.1d
Summary of ORR and CR based on IMWG Criteria - IRC Review, by Penta-refractory
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Yes (N=36) | No (N=100) |
|---|---|---|
| Overall Response Rate - n (%) [a] | 24 ( 66.7) | 68 ( 68.0) |
| 95% CI [b] | 49.0, 81.4 | 57.9, 77.0 |
| Complete Response Rate - n (%) [a] | 12 ( 33.3) | 29 ( 29.0) |
| 95% CI [b] | 18.6, 51.0 | 20.4, 38.9 |

IMWG = International Myeloma Working Group; IRC = Independent Response Committee; CI = Confidence Interval.
[a] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR);
Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR).
The denominator used for rate calculation is the number of subjects in the designated study population.
[b] Clopper-Pearson exact confidence interval (CI).

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Table 12.1d
Summary of ORR and CR based on IMWG Criteria - IRC Review, by Presence of Extramedullary Plasmacytoma
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Yes (N=52) | No (N=81) | Missing (N=3) |
|---|---|---|---|
| Overall Response Rate - n (%) [a] | 35 ( 67.3) | 57 ( 70.4) | 0 |
| 95% CI [b] | 52.9, 79.7 | 59.2, 80.0 | 0.0, 70.8 |
| Complete Response Rate - n (%) [a] | 11 ( 21.2) | 30 ( 37.0) | 0 |
| 95% CI [b] | 11.1, 34.7 | 26.6, 48.5 | 0.0, 70.8 |

IMWG = International Myeloma Working Group; IRC = Independent Response Committee; CI = Confidence Interval.
[a] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR);
Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR).
The denominator used for rate calculation is the number of subjects in the designated study population.
[b] Clopper-Pearson exact confidence interval (CI).

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Progressionsfreies Überleben

Table 3.2d
Summary of Progression-free Survival Based on IMWG Criteria by Age Group 1 - IRC Review
Censoring Rules According to EMA Guideline
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | <65 years (N=89) | >=65 years (N=47) |
|---|---|---|---|
| Progression-free Survival (PFS) | N | 89 | 47 |
| Censored | n (%) | 20 ( 22.5) | 5 ( 10.6) |
| Progressed/Died | n (%) | 69 ( 77.5) | 42 ( 89.4) |
| Progressed | n (%) | 59 ( 66.3) | 37 ( 78.7) |
| Died | n (%) | 10 ( 11.2) | 5 ( 10.6) |
| Progression-free Survival Time (months) [a] | 25th Pcnt. (95% CI) | 4.27 ( 3.06, 5.52) | 4.24 ( 3.02, 6.41) |
| | Median (95% CI) | 9.07 ( 6.21,11.99) | 9.46 ( 6.24,13.54) |
| | 75th Pcnt. (95% CI) | 16.39 (12.91, NE ) | 18.07 (13.14,21.45) |
| 3 Months Event-Free | % (SE) | 85.8 ( 3.80) | 89.4 ( 4.50) |
| 6 Months Event-Free | % (SE) | 63.2 ( 5.26) | 66.0 ( 6.91) |
| 9 Months Event-Free | % (SE) | 50.1 ( 5.46) | 51.1 ( 7.29) |
| 12 Months Event-Free | % (SE) | 39.2 ( 5.34) | 42.6 ( 7.21) |
| 15 Months Event-Free | % (SE) | 26.9 ( 4.88) | 25.5 ( 6.36) |
| 18 Months Event-Free | % (SE) | 23.3 ( 4.65) | 25.5 ( 6.36) |
| 21 Months Event-Free | % (SE) | 19.6 ( 4.37) | 19.1 ( 5.74) |
| 24 Months Event-Free | % (SE) | 18.3 ( 4.27) | 10.2 ( 4.51) |
| 27 Months Event-Free | % (SE) | 15.7 ( 4.39) | 10.2 ( 4.51) |
| 30 Months Event-Free | % (SE) | 15.7 ( 4.39) | 10.2 ( 4.51) |
| 33 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) |
| 36 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) |

Note: CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

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Table 3.2d
Summary of Progression-free Survival Based on IMWG Criteria by Double Refractory - IRC Review
Censoring Rules According to EMA Guideline
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Yes (N=120) | No (N=16) |
|---|---|---|---|
| Progression-free Survival (PFS) | N | 120 | 16 |
| Censored | n (%) | 23 ( 19.2) | 2 ( 12.5) |
| Progressed/Died | n (%) | 97 ( 80.8) | 14 ( 87.5) |
| Progressed | n (%) | 84 ( 70.0) | 12 ( 75.0) |
| Died | n (%) | 13 ( 10.8) | 2 ( 12.5) |
| Progression-free Survival Time (months) [a] | 25th Pcnt. (95% CI) | 4.24 ( 3.22, 5.16) | 4.62 ( 2.23,12.06) |
| | Median (95% CI) | 7.95 ( 6.41,10.87) | 12.50 ( 2.50,18.89) |
| | 75th Pcnt. (95% CI) | 15.77 (13.44,21.45) | 18.96 (12.06, NE ) |
| 3 Months Event-Free | % (SE) | 88.8 ( 2.94) | 75.0 (10.83) |
| 6 Months Event-Free | % (SE) | 62.7 ( 4.51) | 75.0 (10.83) |
| 9 Months Event-Free | % (SE) | 48.7 ( 4.66) | 62.5 (12.10) |
| 12 Months Event-Free | % (SE) | 38.2 ( 4.54) | 56.3 (12.40) |
| 15 Months Event-Free | % (SE) | 25.7 ( 4.10) | 31.3 (11.59) |
| 18 Months Event-Free | % (SE) | 23.1 ( 3.95) | 31.3 (11.59) |
| 21 Months Event-Free | % (SE) | 19.5 ( 3.72) | 18.8 ( 9.76) |
| 24 Months Event-Free | % (SE) | 15.8 ( 3.45) | 12.5 ( 8.27) |
| 27 Months Event-Free | % (SE) | 14.0 ( 3.48) | 12.5 ( 8.27) |
| 30 Months Event-Free | % (SE) | 14.0 ( 3.48) | NE ( NE ) |
| 33 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) |
| 36 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) |

Note: CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

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Table 3.2d
Summary of Progression-free Survival Based on IMWG Criteria by Penta-refractory - IRC Review
Censoring Rules According to EMA Guideline
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Yes (N=36) | No (N=100) |
|---|---|---|---|
| Progression-free Survival (PFS) | N | 36 | 100 |
| Censored | n (%) | 9 ( 25.0) | 16 ( 16.0) |
| Progressed/Died | n (%) | 27 ( 75.0) | 84 ( 84.0) |
| Progressed | n (%) | 21 ( 58.3) | 75 ( 75.0) |
| Died | n (%) | 6 ( 16.7) | 9 ( 9.0) |
| Progression-free Survival Time (months) [a] | 25th Pcnt. (95% CI) | 4.47 ( 1.91, 6.21) | 4.17 ( 3.22, 5.29) |
| | Median (95% CI) | 8.77 ( 5.55,11.96) | 9.07 ( 6.74,12.68) |
| | 75th Pcnt. (95% CI) | 21.03 ( 9.95, NE ) | 16.39 (13.54,21.36) |
| 3 Months Event-Free | % (SE) | 83.3 ( 6.21) | 88.5 ( 3.27) |
| 6 Months Event-Free | % (SE) | 66.7 ( 7.86) | 63.2 ( 4.95) |
| 9 Months Event-Free | % (SE) | 50.0 ( 8.33) | 50.6 ( 5.13) |
| 12 Months Event-Free | % (SE) | 32.9 ( 7.90) | 43.2 ( 5.08) |
| 15 Months Event-Free | % (SE) | 26.9 ( 7.51) | 26.3 ( 4.52) |
| 18 Months Event-Free | % (SE) | 26.9 ( 7.51) | 23.2 ( 4.33) |
| 21 Months Event-Free | % (SE) | 26.9 ( 7.51) | 16.9 ( 3.84) |
| 24 Months Event-Free | % (SE) | 23.9 ( 7.25) | 12.2 ( 3.42) |
| 27 Months Event-Free | % (SE) | 23.9 ( 7.25) | 9.7 ( 3.50) |
| 30 Months Event-Free | % (SE) | 23.9 ( 7.25) | 9.7 ( 3.50) |
| 33 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) |
| 36 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) |

Note: CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

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Table 3.2d
Summary of Progression-free Survival Based on IMWG Criteria by Presence of Extramedullary Plasmacytoma - IRC Review
Censoring Rules According to EMA Guideline
Enrolled Population excluding subjects receiving 150 x 10^6 CAR T cells

| | Statistics | Yes (N=52) | No (N=81) | Missing (N=3) |
|---|---|---|---|---|
| Progression-free Survival (PFS) | N | 52 | 81 | 3 |
| Censored | n (%) | 4 ( 7.7) | 19 ( 23.5) | 2 ( 66.7) |
| Progressed/Died | n (%) | 48 ( 92.3) | 62 ( 76.5) | 1 ( 33.3) |
| Progressed | n (%) | 43 ( 82.7) | 53 ( 65.4) | 0 ( 0.0) |
| Died | n (%) | 5 ( 9.6) | 9 ( 11.1) | 1 ( 33.3) |
| Progression-free Survival Time (months) [a] | 25th Pcnt. (95% CI) | 4.04 ( 3.02, 6.41) | 4.24 ( 3.12, 5.55) | NE* |
| | Median (95% CI) | 7.33 ( 5.95,11.99) | 10.18 ( 6.24,13.34) | NE* |
| | 75th Pcnt. (95% CI) | 13.50 (10.32,17.54) | 21.45 (13.67, NE ) | NE* |
| 3 Months Event-Free | % (SE) | 88.2 ( 4.51) | 87.4 ( 3.71) | NE* |
| 6 Months Event-Free | % (SE) | 64.7 ( 6.69) | 64.6 ( 5.38) | NE* |
| 9 Months Event-Free | % (SE) | 47.1 ( 6.99) | 53.2 ( 5.61) | NE* |
| 12 Months Event-Free | % (SE) | 33.3 ( 6.60) | 45.5 ( 5.62) | NE* |
| 15 Months Event-Free | % (SE) | 19.6 ( 5.56) | 31.2 ( 5.25) | NE* |
| 18 Months Event-Free | % (SE) | 13.7 ( 4.82) | 31.2 ( 5.25) | NE* |
| 21 Months Event-Free | % (SE) | 7.8 ( 3.76) | 27.3 ( 5.05) | NE* |
| 24 Months Event-Free | % (SE) | 5.9 ( 3.29) | 21.7 ( 4.73) | NE* |
| 27 Months Event-Free | % (SE) | 5.9 ( 3.29) | 19.0 ( 4.86) | NE* |
| 30 Months Event-Free | % (SE) | 5.9 ( 3.29) | 19.0 ( 4.86) | NE* |
| 33 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) | NE* |
| 36 Months Event-Free | % (SE) | NE ( NE ) | NE ( NE ) | NE* |

Note: CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

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## 8.3 Verträglichkeit

### 8.3.2 UE Gesamtraten

Table 8.1.2d
Adverse Events (AEs) Summary (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) |
| Subjects with at least one AE | 41 ( 51.3) | 67 ( 83.8) | 80 (100.0) | 80 (100.0) |
| Subjects with at least one AE related to LD-Chemotherapy | 2 ( 2.5) | 58 ( 72.5) | 76 ( 95.0) | 78 ( 97.5) |
| Subjects with at least one AE related to bb2121 | 0 | 6 ( 7.5) | 78 ( 97.5) | 78 ( 97.5) |
| Subjects with at least one SAE | 15 ( 18.8) | 6 ( 7.5) | 51 ( 63.8) | 51 ( 63.8) |
| Subjects with at least one SAE related to LD-Chemotherapy | 0 | 1 ( 1.3) | 13 ( 16.3) | 13 ( 16.3) |
| Subjects with at least one SAE related to bb2121 | 0 | 1 ( 1.3) | 28 ( 35.0) | 28 ( 35.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE | 32 ( 40.0) | 62 ( 77.5) | 80 (100.0) | 80 (100.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to LD-Chemotherapy | 2 ( 2.5) | 49 ( 61.3) | 67 ( 83.8) | 76 ( 95.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to bb2121 | 0 | 1 ( 1.3) | 77 ( 96.3) | 77 ( 96.3) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE | 26 ( 32.5) | 45 ( 56.3) | 79 ( 98.8) | 79 ( 98.8) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to LD-Chemotherapy | 0 | 42 ( 52.5) | 68 ( 85.0) | 70 ( 87.5) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to bb2121 | 0 | 5 ( 6.3) | 58 ( 72.5) | 58 ( 72.5) |

[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 8.1.2d
Adverse Events (AEs) Summary (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) |
| Subjects with at least one AE | 21 ( 47.7) | 40 ( 90.9) | 44 (100.0) | 44 (100.0) |
| Subjects with at least one AE related to LD-Chemotherapy | 0 | 33 ( 75.0) | 43 ( 97.7) | 43 ( 97.7) |
| Subjects with at least one AE related to bb2121 | 0 | 0 | 43 ( 97.7) | 43 ( 97.7) |
| Subjects with at least one SAE | 7 ( 15.9) | 2 ( 4.5) | 35 ( 79.5) | 35 ( 79.5) |
| Subjects with at least one SAE related to LD-Chemotherapy | 0 | 1 ( 2.3) | 8 ( 18.2) | 8 ( 18.2) |
| Subjects with at least one SAE related to bb2121 | 0 | 0 | 15 ( 34.1) | 15 ( 34.1) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE | 18 ( 40.9) | 38 ( 86.4) | 44 (100.0) | 44 (100.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to LD-Chemotherapy | 0 | 30 ( 68.2) | 39 ( 88.6) | 42 ( 95.5) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to bb2121 | 0 | 0 | 43 ( 97.7) | 43 ( 97.7) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE | 13 ( 29.5) | 22 ( 50.0) | 44 (100.0) | 44 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to LD-Chemotherapy | 0 | 21 ( 47.7) | 43 ( 97.7) | 43 ( 97.7) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to bb2121 | 0 | 0 | 24 ( 54.5) | 24 ( 54.5) |

[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 8.1.2d
Adverse Events (AEs) Summary (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) |
| Subjects with at least one AE | 56 ( 50.9) | 98 ( 89.1) | 110 (100.0) | 110 (100.0) |
| Subjects with at least one AE related to LD-Chemotherapy | 2 ( 1.8) | 85 ( 77.3) | 107 ( 97.3) | 109 ( 99.1) |
| Subjects with at least one AE related to bb2121 | 0 | 5 ( 4.5) | 107 ( 97.3) | 107 ( 97.3) |
| Subjects with at least one SAE | 21 ( 19.1) | 6 ( 5.5) | 73 ( 66.4) | 73 ( 66.4) |
| Subjects with at least one SAE related to LD-Chemotherapy | 0 | 2 ( 1.8) | 19 ( 17.3) | 19 ( 17.3) |
| Subjects with at least one SAE related to bb2121 | 0 | 1 ( 0.9) | 36 ( 32.7) | 36 ( 32.7) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE | 45 ( 40.9) | 92 ( 83.6) | 110 (100.0) | 110 (100.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to LD-Chemotherapy | 2 ( 1.8) | 73 ( 66.4) | 96 ( 87.3) | 108 ( 98.2) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to bb2121 | 0 | 0 | 106 ( 96.4) | 106 ( 96.4) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE | 36 ( 32.7) | 63 ( 57.3) | 110 (100.0) | 110 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to LD-Chemotherapy | 0 | 60 ( 54.5) | 101 ( 91.8) | 103 ( 93.6) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to bb2121 | 0 | 5 ( 4.5) | 73 ( 66.4) | 73 ( 66.4) |

[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 8.1.2d
Adverse Events (AEs) Summary (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) |
| Subjects with at least one AE | 6 ( 42.9) | 9 ( 64.3) | 14 (100.0) | 14 (100.0) |
| Subjects with at least one AE related to LD-Chemotherapy | 0 | 6 ( 42.9) | 12 ( 85.7) | 12 ( 85.7) |
| Subjects with at least one AE related to bb2121 | 0 | 1 ( 7.1) | 14 (100.0) | 14 (100.0) |
| Subjects with at least one SAE | 1 ( 7.1) | 2 ( 14.3) | 13 ( 92.9) | 13 ( 92.9) |
| Subjects with at least one SAE related to LD-Chemotherapy | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Subjects with at least one SAE related to bb2121 | 0 | 0 | 7 ( 50.0) | 7 ( 50.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE | 5 ( 35.7) | 8 ( 57.1) | 14 (100.0) | 14 (100.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to LD-Chemotherapy | 0 | 6 ( 42.9) | 10 ( 71.4) | 10 ( 71.4) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to bb2121 | 0 | 1 ( 7.1) | 14 (100.0) | 14 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE | 3 ( 21.4) | 4 ( 28.6) | 13 ( 92.9) | 13 ( 92.9) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to LD-Chemotherapy | 0 | 3 ( 21.4) | 10 ( 71.4) | 10 ( 71.4) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to bb2121 | 0 | 0 | 9 ( 64.3) | 9 ( 64.3) |

[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 8.1.2d
Adverse Events (AEs) Summary (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) |
| Subjects with at least one AE | 18 ( 56.3) | 31 ( 96.9) | 32 (100.0) | 32 (100.0) |
| Subjects with at least one AE related to LD-Chemotherapy | 0 | 26 ( 81.3) | 31 ( 96.9) | 32 (100.0) |
| Subjects with at least one AE related to bb2121 | 0 | 0 | 31 ( 96.9) | 31 ( 96.9) |
| Subjects with at least one SAE | 7 ( 21.9) | 2 ( 6.3) | 19 ( 59.4) | 19 ( 59.4) |
| Subjects with at least one SAE related to LD-Chemotherapy | 0 | 0 | 6 ( 18.8) | 6 ( 18.8) |
| Subjects with at least one SAE related to bb2121 | 0 | 0 | 9 ( 28.1) | 9 ( 28.1) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE | 15 ( 46.9) | 30 ( 93.8) | 32 (100.0) | 32 (100.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to LD-Chemotherapy | 0 | 22 ( 68.8) | 31 ( 96.9) | 32 (100.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to bb2121 | 0 | 0 | 31 ( 96.9) | 31 ( 96.9) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE | 11 ( 34.4) | 23 ( 71.9) | 32 (100.0) | 32 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to LD-Chemotherapy | 0 | 21 ( 65.6) | 30 ( 93.8) | 32 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to bb2121 | 0 | 0 | 16 ( 50.0) | 16 ( 50.0) |

[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_8_1_2.SAS
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Table 8.1.2d
Adverse Events (AEs) Summary (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) |
| Subjects with at least one AE | 44 ( 47.8) | 76 ( 82.6) | 92 (100.0) | 92 (100.0) |
| Subjects with at least one AE related to LD-Chemotherapy | 2 ( 2.2) | 65 ( 70.7) | 88 ( 95.7) | 89 ( 96.7) |
| Subjects with at least one AE related to bb2121 | 0 | 6 ( 6.5) | 90 ( 97.8) | 90 ( 97.8) |
| Subjects with at least one SAE | 15 ( 16.3) | 6 ( 6.5) | 67 ( 72.8) | 67 ( 72.8) |
| Subjects with at least one SAE related to LD-Chemotherapy | 0 | 2 ( 2.2) | 15 ( 16.3) | 15 ( 16.3) |
| Subjects with at least one SAE related to bb2121 | 0 | 1 ( 1.1) | 34 ( 37.0) | 34 ( 37.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE | 35 ( 38.0) | 70 ( 76.1) | 92 (100.0) | 92 (100.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to LD-Chemotherapy | 2 ( 2.2) | 57 ( 62.0) | 75 ( 81.5) | 86 ( 93.5) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to bb2121 | 0 | 1 ( 1.1) | 89 ( 96.7) | 89 ( 96.7) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE | 28 ( 30.4) | 44 ( 47.8) | 91 ( 98.9) | 91 ( 98.9) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to LD-Chemotherapy | 0 | 42 ( 45.7) | 81 ( 88.0) | 81 ( 88.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to bb2121 | 0 | 5 ( 5.4) | 66 ( 71.7) | 66 ( 71.7) |

[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_8_1_2.SAS
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Table 8.1.2d
Adverse Events (AEs) Summary (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) |
| Subjects with at least one AE | 28 ( 56.0) | 45 ( 90.0) | 50 (100.0) | 50 (100.0) |
| Subjects with at least one AE related to LD-Chemotherapy | 1 ( 2.0) | 40 ( 80.0) | 48 ( 96.0) | 50 (100.0) |
| Subjects with at least one AE related to bb2121 | 0 | 3 ( 6.0) | 49 ( 98.0) | 49 ( 98.0) |
| Subjects with at least one SAE | 13 ( 26.0) | 5 ( 10.0) | 37 ( 74.0) | 37 ( 74.0) |
| Subjects with at least one SAE related to LD-Chemotherapy | 0 | 1 ( 2.0) | 11 ( 22.0) | 11 ( 22.0) |
| Subjects with at least one SAE related to bb2121 | 0 | 0 | 17 ( 34.0) | 17 ( 34.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE | 22 ( 44.0) | 43 ( 86.0) | 50 (100.0) | 50 (100.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to LD-Chemotherapy | 1 ( 2.0) | 36 ( 72.0) | 43 ( 86.0) | 49 ( 98.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to bb2121 | 0 | 1 ( 2.0) | 48 ( 96.0) | 48 ( 96.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE | 21 ( 42.0) | 29 ( 58.0) | 50 (100.0) | 50 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to LD-Chemotherapy | 0 | 27 ( 54.0) | 44 ( 88.0) | 46 ( 92.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to bb2121 | 0 | 2 ( 4.0) | 33 ( 66.0) | 33 ( 66.0) |

[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_8_1_2.SAS
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Table 8.1.2d
Adverse Events (AEs) Summary (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) |
| Subjects with at least one AE | 34 ( 45.9) | 62 ( 83.8) | 74 (100.0) | 74 (100.0) |
| Subjects with at least one AE related to LD-Chemotherapy | 1 ( 1.4) | 51 ( 68.9) | 71 ( 95.9) | 71 ( 95.9) |
| Subjects with at least one AE related to bb2121 | 0 | 3 ( 4.1) | 72 ( 97.3) | 72 ( 97.3) |
| Subjects with at least one SAE | 9 ( 12.2) | 3 ( 4.1) | 49 ( 66.2) | 49 ( 66.2) |
| Subjects with at least one SAE related to LD-Chemotherapy | 0 | 1 ( 1.4) | 10 ( 13.5) | 10 ( 13.5) |
| Subjects with at least one SAE related to bb2121 | 0 | 1 ( 1.4) | 26 ( 35.1) | 26 ( 35.1) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE | 28 ( 37.8) | 57 ( 77.0) | 74 (100.0) | 74 (100.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to LD-Chemotherapy | 1 ( 1.4) | 43 ( 58.1) | 63 ( 85.1) | 69 ( 93.2) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AE related to bb2121 | 0 | 0 | 72 ( 97.3) | 72 ( 97.3) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE | 18 ( 24.3) | 38 ( 51.4) | 73 ( 98.6) | 73 ( 98.6) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to LD-Chemotherapy | 0 | 36 ( 48.6) | 67 ( 90.5) | 67 ( 90.5) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AE related to bb2121 | 0 | 3 ( 4.1) | 49 ( 66.2) | 49 ( 66.2) |

[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_8_1_2.SAS
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### 8.3.3 UESI

Table 10.5.1d
Adverse Events of Special Interest (AESI)/Selected Adverse Events Summary, Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | | |
|---|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) | Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI/Selected AEs | 33 ( 41.3) | 51 ( 63.8) | 79 ( 98.8) | 79 ( 98.8) | 79 ( 98.8) |
| Subjects with at least one serious AESI/Selected AEs | 8 ( 10.0) | 2 ( 2.5) | 43 ( 53.8) | 43 ( 53.8) | 46 ( 57.5) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI/Selected AEs | 23 ( 28.8) | 37 ( 46.3) | 78 ( 97.5) | 78 ( 97.5) | 78 ( 97.5) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI/Selected AEs | 22 ( 27.5) | 43 ( 53.8) | 78 ( 97.5) | 79 ( 98.8) | 79 ( 98.8) |

AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms.
[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_5_1.SAS
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Table 10.5.1d
Adverse Events of Special Interest (AESI)/Selected Adverse Events Summary, Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44) | | | | |
|---|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) | Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI/Selected AEs | 14 ( 31.8) | 27 ( 61.4) | 44 (100.0) | 44 (100.0) | 44 (100.0) |
| Subjects with at least one serious AESI/Selected AEs | 2 ( 4.5) | 1 ( 2.3) | 26 ( 59.1) | 26 ( 59.1) | 27 ( 61.4) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI/Selected AEs | 11 ( 25.0) | 23 ( 52.3) | 44 (100.0) | 44 (100.0) | 44 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI/Selected AEs | 10 ( 22.7) | 22 ( 50.0) | 44 (100.0) | 44 (100.0) | 44 (100.0) |

AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms.
[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_5_1.SAS
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Table 10.5.1d
Adverse Events of Special Interest (AESI)/Selected Adverse Events Summary, Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110) | | | | |
|---|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) | Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI/Selected AEs | 42 ( 38.2) | 73 ( 66.4) | 110 (100.0) | 110 (100.0) | 110 (100.0) |
| Subjects with at least one serious AESI/Selected AEs | 10 ( 9.1) | 2 ( 1.8) | 57 ( 51.8) | 57 ( 51.8) | 61 ( 55.5) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI/Selected AEs | 30 ( 27.3) | 56 ( 50.9) | 109 ( 99.1) | 109 ( 99.1) | 109 ( 99.1) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI/Selected AEs | 29 ( 26.4) | 62 ( 56.4) | 109 ( 99.1) | 110 (100.0) | 110 (100.0) |

AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms.
[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_5_1.SAS
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Table 10.5.1d
Adverse Events of Special Interest (AESI)/Selected Adverse Events Summary, Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14) | | | | |
|---|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) | Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI/Selected AEs | 5 ( 35.7) | 5 ( 35.7) | 13 ( 92.9) | 13 ( 92.9) | 13 ( 92.9) |
| Subjects with at least one serious AESI/Selected AEs | 0 | 1 ( 7.1) | 12 ( 85.7) | 12 ( 85.7) | 12 ( 85.7) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI/Selected AEs | 4 ( 28.6) | 4 ( 28.6) | 13 ( 92.9) | 13 ( 92.9) | 13 ( 92.9) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI/Selected AEs | 3 ( 21.4) | 3 ( 21.4) | 13 ( 92.9) | 13 ( 92.9) | 13 ( 92.9) |

AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms.
[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_5_1.SAS
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Table 10.5.1d
Adverse Events of Special Interest (AESI)/Selected Adverse Events Summary, Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | | |
|---|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) | Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI/Selected AEs | 15 ( 46.9) | 24 ( 75.0) | 32 (100.0) | 32 (100.0) | 32 (100.0) |
| Subjects with at least one serious AESI/Selected AEs | 3 ( 9.4) | 0 | 13 ( 40.6) | 13 ( 40.6) | 14 ( 43.8) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI/Selected AEs | 11 ( 34.4) | 19 ( 59.4) | 31 ( 96.9) | 31 ( 96.9) | 31 ( 96.9) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI/Selected AEs | 10 ( 31.3) | 23 ( 71.9) | 31 ( 96.9) | 32 (100.0) | 32 (100.0) |

AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms.
[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_5_1.SAS
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Table 10.5.1d
Adverse Events of Special Interest (AESI)/Selected Adverse Events Summary, Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | | |
|---|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) | Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI/Selected AEs | 32 ( 34.8) | 54 ( 58.7) | 91 ( 98.9) | 91 ( 98.9) | 91 ( 98.9) |
| Subjects with at least one serious AESI/Selected AEs | 7 ( 7.6) | 3 ( 3.3) | 56 ( 60.9) | 56 ( 60.9) | 59 ( 64.1) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI/Selected AEs | 23 ( 25.0) | 41 ( 44.6) | 91 ( 98.9) | 91 ( 98.9) | 91 ( 98.9) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI/Selected AEs | 22 ( 23.9) | 42 ( 45.7) | 91 ( 98.9) | 91 ( 98.9) | 91 ( 98.9) |

AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms.
[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_5_1.SAS
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Table 10.5.1d
Adverse Events of Special Interest (AESI)/Selected Adverse Events Summary, Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | | |
|---|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) | Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI/Selected AEs | 23 ( 46.0) | 33 ( 66.0) | 50 (100.0) | 50 (100.0) | 50 (100.0) |
| Subjects with at least one serious AESI/Selected AEs | 6 ( 12.0) | 1 ( 2.0) | 29 ( 58.0) | 29 ( 58.0) | 31 ( 62.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI/Selected AEs | 14 ( 28.0) | 23 ( 46.0) | 49 ( 98.0) | 49 ( 98.0) | 49 ( 98.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI/Selected AEs | 18 ( 36.0) | 28 ( 56.0) | 49 ( 98.0) | 50 (100.0) | 50 (100.0) |

AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms.
[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_10_5_1.SAS
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Table 10.5.1d
Adverse Events of Special Interest (AESI)/Selected Adverse Events Summary, Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | | |
|---|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b] n (%) | LD-Chemo to bb2121 Infusion n (%) | On or After bb2121 Infusion n (%) | LD-Chemo to End of Follow-up n (%) | Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI/Selected AEs | 24 ( 32.4) | 45 ( 60.8) | 73 ( 98.6) | 73 ( 98.6) | 73 ( 98.6) |
| Subjects with at least one serious AESI/Selected AEs | 4 ( 5.4) | 2 ( 2.7) | 40 ( 54.1) | 40 ( 54.1) | 42 ( 56.8) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI/Selected AEs | 20 ( 27.0) | 37 ( 50.0) | 73 ( 98.6) | 73 ( 98.6) | 73 ( 98.6) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI/Selected AEs | 14 ( 18.9) | 37 ( 50.0) | 73 ( 98.6) | 73 ( 98.6) | 73 ( 98.6) |

AESI/Selected AEs categories used either MedDRA v22.0 SMQ or sub-SMQ or SOC or HLT or list of preferred terms.
[a] Grade using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
Missing subgroup categories are not presented.
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## 8.3.4 UE nach SOC und PT



Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one AE | 41 ( 51.3) | 67 ( 83.8) | 80 (100.0) | 80 (100.0) |
| Blood and lymphatic system disorders | 24 ( 30.0) | 46 ( 57.5) | 76 ( 95.0) | 78 ( 97.5) |
| Neutropenia | 9 ( 11.3) | 25 ( 31.3) | 74 ( 92.5) | 76 ( 95.0) |
| Anaemia | 11 ( 13.8) | 26 ( 32.5) | 55 ( 68.8) | 58 ( 72.5) |
| Thrombocytopenia | 14 ( 17.5) | 21 ( 26.3) | 52 ( 65.0) | 54 ( 67.5) |
| Leukopenia | 4 ( 5.0) | 20 ( 25.0) | 34 ( 42.5) | 37 ( 46.3) |
| Lymphopenia | 4 ( 5.0) | 16 ( 20.0) | 23 ( 28.8) | 26 ( 32.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 2 ( 2.5) | 1 ( 1.3) | 13 ( 16.3) | 14 ( 17.5) |
| Immune system disorders | 0 | 1 ( 1.3) | 70 ( 87.5) | 70 ( 87.5) |
| Cytokine release syndrome | 0 | 0 | 66 ( 82.5) | 66 ( 82.5) |
| Hypogammaglobulinaemia | 0 | 1 ( 1.3) | 14 ( 17.5) | 15 ( 18.8) |
| General disorders and administration site conditions | 6 ( 7.5) | 13 ( 16.3) | 61 ( 76.3) | 62 ( 77.5) |
| Fatigue | 1 ( 1.3) | 4 ( 5.0) | 23 ( 28.8) | 25 ( 31.3) |
| Pyrexia | 3 ( 3.8) | 4 ( 5.0) | 16 ( 20.0) | 19 ( 23.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| General physical health deterioration | 0 | 0 | 13 ( 16.3) | 13 ( 16.3) |
| Oedema peripheral | 3 ( 3.8) | 2 ( 2.5) | 8 ( 10.0) | 9 ( 11.3) |
| Asthenia | 1 ( 1.3) | 2 ( 2.5) | 13 ( 16.3) | 15 ( 18.8) |
| Chills | 1 ( 1.3) | 1 ( 1.3) | 8 ( 10.0) | 9 ( 11.3) |
| Metabolism and nutrition disorders | 8 ( 10.0) | 17 ( 21.3) | 59 ( 73.8) | 60 ( 75.0) |
| Hypokalaemia | 0 | 5 ( 6.3) | 31 ( 38.8) | 33 ( 41.3) |
| Hypophosphataemia | 2 ( 2.5) | 1 ( 1.3) | 24 ( 30.0) | 24 ( 30.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypocalcaemia | 2 ( 2.5) | 5 ( 6.3) | 20 ( 25.0) | 22 ( 27.5) |
| Hypomagnesaemia | 1 ( 1.3) | 1 ( 1.3) | 18 ( 22.5) | 19 ( 23.8) |
| Decreased appetite | 1 ( 1.3) | 3 ( 3.8) | 14 ( 17.5) | 17 ( 21.3) |
| Hyponatraemia | 2 ( 2.5) | 2 ( 2.5) | 14 ( 17.5) | 14 ( 17.5) |
| Hypoalbuminaemia | 1 ( 1.3) | 5 ( 6.3) | 12 ( 15.0) | 12 ( 15.0) |
| Gastrointestinal disorders | 8 ( 10.0) | 40 ( 50.0) | 64 ( 80.0) | 72 ( 90.0) |
| Diarrhoea | 1 ( 1.3) | 5 ( 6.3) | 27 ( 33.8) | 30 ( 37.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Nausea | 3 ( 3.8) | 28 ( 35.0) | 24 ( 30.0) | 47 ( 58.8) |
| Constipation | 2 ( 2.5) | 10 ( 12.5) | 14 ( 17.5) | 21 ( 26.3) |
| Vomiting | 2 ( 2.5) | 3 ( 3.8) | 13 ( 16.3) | 15 ( 18.8) |
| Infections and infestations | 10 ( 12.5) | 5 ( 6.3) | 60 ( 75.0) | 60 ( 75.0) |
| Upper respiratory tract infection | 1 ( 1.3) | 0 | 14 ( 17.5) | 14 ( 17.5) |
| Pneumonia | 0 | 1 ( 1.3) | 9 ( 11.3) | 10 ( 12.5) |
| Musculoskeletal and connective tissue disorders | 11 ( 13.8) | 7 ( 8.8) | 44 ( 55.0) | 46 ( 57.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Arthralgia | 2 ( 2.5) | 3 ( 3.8) | 11 ( 13.8) | 14 ( 17.5) |
| Back pain | 3 ( 3.8) | 1 ( 1.3) | 12 ( 15.0) | 13 ( 16.3) |
| Bone pain | 2 ( 2.5) | 0 | 7 ( 8.8) | 7 ( 8.8) |
| Investigations | 6 ( 7.5) | 9 ( 11.3) | 44 ( 55.0) | 45 ( 56.3) |
| Aspartate aminotransferase increased | 1 ( 1.3) | 2 ( 2.5) | 13 ( 16.3) | 14 ( 17.5) |
| Alanine aminotransferase increased | 1 ( 1.3) | 1 ( 1.3) | 10 ( 12.5) | 10 ( 12.5) |
| Blood alkaline phosphatase increased | 1 ( 1.3) | 1 ( 1.3) | 11 ( 13.8) | 11 ( 13.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Weight decreased | 1 ( 1.3) | 1 ( 1.3) | 10 ( 12.5) | 10 ( 12.5) |
| C-reactive protein increased | 0 | 1 ( 1.3) | 12 ( 15.0) | 12 ( 15.0) |
| Nervous system disorders | 5 ( 6.3) | 12 ( 15.0) | 43 ( 53.8) | 45 ( 56.3) |
| Headache | 2 ( 2.5) | 7 ( 8.8) | 20 ( 25.0) | 25 ( 31.3) |
| Dizziness | 0 | 1 ( 1.3) | 10 ( 12.5) | 11 ( 13.8) |
| Respiratory, thoracic and mediastinal disorders | 3 ( 3.8) | 4 ( 5.0) | 40 ( 50.0) | 41 ( 51.3) |
| Cough | 2 ( 2.5) | 1 ( 1.3) | 15 ( 18.8) | 15 ( 18.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Psychiatric disorders | 1 ( 1.3) | 7 ( 8.8) | 26 ( 32.5) | 30 ( 37.5) |
| Confusional state | 0 | 0 | 9 ( 11.3) | 9 ( 11.3) |
| Anxiety | 1 ( 1.3) | 4 ( 5.0) | 8 ( 10.0) | 12 ( 15.0) |
| Insomnia | 0 | 2 ( 2.5) | 6 ( 7.5) | 7 ( 8.8) |
| Skin and subcutaneous tissue disorders | 1 ( 1.3) | 4 ( 5.0) | 29 ( 36.3) | 33 ( 41.3) |
| Vascular disorders | 2 ( 2.5) | 2 ( 2.5) | 18 ( 22.5) | 20 ( 25.0) |
| Hypotension | 0 | 1 ( 1.3) | 12 ( 15.0) | 13 ( 16.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Hypertension | 0 | 1 ( 1.3) | 4 ( 5.0) | 5 ( 6.3) |
| Cardiac disorders | 3 ( 3.8) | 4 ( 5.0) | 18 ( 22.5) | 19 ( 23.8) |
| Tachycardia | 0 | 2 ( 2.5) | 9 ( 11.3) | 10 ( 12.5) |
| Renal and urinary disorders | 3 ( 3.8) | 2 ( 2.5) | 16 ( 20.0) | 17 ( 21.3) |
| Injury, poisoning and procedural complications | 2 ( 2.5) | 1 ( 1.3) | 14 ( 17.5) | 15 ( 18.8) |
| Eye disorders | 1 ( 1.3) | 2 ( 2.5) | 15 ( 18.8) | 17 ( 21.3) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 1.3) | 1 ( 1.3) | 9 ( 11.3) | 9 ( 11.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one AE | 21 ( 47.7) | 40 ( 90.9) | 44 (100.0) | 44 (100.0) |
| Blood and lymphatic system disorders | 13 ( 29.5) | 24 ( 54.5) | 44 (100.0) | 44 (100.0) |
| Neutropenia | 3 ( 6.8) | 13 ( 29.5) | 39 ( 88.6) | 40 ( 90.9) |
| Anaemia | 9 ( 20.5) | 10 ( 22.7) | 31 ( 70.5) | 31 ( 70.5) |
| Thrombocytopenia | 5 ( 11.4) | 7 ( 15.9) | 26 ( 59.1) | 27 ( 61.4) |
| Leukopenia | 1 ( 2.3) | 11 ( 25.0) | 18 ( 40.9) | 18 ( 40.9) |
| Lymphopenia | 4 ( 9.1) | 9 ( 20.5) | 11 ( 25.0) | 11 ( 25.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 0 | 0 | 6 ( 13.6) | 6 ( 13.6) |
| Immune system disorders | 0 | 0 | 40 ( 90.9) | 40 ( 90.9) |
| Cytokine release syndrome | 0 | 0 | 39 ( 88.6) | 39 ( 88.6) |
| Hypogammaglobulinaemia | 0 | 0 | 12 ( 27.3) | 12 ( 27.3) |
| General disorders and administration site conditions | 6 ( 13.6) | 12 ( 27.3) | 39 ( 88.6) | 39 ( 88.6) |
| Fatigue | 4 ( 9.1) | 7 ( 15.9) | 20 ( 45.5) | 24 ( 54.5) |
| Pyrexia | 1 ( 2.3) | 3 ( 6.8) | 16 ( 36.4) | 17 ( 38.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| General physical health deterioration | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |
| Oedema peripheral | 1 ( 2.3) | 2 ( 4.5) | 10 ( 22.7) | 10 ( 22.7) |
| Asthenia | 0 | 2 ( 4.5) | 4 ( 9.1) | 6 ( 13.6) |
| Chills | 0 | 1 ( 2.3) | 5 ( 11.4) | 6 ( 13.6) |
| Metabolism and nutrition disorders | 7 ( 15.9) | 16 ( 36.4) | 36 ( 81.8) | 38 ( 86.4) |
| Hypokalaemia | 2 ( 4.5) | 4 ( 9.1) | 14 ( 31.8) | 17 ( 38.6) |
| Hypophosphataemia | 1 ( 2.3) | 1 ( 2.3) | 14 ( 31.8) | 15 ( 34.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypocalcaemia | 1 ( 2.3) | 1 ( 2.3) | 14 ( 31.8) | 14 ( 31.8) |
| Hypomagnesaemia | 0 | 4 ( 9.1) | 11 ( 25.0) | 11 ( 25.0) |
| Decreased appetite | 0 | 8 ( 18.2) | 13 ( 29.5) | 17 ( 38.6) |
| Hyponatraemia | 2 ( 4.5) | 2 ( 4.5) | 9 ( 20.5) | 9 ( 20.5) |
| Hypoalbuminaemia | 1 ( 2.3) | 2 ( 4.5) | 8 ( 18.2) | 10 ( 22.7) |
| Gastrointestinal disorders | 6 ( 13.6) | 28 ( 63.6) | 30 ( 68.2) | 39 ( 88.6) |
| Diarrhoea | 1 ( 2.3) | 6 ( 13.6) | 16 ( 36.4) | 21 ( 47.7) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Nausea | 3 ( 6.8) | 16 ( 36.4) | 12 ( 27.3) | 23 ( 52.3) |
| Constipation | 0 | 9 ( 20.5) | 7 ( 15.9) | 15 ( 34.1) |
| Vomiting | 0 | 4 ( 9.1) | 7 ( 15.9) | 11 ( 25.0) |
| Infections and infestations | 0 | 2 ( 4.5) | 27 ( 61.4) | 27 ( 61.4) |
| Upper respiratory tract infection | 0 | 0 | 5 ( 11.4) | 5 ( 11.4) |
| Pneumonia | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |
| Musculoskeletal and connective tissue disorders | 4 ( 9.1) | 7 ( 15.9) | 29 ( 65.9) | 31 ( 70.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Arthralgia | 1 ( 2.3) | 0 | 6 ( 13.6) | 6 ( 13.6) |
| Back pain | 2 ( 4.5) | 4 ( 9.1) | 5 ( 11.4) | 8 ( 18.2) |
| Bone pain | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |
| Investigations | 4 ( 9.1) | 6 ( 13.6) | 25 ( 56.8) | 25 ( 56.8) |
| Aspartate aminotransferase increased | 1 ( 2.3) | 0 | 8 ( 18.2) | 8 ( 18.2) |
| Alanine aminotransferase increased | 1 ( 2.3) | 0 | 7 ( 15.9) | 7 ( 15.9) |
| Blood alkaline phosphatase increased | 1 ( 2.3) | 0 | 6 ( 13.6) | 6 ( 13.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Weight decreased | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |
| C-reactive protein increased | 0 | 0 | 3 ( 6.8) | 3 ( 6.8) |
| Nervous system disorders | 1 ( 2.3) | 11 ( 25.0) | 26 ( 59.1) | 30 ( 68.2) |
| Headache | 0 | 7 ( 15.9) | 6 ( 13.6) | 13 ( 29.5) |
| Dizziness | 0 | 2 ( 4.5) | 7 ( 15.9) | 9 ( 20.5) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 4.5) | 3 ( 6.8) | 23 ( 52.3) | 25 ( 56.8) |
| Cough | 0 | 1 ( 2.3) | 8 ( 18.2) | 9 ( 20.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Psychiatric disorders | 2 ( 4.5) | 2 ( 4.5) | 20 ( 45.5) | 21 ( 47.7) |
| Confusional state | 0 | 0 | 8 ( 18.2) | 8 ( 18.2) |
| Anxiety | 0 | 1 ( 2.3) | 5 ( 11.4) | 6 ( 13.6) |
| Insomnia | 0 | 1 ( 2.3) | 5 ( 11.4) | 6 ( 13.6) |
| Skin and subcutaneous tissue disorders | 0 | 0 | 15 ( 34.1) | 15 ( 34.1) |
| Vascular disorders | 0 | 5 ( 11.4) | 19 ( 43.2) | 20 ( 45.5) |
| Hypotension | 0 | 3 ( 6.8) | 9 ( 20.5) | 11 ( 25.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypertension | 0 | 2 ( 4.5) | 9 ( 20.5) | 9 ( 20.5) |
| Cardiac disorders | 1 ( 2.3) | 2 ( 4.5) | 14 ( 31.8) | 14 ( 31.8) |
| Tachycardia | 0 | 1 ( 2.3) | 9 ( 20.5) | 9 ( 20.5) |
| Renal and urinary disorders | 2 ( 4.5) | 3 ( 6.8) | 12 ( 27.3) | 14 ( 31.8) |
| Injury, poisoning and procedural complications | 0 | 1 ( 2.3) | 11 ( 25.0) | 12 ( 27.3) |
| Eye disorders | 0 | 1 ( 2.3) | 3 ( 6.8) | 4 ( 9.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 6 ( 13.6) | 6 ( 13.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one AE | 56 ( 50.9) | 98 ( 89.1) | 110 (100.0) | 110 (100.0) |
| Blood and lymphatic system disorders | 34 ( 30.9) | 68 ( 61.8) | 108 ( 98.2) | 110 (100.0) |
| Neutropenia | 11 ( 10.0) | 36 ( 32.7) | 101 ( 91.8) | 104 ( 94.5) |
| Anaemia | 19 ( 17.3) | 35 ( 31.8) | 80 ( 72.7) | 83 ( 75.5) |
| Thrombocytopenia | 17 ( 15.5) | 26 ( 23.6) | 70 ( 63.6) | 73 ( 66.4) |
| Leukopenia | 5 ( 4.5) | 30 ( 27.3) | 49 ( 44.5) | 51 ( 46.4) |
| Lymphopenia | 8 ( 7.3) | 25 ( 22.7) | 33 ( 30.0) | 36 ( 32.7) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Febrile neutropenia | 2 ( 1.8) | 1 ( 0.9) | 17 ( 15.5) | 18 ( 16.4) |
| Immune system disorders | 0 | 1 ( 0.9) | 97 ( 88.2) | 97 ( 88.2) |
| Cytokine release syndrome | 0 | 0 | 93 ( 84.5) | 93 ( 84.5) |
| Hypogammaglobulinaemia | 0 | 1 ( 0.9) | 22 ( 20.0) | 23 ( 20.9) |
| General disorders and administration site conditions | 11 ( 10.0) | 22 ( 20.0) | 91 ( 82.7) | 92 ( 83.6) |
| Fatigue | 5 ( 4.5) | 10 ( 9.1) | 41 ( 37.3) | 46 ( 41.8) |
| Pyrexia | 3 ( 2.7) | 6 ( 5.5) | 29 ( 26.4) | 33 ( 30.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| General physical health deterioration | 0 | 0 | 19 ( 17.3) | 19 ( 17.3) |
| Oedema peripheral | 4 ( 3.6) | 3 ( 2.7) | 15 ( 13.6) | 16 ( 14.5) |
| Asthenia | 1 ( 0.9) | 4 ( 3.6) | 15 ( 13.6) | 19 ( 17.3) |
| Chills | 1 ( 0.9) | 2 ( 1.8) | 12 ( 10.9) | 14 ( 12.7) |
| Metabolism and nutrition disorders | 14 ( 12.7) | 31 ( 28.2) | 85 ( 77.3) | 88 ( 80.0) |
| Hypokalaemia | 2 ( 1.8) | 9 ( 8.2) | 40 ( 36.4) | 45 ( 40.9) |
| Hypophosphataemia | 3 ( 2.7) | 2 ( 1.8) | 36 ( 32.7) | 37 ( 33.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypocalcaemia | 3 ( 2.7) | 6 ( 5.5) | 33 ( 30.0) | 35 ( 31.8) |
| Hypomagnesaemia | 0 | 5 ( 4.5) | 27 ( 24.5) | 28 ( 25.5) |
| Decreased appetite | 1 ( 0.9) | 11 ( 10.0) | 25 ( 22.7) | 32 ( 29.1) |
| Hyponatraemia | 4 ( 3.6) | 3 ( 2.7) | 22 ( 20.0) | 22 ( 20.0) |
| Hypoalbuminaemia | 2 ( 1.8) | 6 ( 5.5) | 18 ( 16.4) | 20 ( 18.2) |
| Gastrointestinal disorders | 14 ( 12.7) | 61 ( 55.5) | 83 ( 75.5) | 99 ( 90.0) |
| Diarrhoea | 2 ( 1.8) | 11 ( 10.0) | 39 ( 35.5) | 47 ( 42.7) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Nausea | 6 ( 5.5) | 41 ( 37.3) | 32 ( 29.1) | 63 ( 57.3) |
| Constipation | 2 ( 1.8) | 16 ( 14.5) | 19 ( 17.3) | 32 ( 29.1) |
| Vomiting | 2 ( 1.8) | 5 ( 4.5) | 17 ( 15.5) | 21 ( 19.1) |
| Infections and infestations | 9 ( 8.2) | 6 ( 5.5) | 77 ( 70.0) | 77 ( 70.0) |
| Upper respiratory tract infection | 1 ( 0.9) | 0 | 18 ( 16.4) | 18 ( 16.4) |
| Pneumonia | 0 | 1 ( 0.9) | 14 ( 12.7) | 15 ( 13.6) |
| Musculoskeletal and connective tissue disorders | 13 ( 11.8) | 12 ( 10.9) | 66 ( 60.0) | 69 ( 62.7) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Arthralgia | 1 ( 0.9) | 3 ( 2.7) | 16 ( 14.5) | 19 ( 17.3) |
| Back pain | 5 ( 4.5) | 4 ( 3.6) | 15 ( 13.6) | 18 ( 16.4) |
| Bone pain | 2 ( 1.8) | 0 | 12 ( 10.9) | 12 ( 10.9) |
| Investigations | 9 ( 8.2) | 14 ( 12.7) | 64 ( 58.2) | 65 ( 59.1) |
| Aspartate aminotransferase increased | 1 ( 0.9) | 2 ( 1.8) | 21 ( 19.1) | 22 ( 20.0) |
| Alanine aminotransferase increased | 1 ( 0.9) | 1 ( 0.9) | 17 ( 15.5) | 17 ( 15.5) |
| Blood alkaline phosphatase increased | 2 ( 1.8) | 1 ( 0.9) | 16 ( 14.5) | 16 ( 14.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Weight decreased | 1 ( 0.9) | 0 | 16 ( 14.5) | 16 ( 14.5) |
| C-reactive protein increased | 0 | 1 ( 0.9) | 14 ( 12.7) | 14 ( 12.7) |
| Nervous system disorders | 5 ( 4.5) | 22 ( 20.0) | 63 ( 57.3) | 68 ( 61.8) |
| Headache | 1 ( 0.9) | 14 ( 12.7) | 26 ( 23.6) | 38 ( 34.5) |
| Dizziness | 0 | 3 ( 2.7) | 15 ( 13.6) | 18 ( 16.4) |
| Respiratory, thoracic and mediastinal disorders | 5 ( 4.5) | 6 ( 5.5) | 58 ( 52.7) | 61 ( 55.5) |
| Cough | 2 ( 1.8) | 2 ( 1.8) | 23 ( 20.9) | 24 ( 21.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
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Missing subgroup categories are not presented.
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Psychiatric disorders | 3 ( 2.7) | 9 ( 8.2) | 43 ( 39.1) | 48 ( 43.6) |
| Confusional state | 0 | 0 | 15 ( 13.6) | 15 ( 13.6) |
| Anxiety | 1 ( 0.9) | 5 ( 4.5) | 12 ( 10.9) | 17 ( 15.5) |
| Insomnia | 0 | 3 ( 2.7) | 11 ( 10.0) | 13 ( 11.8) |
| Skin and subcutaneous tissue disorders | 1 ( 0.9) | 4 ( 3.6) | 39 ( 35.5) | 43 ( 39.1) |
| Vascular disorders | 2 ( 1.8) | 7 ( 6.4) | 33 ( 30.0) | 36 ( 32.7) |
| Hypotension | 0 | 4 ( 3.6) | 19 ( 17.3) | 22 ( 20.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypertension | 0 | 3 ( 2.7) | 12 ( 10.9) | 13 ( 11.8) |
| Cardiac disorders | 4 ( 3.6) | 6 ( 5.5) | 30 ( 27.3) | 31 ( 28.2) |
| Tachycardia | 0 | 3 ( 2.7) | 17 ( 15.5) | 18 ( 16.4) |
| Renal and urinary disorders | 5 ( 4.5) | 4 ( 3.6) | 27 ( 24.5) | 29 ( 26.4) |
| Injury, poisoning and procedural complications | 2 ( 1.8) | 2 ( 1.8) | 23 ( 20.9) | 25 ( 22.7) |
| Eye disorders | 1 ( 0.9) | 2 ( 1.8) | 16 ( 14.5) | 18 ( 16.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 1 ( 0.9) | 12 ( 10.9) | 12 ( 10.9) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one AE | 6 ( 42.9) | 9 ( 64.3) | 14 (100.0) | 14 (100.0) |
| Blood and lymphatic system disorders | 3 ( 21.4) | 2 ( 14.3) | 12 ( 85.7) | 12 ( 85.7) |
| Neutropenia | 1 ( 7.1) | 2 ( 14.3) | 12 ( 85.7) | 12 ( 85.7) |
| Anaemia | 1 ( 7.1) | 1 ( 7.1) | 6 ( 42.9) | 6 ( 42.9) |
| Thrombocytopenia | 2 ( 14.3) | 2 ( 14.3) | 8 ( 57.1) | 8 ( 57.1) |
| Leukopenia | 0 | 1 ( 7.1) | 3 ( 21.4) | 4 ( 28.6) |
| Lymphopenia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Immune system disorders | 0 | 0 | 13 ( 92.9) | 13 ( 92.9) |
| Cytokine release syndrome | 0 | 0 | 12 ( 85.7) | 12 ( 85.7) |
| Hypogammaglobulinaemia | 0 | 0 | 4 ( 28.6) | 4 ( 28.6) |
| General disorders and administration site conditions | 1 ( 7.1) | 3 ( 21.4) | 9 ( 64.3) | 9 ( 64.3) |
| Fatigue | 0 | 1 ( 7.1) | 2 ( 14.3) | 3 ( 21.4) |
| Pyrexia | 1 ( 7.1) | 1 ( 7.1) | 3 ( 21.4) | 3 ( 21.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| General physical health deterioration | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Oedema peripheral | 0 | 1 ( 7.1) | 3 ( 21.4) | 3 ( 21.4) |
| Asthenia | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Chills | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Metabolism and nutrition disorders | 1 ( 7.1) | 2 ( 14.3) | 10 ( 71.4) | 10 ( 71.4) |
| Hypokalaemia | 0 | 0 | 5 ( 35.7) | 5 ( 35.7) |
| Hypophosphataemia | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Hypocalcaemia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Hypomagnesaemia | 1 ( 7.1) | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Decreased appetite | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Hyponatraemia | 0 | 1 ( 7.1) | 1 ( 7.1) | 1 ( 7.1) |
| Hypoalbuminaemia | 0 | 1 ( 7.1) | 2 ( 14.3) | 2 ( 14.3) |
| Gastrointestinal disorders | 0 | 7 ( 50.0) | 11 ( 78.6) | 12 ( 85.7) |
| Diarrhoea | 0 | 0 | 4 ( 28.6) | 4 ( 28.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Nausea | 0 | 3 ( 21.4) | 4 ( 28.6) | 7 ( 50.0) |
| Constipation | 0 | 3 ( 21.4) | 2 ( 14.3) | 4 ( 28.6) |
| Vomiting | 0 | 2 ( 14.3) | 3 ( 21.4) | 5 ( 35.7) |
| Infections and infestations | 1 ( 7.1) | 1 ( 7.1) | 10 ( 71.4) | 10 ( 71.4) |
| Upper respiratory tract infection | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Pneumonia | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Musculoskeletal and connective tissue disorders | 2 ( 14.3) | 2 ( 14.3) | 7 ( 50.0) | 8 ( 57.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Arthralgia | 2 ( 14.3) | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Back pain | 0 | 1 ( 7.1) | 2 ( 14.3) | 3 ( 21.4) |
| Bone pain | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Investigations | 1 ( 7.1) | 1 ( 7.1) | 5 ( 35.7) | 5 ( 35.7) |
| Aspartate aminotransferase increased | 1 ( 7.1) | 0 | 0 | 0 |
| Alanine aminotransferase increased | 1 ( 7.1) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Weight decreased | 0 | 1 ( 7.1) | 1 ( 7.1) | 1 ( 7.1) |
| C-reactive protein increased | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Nervous system disorders | 1 ( 7.1) | 1 ( 7.1) | 6 ( 42.9) | 7 ( 50.0) |
| Headache | 1 ( 7.1) | 0 | 0 | 0 |
| Dizziness | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Respiratory, thoracic and mediastinal disorders | 0 | 1 ( 7.1) | 5 ( 35.7) | 5 ( 35.7) |
| Cough | 0 | 0 | 0 | 0 |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Psychiatric disorders | 0 | 0 | 3 ( 21.4) | 3 ( 21.4) |
| Confusional state | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Anxiety | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Insomnia | 0 | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 0 | 0 | 5 ( 35.7) | 5 ( 35.7) |
| Vascular disorders | 0 | 0 | 4 ( 28.6) | 4 ( 28.6) |
| Hypotension | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Hypertension | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Cardiac disorders | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Tachycardia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Renal and urinary disorders | 0 | 1 ( 7.1) | 1 ( 7.1) | 2 ( 14.3) |
| Injury, poisoning and procedural complications | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Eye disorders | 0 | 1 ( 7.1) | 2 ( 14.3) | 3 ( 21.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 7.1) | 0 | 3 ( 21.4) | 3 ( 21.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one AE | 18 ( 56.3) | 31 ( 96.9) | 32 (100.0) | 32 (100.0) |
| Blood and lymphatic system disorders | 12 ( 37.5) | 23 ( 71.9) | 30 ( 93.8) | 32 (100.0) |
| Neutropenia | 3 ( 9.4) | 12 ( 37.5) | 29 ( 90.6) | 30 ( 93.8) |
| Anaemia | 8 ( 25.0) | 11 ( 34.4) | 24 ( 75.0) | 25 ( 78.1) |
| Thrombocytopenia | 3 ( 9.4) | 5 ( 15.6) | 20 ( 62.5) | 21 ( 65.6) |
| Leukopenia | 2 ( 6.3) | 11 ( 34.4) | 16 ( 50.0) | 17 ( 53.1) |
| Lymphopenia | 4 ( 12.5) | 10 ( 31.3) | 13 ( 40.6) | 13 ( 40.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 0 | 1 ( 3.1) | 4 ( 12.5) | 5 ( 15.6) |
| Immune system disorders | 0 | 0 | 25 ( 78.1) | 25 ( 78.1) |
| Cytokine release syndrome | 0 | 0 | 24 ( 75.0) | 24 ( 75.0) |
| Hypogammaglobulinaemia | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| General disorders and administration site conditions | 2 ( 6.3) | 10 ( 31.3) | 26 ( 81.3) | 26 ( 81.3) |
| Fatigue | 1 ( 3.1) | 3 ( 9.4) | 13 ( 40.6) | 13 ( 40.6) |
| Pyrexia | 1 ( 3.1) | 4 ( 12.5) | 8 ( 25.0) | 10 ( 31.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| General physical health deterioration | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Oedema peripheral | 1 ( 3.1) | 1 ( 3.1) | 4 ( 12.5) | 4 ( 12.5) |
| Asthenia | 0 | 1 ( 3.1) | 3 ( 9.4) | 4 ( 12.5) |
| Chills | 0 | 1 ( 3.1) | 5 ( 15.6) | 6 ( 18.8) |
| Metabolism and nutrition disorders | 3 ( 9.4) | 11 ( 34.4) | 24 ( 75.0) | 24 ( 75.0) |
| Hypokalaemia | 1 ( 3.1) | 3 ( 9.4) | 9 ( 28.1) | 11 ( 34.4) |
| Hypophosphataemia | 1 ( 3.1) | 1 ( 3.1) | 9 ( 28.1) | 10 ( 31.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypocalcaemia | 1 ( 3.1) | 1 ( 3.1) | 8 ( 25.0) | 8 ( 25.0) |
| Hypomagnesaemia | 0 | 3 ( 9.4) | 7 ( 21.9) | 8 ( 25.0) |
| Decreased appetite | 0 | 4 ( 12.5) | 9 ( 28.1) | 12 ( 37.5) |
| Hyponatraemia | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Hypoalbuminaemia | 1 ( 3.1) | 4 ( 12.5) | 6 ( 18.8) | 8 ( 25.0) |
| Gastrointestinal disorders | 3 ( 9.4) | 24 ( 75.0) | 28 ( 87.5) | 31 ( 96.9) |
| Diarrhoea | 0 | 5 ( 15.6) | 7 ( 21.9) | 11 ( 34.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Nausea | 1 ( 3.1) | 16 ( 50.0) | 11 ( 34.4) | 22 ( 68.8) |
| Constipation | 0 | 5 ( 15.6) | 8 ( 25.0) | 12 ( 37.5) |
| Vomiting | 0 | 4 ( 12.5) | 7 ( 21.9) | 10 ( 31.3) |
| Infections and infestations | 4 ( 12.5) | 0 | 21 ( 65.6) | 21 ( 65.6) |
| Upper respiratory tract infection | 0 | 0 | 6 ( 18.8) | 6 ( 18.8) |
| Pneumonia | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Musculoskeletal and connective tissue disorders | 2 ( 6.3) | 7 ( 21.9) | 23 ( 71.9) | 25 ( 78.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Arthralgia | 0 | 2 ( 6.3) | 4 ( 12.5) | 6 ( 18.8) |
| Back pain | 1 ( 3.1) | 3 ( 9.4) | 9 ( 28.1) | 12 ( 37.5) |
| Bone pain | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Investigations | 4 ( 12.5) | 6 ( 18.8) | 21 ( 65.6) | 22 ( 68.8) |
| Aspartate aminotransferase increased | 1 ( 3.1) | 0 | 8 ( 25.0) | 8 ( 25.0) |
| Alanine aminotransferase increased | 1 ( 3.1) | 0 | 6 ( 18.8) | 6 ( 18.8) |
| Blood alkaline phosphatase increased | 2 ( 6.3) | 0 | 8 ( 25.0) | 8 ( 25.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Weight decreased | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |
| C-reactive protein increased | 0 | 1 ( 3.1) | 4 ( 12.5) | 4 ( 12.5) |
| Nervous system disorders | 1 ( 3.1) | 9 ( 28.1) | 18 ( 56.3) | 19 ( 59.4) |
| Headache | 1 ( 3.1) | 4 ( 12.5) | 11 ( 34.4) | 14 ( 43.8) |
| Dizziness | 0 | 2 ( 6.3) | 5 ( 15.6) | 7 ( 21.9) |
| Respiratory, thoracic and mediastinal disorders | 4 ( 12.5) | 3 ( 9.4) | 16 ( 50.0) | 18 ( 56.3) |
| Cough | 2 ( 6.3) | 1 ( 3.1) | 8 ( 25.0) | 8 ( 25.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Psychiatric disorders | 1 ( 3.1) | 3 ( 9.4) | 10 ( 31.3) | 12 ( 37.5) |
| Confusional state | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Anxiety | 1 ( 3.1) | 1 ( 3.1) | 5 ( 15.6) | 6 ( 18.8) |
| Insomnia | 0 | 1 ( 3.1) | 1 ( 3.1) | 2 ( 6.3) |
| Skin and subcutaneous tissue disorders | 0 | 2 ( 6.3) | 11 ( 34.4) | 13 ( 40.6) |
| Vascular disorders | 2 ( 6.3) | 3 ( 9.4) | 10 ( 31.3) | 11 ( 34.4) |
| Hypotension | 0 | 2 ( 6.3) | 5 ( 15.6) | 7 ( 21.9) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypertension | 0 | 1 ( 3.1) | 3 ( 9.4) | 3 ( 9.4) |
| Cardiac disorders | 2 ( 6.3) | 3 ( 9.4) | 10 ( 31.3) | 11 ( 34.4) |
| Tachycardia | 0 | 2 ( 6.3) | 7 ( 21.9) | 8 ( 25.0) |
| Renal and urinary disorders | 1 ( 3.1) | 2 ( 6.3) | 6 ( 18.8) | 8 ( 25.0) |
| Injury, poisoning and procedural complications | 1 ( 3.1) | 1 ( 3.1) | 7 ( 21.9) | 8 ( 25.0) |
| Eye disorders | 1 ( 3.1) | 0 | 6 ( 18.8) | 6 ( 18.8) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one AE | 44 ( 47.8) | 76 ( 82.6) | 92 (100.0) | 92 (100.0) |
| Blood and lymphatic system disorders | 25 ( 27.2) | 47 ( 51.1) | 90 ( 97.8) | 90 ( 97.8) |
| Neutropenia | 9 ( 9.8) | 26 ( 28.3) | 84 ( 91.3) | 86 ( 93.5) |
| Anaemia | 12 ( 13.0) | 25 ( 27.2) | 62 ( 67.4) | 64 ( 69.6) |
| Thrombocytopenia | 16 ( 17.4) | 23 ( 25.0) | 58 ( 63.0) | 60 ( 65.2) |
| Leukopenia | 3 ( 3.3) | 20 ( 21.7) | 36 ( 39.1) | 38 ( 41.3) |
| Lymphopenia | 4 ( 4.3) | 15 ( 16.3) | 21 ( 22.8) | 24 ( 26.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Febrile neutropenia | 2 ( 2.2) | 0 | 15 ( 16.3) | 15 ( 16.3) |
| Immune system disorders | 0 | 1 ( 1.1) | 85 ( 92.4) | 85 ( 92.4) |
| Cytokine release syndrome | 0 | 0 | 81 ( 88.0) | 81 ( 88.0) |
| Hypogammaglobulinaemia | 0 | 1 ( 1.1) | 22 ( 23.9) | 23 ( 25.0) |
| General disorders and administration site conditions | 10 ( 10.9) | 15 ( 16.3) | 74 ( 80.4) | 75 ( 81.5) |
| Fatigue | 4 ( 4.3) | 8 ( 8.7) | 30 ( 32.6) | 36 ( 39.1) |
| Pyrexia | 3 ( 3.3) | 3 ( 3.3) | 24 ( 26.1) | 26 ( 28.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| General physical health deterioration | 0 | 0 | 16 ( 17.4) | 16 ( 17.4) |
| Oedema peripheral | 3 ( 3.3) | 3 ( 3.3) | 14 ( 15.2) | 15 ( 16.3) |
| Asthenia | 1 ( 1.1) | 3 ( 3.3) | 14 ( 15.2) | 17 ( 18.5) |
| Chills | 1 ( 1.1) | 1 ( 1.1) | 8 ( 8.7) | 9 ( 9.8) |
| Metabolism and nutrition disorders | 12 ( 13.0) | 22 ( 23.9) | 71 ( 77.2) | 74 ( 80.4) |
| Hypokalaemia | 1 ( 1.1) | 6 ( 6.5) | 36 ( 39.1) | 39 ( 42.4) |
| Hypophosphataemia | 2 ( 2.2) | 1 ( 1.1) | 29 ( 31.5) | 29 ( 31.5) |

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[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypocalcaemia | 2 ( 2.2) | 5 ( 5.4) | 26 ( 28.3) | 28 ( 30.4) |
| Hypomagnesaemia | 1 ( 1.1) | 2 ( 2.2) | 22 ( 23.9) | 22 ( 23.9) |
| Decreased appetite | 1 ( 1.1) | 7 ( 7.6) | 18 ( 19.6) | 22 ( 23.9) |
| Hyponatraemia | 4 ( 4.3) | 4 ( 4.3) | 19 ( 20.7) | 19 ( 20.7) |
| Hypoalbuminaemia | 1 ( 1.1) | 3 ( 3.3) | 14 ( 15.2) | 14 ( 15.2) |
| Gastrointestinal disorders | 11 ( 12.0) | 44 ( 47.8) | 66 ( 71.7) | 80 ( 87.0) |
| Diarrhoea | 2 ( 2.2) | 6 ( 6.5) | 36 ( 39.1) | 40 ( 43.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Missing subgroup categories are not presented.
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Table 9.1.1.1d
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(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Nausea | 5 ( 5.4) | 28 ( 30.4) | 25 ( 27.2) | 48 ( 52.2) |
| Constipation | 2 ( 2.2) | 14 ( 15.2) | 13 ( 14.1) | 24 ( 26.1) |
| Vomiting | 2 ( 2.2) | 3 ( 3.3) | 13 ( 14.1) | 16 ( 17.4) |
| Infections and infestations | 6 ( 6.5) | 7 ( 7.6) | 66 ( 71.7) | 66 ( 71.7) |
| Upper respiratory tract infection | 1 ( 1.1) | 0 | 13 ( 14.1) | 13 ( 14.1) |
| Pneumonia | 0 | 1 ( 1.1) | 12 ( 13.0) | 13 ( 14.1) |
| Musculoskeletal and connective tissue disorders | 13 ( 14.1) | 7 ( 7.6) | 50 ( 54.3) | 52 ( 56.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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Missing subgroup categories are not presented.
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Arthralgia | 3 ( 3.3) | 1 ( 1.1) | 13 ( 14.1) | 14 ( 15.2) |
| Back pain | 4 ( 4.3) | 2 ( 2.2) | 8 ( 8.7) | 9 ( 9.8) |
| Bone pain | 2 ( 2.2) | 0 | 10 ( 10.9) | 10 ( 10.9) |
| Investigations | 6 ( 6.5) | 9 ( 9.8) | 48 ( 52.2) | 48 ( 52.2) |
| Aspartate aminotransferase increased | 1 ( 1.1) | 2 ( 2.2) | 13 ( 14.1) | 14 ( 15.2) |
| Alanine aminotransferase increased | 1 ( 1.1) | 1 ( 1.1) | 11 ( 12.0) | 11 ( 12.0) |
| Blood alkaline phosphatase increased | 0 | 1 ( 1.1) | 9 ( 9.8) | 9 ( 9.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Weight decreased | 1 ( 1.1) | 1 ( 1.1) | 14 ( 15.2) | 14 ( 15.2) |
| C-reactive protein increased | 0 | 0 | 11 ( 12.0) | 11 ( 12.0) |
| Nervous system disorders | 5 ( 5.4) | 14 ( 15.2) | 51 ( 55.4) | 56 ( 60.9) |
| Headache | 1 ( 1.1) | 10 ( 10.9) | 15 ( 16.3) | 24 ( 26.1) |
| Dizziness | 0 | 1 ( 1.1) | 12 ( 13.0) | 13 ( 14.1) |
| Respiratory, thoracic and mediastinal disorders | 1 ( 1.1) | 4 ( 4.3) | 47 ( 51.1) | 48 ( 52.2) |
| Cough | 0 | 1 ( 1.1) | 15 ( 16.3) | 16 ( 17.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Psychiatric disorders | 2 ( 2.2) | 6 ( 6.5) | 36 ( 39.1) | 39 ( 42.4) |
| Confusional state | 0 | 0 | 15 ( 16.3) | 15 ( 16.3) |
| Anxiety | 0 | 4 ( 4.3) | 8 ( 8.7) | 12 ( 13.0) |
| Insomnia | 0 | 2 ( 2.2) | 10 ( 10.9) | 11 ( 12.0) |
| Skin and subcutaneous tissue disorders | 1 ( 1.1) | 2 ( 2.2) | 33 ( 35.9) | 35 ( 38.0) |
| Vascular disorders | 0 | 4 ( 4.3) | 27 ( 29.3) | 29 ( 31.5) |
| Hypotension | 0 | 2 ( 2.2) | 16 ( 17.4) | 17 ( 18.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypertension | 0 | 2 ( 2.2) | 10 ( 10.9) | 11 ( 12.0) |
| Cardiac disorders | 2 ( 2.2) | 3 ( 3.3) | 22 ( 23.9) | 22 ( 23.9) |
| Tachycardia | 0 | 1 ( 1.1) | 11 ( 12.0) | 11 ( 12.0) |
| Renal and urinary disorders | 4 ( 4.3) | 3 ( 3.3) | 22 ( 23.9) | 23 ( 25.0) |
| Injury, poisoning and procedural complications | 1 ( 1.1) | 1 ( 1.1) | 18 ( 19.6) | 19 ( 20.7) |
| Eye disorders | 0 | 3 ( 3.3) | 12 ( 13.0) | 15 ( 16.3) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 1.1) | 1 ( 1.1) | 11 ( 12.0) | 11 ( 12.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one AE | 28 ( 56.0) | 45 ( 90.0) | 50 (100.0) | 50 (100.0) |
| Blood and lymphatic system disorders | 19 ( 38.0) | 30 ( 60.0) | 48 ( 96.0) | 50 (100.0) |
| Neutropenia | 6 ( 12.0) | 14 ( 28.0) | 45 ( 90.0) | 46 ( 92.0) |
| Anaemia | 10 ( 20.0) | 16 ( 32.0) | 32 ( 64.0) | 34 ( 68.0) |
| Thrombocytopenia | 10 ( 20.0) | 13 ( 26.0) | 27 ( 54.0) | 29 ( 58.0) |
| Leukopenia | 2 ( 4.0) | 9 ( 18.0) | 18 ( 36.0) | 19 ( 38.0) |
| Lymphopenia | 3 ( 6.0) | 8 ( 16.0) | 11 ( 22.0) | 13 ( 26.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 1 ( 2.0) | 1 ( 2.0) | 7 ( 14.0) | 8 ( 16.0) |
| Immune system disorders | 0 | 0 | 43 ( 86.0) | 43 ( 86.0) |
| Cytokine release syndrome | 0 | 0 | 41 ( 82.0) | 41 ( 82.0) |
| Hypogammaglobulinaemia | 0 | 0 | 9 ( 18.0) | 9 ( 18.0) |
| General disorders and administration site conditions | 6 ( 12.0) | 13 ( 26.0) | 38 ( 76.0) | 39 ( 78.0) |
| Fatigue | 1 ( 2.0) | 5 ( 10.0) | 14 ( 28.0) | 18 ( 36.0) |
| Pyrexia | 3 ( 6.0) | 4 ( 8.0) | 11 ( 22.0) | 12 ( 24.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| General physical health deterioration | 0 | 0 | 10 ( 20.0) | 10 ( 20.0) |
| Oedema peripheral | 3 ( 6.0) | 2 ( 4.0) | 9 ( 18.0) | 9 ( 18.0) |
| Asthenia | 0 | 3 ( 6.0) | 5 ( 10.0) | 8 ( 16.0) |
| Chills | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Metabolism and nutrition disorders | 7 ( 14.0) | 15 ( 30.0) | 39 ( 78.0) | 41 ( 82.0) |
| Hypokalaemia | 1 ( 2.0) | 4 ( 8.0) | 17 ( 34.0) | 20 ( 40.0) |
| Hypophosphataemia | 2 ( 4.0) | 1 ( 2.0) | 13 ( 26.0) | 14 ( 28.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Hypocalcaemia | 1 ( 2.0) | 2 ( 4.0) | 10 ( 20.0) | 10 ( 20.0) |
| Hypomagnesaemia | 1 ( 2.0) | 2 ( 4.0) | 11 ( 22.0) | 12 ( 24.0) |
| Decreased appetite | 1 ( 2.0) | 1 ( 2.0) | 11 ( 22.0) | 12 ( 24.0) |
| Hyponatraemia | 0 | 2 ( 4.0) | 7 ( 14.0) | 7 ( 14.0) |
| Hypoalbuminaemia | 2 ( 4.0) | 5 ( 10.0) | 10 ( 20.0) | 12 ( 24.0) |
| Gastrointestinal disorders | 8 ( 16.0) | 27 ( 54.0) | 36 ( 72.0) | 43 ( 86.0) |
| Diarrhoea | 1 ( 2.0) | 6 ( 12.0) | 16 ( 32.0) | 19 ( 38.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Nausea | 3 ( 6.0) | 17 ( 34.0) | 10 ( 20.0) | 25 ( 50.0) |
| Constipation | 2 ( 4.0) | 6 ( 12.0) | 8 ( 16.0) | 12 ( 24.0) |
| Vomiting | 1 ( 2.0) | 4 ( 8.0) | 8 ( 16.0) | 12 ( 24.0) |
| Infections and infestations | 4 ( 8.0) | 2 ( 4.0) | 36 ( 72.0) | 36 ( 72.0) |
| Upper respiratory tract infection | 0 | 0 | 10 ( 20.0) | 10 ( 20.0) |
| Pneumonia | 0 | 0 | 5 ( 10.0) | 5 ( 10.0) |
| Musculoskeletal and connective tissue disorders | 9 ( 18.0) | 6 ( 12.0) | 26 ( 52.0) | 27 ( 54.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Arthralgia | 2 ( 4.0) | 0 | 5 ( 10.0) | 5 ( 10.0) |
| Back pain | 4 ( 8.0) | 3 ( 6.0) | 7 ( 14.0) | 9 ( 18.0) |
| Bone pain | 1 ( 2.0) | 0 | 6 ( 12.0) | 6 ( 12.0) |
| Investigations | 2 ( 4.0) | 8 ( 16.0) | 27 ( 54.0) | 28 ( 56.0) |
| Aspartate aminotransferase increased | 1 ( 2.0) | 1 ( 2.0) | 7 ( 14.0) | 8 ( 16.0) |
| Alanine aminotransferase increased | 1 ( 2.0) | 0 | 5 ( 10.0) | 5 ( 10.0) |
| Blood alkaline phosphatase increased | 1 ( 2.0) | 0 | 8 ( 16.0) | 8 ( 16.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Weight decreased | 0 | 1 ( 2.0) | 10 ( 20.0) | 10 ( 20.0) |
| C-reactive protein increased | 0 | 1 ( 2.0) | 8 ( 16.0) | 8 ( 16.0) |
| Nervous system disorders | 4 ( 8.0) | 6 ( 12.0) | 26 ( 52.0) | 28 ( 56.0) |
| Headache | 1 ( 2.0) | 2 ( 4.0) | 8 ( 16.0) | 10 ( 20.0) |
| Dizziness | 0 | 3 ( 6.0) | 8 ( 16.0) | 11 ( 22.0) |
| Respiratory, thoracic and mediastinal disorders | 3 ( 6.0) | 2 ( 4.0) | 24 ( 48.0) | 25 ( 50.0) |
| Cough | 1 ( 2.0) | 0 | 8 ( 16.0) | 8 ( 16.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Psychiatric disorders | 2 ( 4.0) | 3 ( 6.0) | 19 ( 38.0) | 21 ( 42.0) |
| Confusional state | 0 | 0 | 5 ( 10.0) | 5 ( 10.0) |
| Anxiety | 1 ( 2.0) | 1 ( 2.0) | 6 ( 12.0) | 7 ( 14.0) |
| Insomnia | 0 | 1 ( 2.0) | 7 ( 14.0) | 8 ( 16.0) |
| Skin and subcutaneous tissue disorders | 1 ( 2.0) | 3 ( 6.0) | 16 ( 32.0) | 19 ( 38.0) |
| Vascular disorders | 1 ( 2.0) | 5 ( 10.0) | 15 ( 30.0) | 18 ( 36.0) |
| Hypotension | 0 | 3 ( 6.0) | 5 ( 10.0) | 8 ( 16.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Hypertension | 0 | 2 ( 4.0) | 7 ( 14.0) | 8 ( 16.0) |
| Cardiac disorders | 1 ( 2.0) | 2 ( 4.0) | 14 ( 28.0) | 14 ( 28.0) |
| Tachycardia | 0 | 0 | 8 ( 16.0) | 8 ( 16.0) |
| Renal and urinary disorders | 2 ( 4.0) | 3 ( 6.0) | 9 ( 18.0) | 11 ( 22.0) |
| Injury, poisoning and procedural complications | 2 ( 4.0) | 2 ( 4.0) | 7 ( 14.0) | 9 ( 18.0) |
| Eye disorders | 1 ( 2.0) | 1 ( 2.0) | 5 ( 10.0) | 6 ( 12.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 2.0) | 1 ( 2.0) | 6 ( 12.0) | 6 ( 12.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one AE | 34 ( 45.9) | 62 ( 83.8) | 74 (100.0) | 74 (100.0) |
| Blood and lymphatic system disorders | 18 ( 24.3) | 40 ( 54.1) | 72 ( 97.3) | 72 ( 97.3) |
| Neutropenia | 6 ( 8.1) | 24 ( 32.4) | 68 ( 91.9) | 70 ( 94.6) |
| Anaemia | 10 ( 13.5) | 20 ( 27.0) | 54 ( 73.0) | 55 ( 74.3) |
| Thrombocytopenia | 9 ( 12.2) | 15 ( 20.3) | 51 ( 68.9) | 52 ( 70.3) |
| Leukopenia | 3 ( 4.1) | 22 ( 29.7) | 34 ( 45.9) | 36 ( 48.6) |
| Lymphopenia | 5 ( 6.8) | 17 ( 23.0) | 23 ( 31.1) | 24 ( 32.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 1 ( 1.4) | 0 | 12 ( 16.2) | 12 ( 16.2) |
| Immune system disorders | 0 | 1 ( 1.4) | 67 ( 90.5) | 67 ( 90.5) |
| Cytokine release syndrome | 0 | 0 | 64 ( 86.5) | 64 ( 86.5) |
| Hypogammaglobulinaemia | 0 | 1 ( 1.4) | 17 ( 23.0) | 18 ( 24.3) |
| General disorders and administration site conditions | 6 ( 8.1) | 12 ( 16.2) | 62 ( 83.8) | 62 ( 83.8) |
| Fatigue | 4 ( 5.4) | 6 ( 8.1) | 29 ( 39.2) | 31 ( 41.9) |
| Pyrexia | 1 ( 1.4) | 3 ( 4.1) | 21 ( 28.4) | 24 ( 32.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| General physical health deterioration | 0 | 0 | 10 ( 13.5) | 10 ( 13.5) |
| Oedema peripheral | 1 ( 1.4) | 2 ( 2.7) | 9 ( 12.2) | 10 ( 13.5) |
| Asthenia | 1 ( 1.4) | 1 ( 1.4) | 12 ( 16.2) | 13 ( 17.6) |
| Chills | 1 ( 1.4) | 2 ( 2.7) | 10 ( 13.5) | 12 ( 16.2) |
| Metabolism and nutrition disorders | 8 ( 10.8) | 18 ( 24.3) | 56 ( 75.7) | 57 ( 77.0) |
| Hypokalaemia | 1 ( 1.4) | 5 ( 6.8) | 28 ( 37.8) | 30 ( 40.5) |
| Hypophosphataemia | 1 ( 1.4) | 1 ( 1.4) | 25 ( 33.8) | 25 ( 33.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Hypocalcaemia | 2 ( 2.7) | 4 ( 5.4) | 24 ( 32.4) | 26 ( 35.1) |
| Hypomagnesaemia | 0 | 3 ( 4.1) | 18 ( 24.3) | 18 ( 24.3) |
| Decreased appetite | 0 | 10 ( 13.5) | 16 ( 21.6) | 22 ( 29.7) |
| Hyponatraemia | 4 ( 5.4) | 2 ( 2.7) | 16 ( 21.6) | 16 ( 21.6) |
| Hypoalbuminaemia | 0 | 2 ( 2.7) | 10 ( 13.5) | 10 ( 13.5) |
| Gastrointestinal disorders | 6 ( 8.1) | 41 ( 55.4) | 58 ( 78.4) | 68 ( 91.9) |
| Diarrhoea | 1 ( 1.4) | 5 ( 6.8) | 27 ( 36.5) | 32 ( 43.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Nausea | 3 ( 4.1) | 27 ( 36.5) | 26 ( 35.1) | 45 ( 60.8) |
| Constipation | 0 | 13 ( 17.6) | 13 ( 17.6) | 24 ( 32.4) |
| Vomiting | 1 ( 1.4) | 3 ( 4.1) | 12 ( 16.2) | 14 ( 18.9) |
| Infections and infestations | 6 ( 8.1) | 5 ( 6.8) | 51 ( 68.9) | 51 ( 68.9) |
| Upper respiratory tract infection | 1 ( 1.4) | 0 | 9 ( 12.2) | 9 ( 12.2) |
| Pneumonia | 0 | 1 ( 1.4) | 11 ( 14.9) | 12 ( 16.2) |
| Musculoskeletal and connective tissue disorders | 6 ( 8.1) | 8 ( 10.8) | 47 ( 63.5) | 50 ( 67.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Arthralgia | 1 ( 1.4) | 3 ( 4.1) | 12 ( 16.2) | 15 ( 20.3) |
| Back pain | 1 ( 1.4) | 2 ( 2.7) | 10 ( 13.5) | 12 ( 16.2) |
| Bone pain | 1 ( 1.4) | 0 | 8 ( 10.8) | 8 ( 10.8) |
| Investigations | 8 ( 10.8) | 7 ( 9.5) | 42 ( 56.8) | 42 ( 56.8) |
| Aspartate aminotransferase increased | 1 ( 1.4) | 1 ( 1.4) | 14 ( 18.9) | 14 ( 18.9) |
| Alanine aminotransferase increased | 1 ( 1.4) | 1 ( 1.4) | 12 ( 16.2) | 12 ( 16.2) |
| Blood alkaline phosphatase increased | 1 ( 1.4) | 1 ( 1.4) | 9 ( 12.2) | 9 ( 12.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Weight decreased | 1 ( 1.4) | 0 | 7 ( 9.5) | 7 ( 9.5) |
| C-reactive protein increased | 0 | 0 | 7 ( 9.5) | 7 ( 9.5) |
| Nervous system disorders | 2 ( 2.7) | 17 ( 23.0) | 43 ( 58.1) | 47 ( 63.5) |
| Headache | 1 ( 1.4) | 12 ( 16.2) | 18 ( 24.3) | 28 ( 37.8) |
| Dizziness | 0 | 0 | 9 ( 12.2) | 9 ( 12.2) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 2.7) | 5 ( 6.8) | 39 ( 52.7) | 41 ( 55.4) |
| Cough | 1 ( 1.4) | 2 ( 2.7) | 15 ( 20.3) | 16 ( 21.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Psychiatric disorders | 1 ( 1.4) | 6 ( 8.1) | 27 ( 36.5) | 30 ( 40.5) |
| Confusional state | 0 | 0 | 12 ( 16.2) | 12 ( 16.2) |
| Anxiety | 0 | 4 ( 5.4) | 7 ( 9.5) | 11 ( 14.9) |
| Insomnia | 0 | 2 ( 2.7) | 4 ( 5.4) | 5 ( 6.8) |
| Skin and subcutaneous tissue disorders | 0 | 1 ( 1.4) | 28 ( 37.8) | 29 ( 39.2) |
| Vascular disorders | 1 ( 1.4) | 2 ( 2.7) | 22 ( 29.7) | 22 ( 29.7) |
| Hypotension | 0 | 1 ( 1.4) | 16 ( 21.6) | 16 ( 21.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.1.1.1d
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Hypertension | 0 | 1 ( 1.4) | 6 ( 8.1) | 6 ( 8.1) |
| Cardiac disorders | 3 ( 4.1) | 4 ( 5.4) | 18 ( 24.3) | 19 ( 25.7) |
| Tachycardia | 0 | 3 ( 4.1) | 10 ( 13.5) | 11 ( 14.9) |
| Renal and urinary disorders | 3 ( 4.1) | 2 ( 2.7) | 19 ( 25.7) | 20 ( 27.0) |
| Injury, poisoning and procedural complications | 0 | 0 | 18 ( 24.3) | 18 ( 24.3) |
| Eye disorders | 0 | 2 ( 2.7) | 13 ( 17.6) | 15 ( 20.3) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 9 ( 12.2) | 9 ( 12.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

### 8.3.4.1 UE Grad 1 und 2 nach SOC und PT



Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one Grade 1 or 2 AE | 32 ( 40.0) | 62 ( 77.5) | 80 (100.0) | 80 (100.0) |
| Immune system disorders | 0 | 1 ( 1.3) | 67 ( 83.8) | 67 ( 83.8) |
| Cytokine release syndrome | 0 | 0 | 65 ( 81.3) | 65 ( 81.3) |
| Hypogammaglobulinaemia | 0 | 1 ( 1.3) | 13 ( 16.3) | 14 ( 17.5) |
| Gastrointestinal disorders | 8 ( 10.0) | 39 ( 48.8) | 64 ( 80.0) | 72 ( 90.0) |
| Diarrhoea | 1 ( 1.3) | 5 ( 6.3) | 27 ( 33.8) | 30 ( 37.5) |
| Nausea | 3 ( 3.8) | 28 ( 35.0) | 24 ( 30.0) | 47 ( 58.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Constipation | 2 ( 2.5) | 10 ( 12.5) | 14 ( 17.5) | 21 ( 26.3) |
| Vomiting | 2 ( 2.5) | 3 ( 3.8) | 13 ( 16.3) | 15 ( 18.8) |
| Dry mouth | 0 | 0 | 4 ( 5.0) | 4 ( 5.0) |
| Dyspepsia | 0 | 0 | 5 ( 6.3) | 5 ( 6.3) |
| Blood and lymphatic system disorders | 15 ( 18.8) | 25 ( 31.3) | 60 ( 75.0) | 61 ( 76.3) |
| Neutropenia | 4 ( 5.0) | 7 ( 8.8) | 44 ( 55.0) | 44 ( 55.0) |
| Anaemia | 8 ( 10.0) | 14 ( 17.5) | 32 ( 40.0) | 32 ( 40.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Thrombocytopenia | 8 ( 10.0) | 9 ( 11.3) | 26 ( 32.5) | 28 ( 35.0) |
| Leukopenia | 1 ( 1.3) | 9 ( 11.3) | 18 ( 22.5) | 18 ( 22.5) |
| Lymphopenia | 0 | 2 ( 2.5) | 14 ( 17.5) | 14 ( 17.5) |
| General disorders and administration site conditions | 6 ( 7.5) | 12 ( 15.0) | 58 ( 72.5) | 60 ( 75.0) |
| Fatigue | 1 ( 1.3) | 4 ( 5.0) | 22 ( 27.5) | 24 ( 30.0) |
| Pyrexia | 3 ( 3.8) | 3 ( 3.8) | 15 ( 18.8) | 18 ( 22.5) |
| Oedema peripheral | 3 ( 3.8) | 2 ( 2.5) | 8 ( 10.0) | 9 ( 11.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Asthenia | 1 ( 1.3) | 2 ( 2.5) | 13 ( 16.3) | 15 ( 18.8) |
| Chills | 1 ( 1.3) | 1 ( 1.3) | 8 ( 10.0) | 9 ( 11.3) |
| Metabolism and nutrition disorders | 6 ( 7.5) | 16 ( 20.0) | 57 ( 71.3) | 59 ( 73.8) |
| Hypokalaemia | 0 | 5 ( 6.3) | 30 ( 37.5) | 32 ( 40.0) |
| Hypocalcaemia | 2 ( 2.5) | 4 ( 5.0) | 19 ( 23.8) | 20 ( 25.0) |
| Hypomagnesaemia | 1 ( 1.3) | 1 ( 1.3) | 18 ( 22.5) | 19 ( 23.8) |
| Decreased appetite | 1 ( 1.3) | 3 ( 3.8) | 14 ( 17.5) | 17 ( 21.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypophosphataemia | 2 ( 2.5) | 1 ( 1.3) | 18 ( 22.5) | 19 ( 23.8) |
| Hyponatraemia | 1 ( 1.3) | 2 ( 2.5) | 12 ( 15.0) | 13 ( 16.3) |
| Hypoalbuminaemia | 1 ( 1.3) | 5 ( 6.3) | 10 ( 12.5) | 10 ( 12.5) |
| Hypercalcaemia | 1 ( 1.3) | 0 | 5 ( 6.3) | 5 ( 6.3) |
| Hyperglycaemia | 1 ( 1.3) | 0 | 3 ( 3.8) | 3 ( 3.8) |
| Hyperuricaemia | 2 ( 2.5) | 2 ( 2.5) | 2 ( 2.5) | 4 ( 5.0) |
| Infections and infestations | 7 ( 8.8) | 3 ( 3.8) | 57 ( 71.3) | 58 ( 72.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Upper respiratory tract infection | 1 ( 1.3) | 0 | 14 ( 17.5) | 14 ( 17.5) |
| Pneumonia | 0 | 0 | 6 ( 7.5) | 6 ( 7.5) |
| Nasopharyngitis | 0 | 0 | 5 ( 6.3) | 5 ( 6.3) |
| Musculoskeletal and connective tissue disorders | 8 ( 10.0) | 7 ( 8.8) | 42 ( 52.5) | 44 ( 55.0) |
| Back pain | 2 ( 2.5) | 1 ( 1.3) | 12 ( 15.0) | 13 ( 16.3) |
| Arthralgia | 1 ( 1.3) | 3 ( 3.8) | 10 ( 12.5) | 13 ( 16.3) |
| Bone pain | 1 ( 1.3) | 0 | 6 ( 7.5) | 6 ( 7.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Musculoskeletal chest pain | 1 ( 1.3) | 0 | 6 ( 7.5) | 6 ( 7.5) |
| Musculoskeletal pain | 0 | 1 ( 1.3) | 3 ( 3.8) | 3 ( 3.8) |
| Myalgia | 0 | 0 | 4 ( 5.0) | 4 ( 5.0) |
| Pain in extremity | 2 ( 2.5) | 2 ( 2.5) | 3 ( 3.8) | 5 ( 6.3) |
| Investigations | 6 ( 7.5) | 9 ( 11.3) | 42 ( 52.5) | 43 ( 53.8) |
| Aspartate aminotransferase increased | 1 ( 1.3) | 2 ( 2.5) | 13 ( 16.3) | 14 ( 17.5) |
| Weight decreased | 1 ( 1.3) | 1 ( 1.3) | 10 ( 12.5) | 10 ( 12.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Alanine aminotransferase increased | 1 ( 1.3) | 1 ( 1.3) | 9 ( 11.3) | 9 ( 11.3) |
| Blood alkaline phosphatase increased | 1 ( 1.3) | 1 ( 1.3) | 9 ( 11.3) | 9 ( 11.3) |
| C-reactive protein increased | 0 | 1 ( 1.3) | 10 ( 12.5) | 10 ( 12.5) |
| Weight increased | 0 | 0 | 5 ( 6.3) | 5 ( 6.3) |
| Blood creatinine increased | 1 ( 1.3) | 2 ( 2.5) | 2 ( 2.5) | 4 ( 5.0) |
| Nervous system disorders | 4 ( 5.0) | 12 ( 15.0) | 41 ( 51.3) | 43 ( 53.8) |
| Headache | 2 ( 2.5) | 7 ( 8.8) | 20 ( 25.0) | 25 ( 31.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dizziness | 0 | 1 ( 1.3) | 10 ( 12.5) | 11 ( 13.8) |
| Tremor | 0 | 0 | 4 ( 5.0) | 4 ( 5.0) |
| Aphasia | 0 | 0 | 3 ( 3.8) | 3 ( 3.8) |
| Somnolence | 0 | 1 ( 1.3) | 6 ( 7.5) | 7 ( 8.8) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 2.5) | 3 ( 3.8) | 38 ( 47.5) | 38 ( 47.5) |
| Cough | 2 ( 2.5) | 1 ( 1.3) | 15 ( 18.8) | 15 ( 18.8) |
| Nasal congestion | 0 | 0 | 7 ( 8.8) | 7 ( 8.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dyspnoea | 0 | 0 | 6 ( 7.5) | 6 ( 7.5) |
| Oropharyngeal pain | 0 | 0 | 6 ( 7.5) | 6 ( 7.5) |
| Epistaxis | 0 | 0 | 7 ( 8.8) | 7 ( 8.8) |
| Psychiatric disorders | 1 ( 1.3) | 7 ( 8.8) | 25 ( 31.3) | 30 ( 37.5) |
| Confusional state | 0 | 0 | 9 ( 11.3) | 9 ( 11.3) |
| Anxiety | 1 ( 1.3) | 4 ( 5.0) | 7 ( 8.8) | 11 ( 13.8) |
| Insomnia | 0 | 2 ( 2.5) | 6 ( 7.5) | 7 ( 8.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Skin and subcutaneous tissue disorders | 1 ( 1.3) | 4 ( 5.0) | 27 ( 33.8) | 31 ( 38.8) |
| Alopecia | 0 | 0 | 5 ( 6.3) | 5 ( 6.3) |
| Rash | 0 | 0 | 4 ( 5.0) | 4 ( 5.0) |
| Vascular disorders | 2 ( 2.5) | 1 ( 1.3) | 16 ( 20.0) | 17 ( 21.3) |
| Hypotension | 0 | 1 ( 1.3) | 11 ( 13.8) | 12 ( 15.0) |
| Hypertension | 0 | 0 | 4 ( 5.0) | 4 ( 5.0) |
| Cardiac disorders | 3 ( 3.8) | 4 ( 5.0) | 17 ( 21.3) | 18 ( 22.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Tachycardia | 0 | 2 ( 2.5) | 9 ( 11.3) | 10 ( 12.5) |
| Renal and urinary disorders | 1 ( 1.3) | 2 ( 2.5) | 13 ( 16.3) | 14 ( 17.5) |
| Acute kidney injury | 0 | 0 | 3 ( 3.8) | 3 ( 3.8) |
| Injury, poisoning and procedural complications | 2 ( 2.5) | 0 | 13 ( 16.3) | 13 ( 16.3) |
| Infusion related reaction | 0 | 0 | 5 ( 6.3) | 5 ( 6.3) |
| Eye disorders | 1 ( 1.3) | 2 ( 2.5) | 15 ( 18.8) | 17 ( 21.3) |
| Diplopia | 0 | 2 ( 2.5) | 4 ( 5.0) | 6 ( 7.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 1.3) | 1 ( 1.3) | 7 ( 8.8) | 7 ( 8.8) |
| Reproductive system and breast disorders | 0 | 0 | 5 ( 6.3) | 5 ( 6.3) |
| Hepatobiliary disorders | 0 | 0 | 4 ( 5.0) | 4 ( 5.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one Grade 1 or 2 AE | 18 ( 40.9) | 38 ( 86.4) | 44 (100.0) | 44 (100.0) |
| Immune system disorders | 0 | 0 | 40 ( 90.9) | 40 ( 90.9) |
| Cytokine release syndrome | 0 | 0 | 39 ( 88.6) | 39 ( 88.6) |
| Hypogammaglobulinaemia | 0 | 0 | 10 ( 22.7) | 10 ( 22.7) |
| Gastrointestinal disorders | 5 ( 11.4) | 28 ( 63.6) | 30 ( 68.2) | 39 ( 88.6) |
| Diarrhoea | 1 ( 2.3) | 6 ( 13.6) | 16 ( 36.4) | 21 ( 47.7) |
| Nausea | 3 ( 6.8) | 16 ( 36.4) | 12 ( 27.3) | 23 ( 52.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Constipation | 0 | 9 ( 20.5) | 7 ( 15.9) | 15 ( 34.1) |
| Vomiting | 0 | 4 ( 9.1) | 7 ( 15.9) | 11 ( 25.0) |
| Dry mouth | 0 | 1 ( 2.3) | 5 ( 11.4) | 5 ( 11.4) |
| Dyspepsia | 0 | 2 ( 4.5) | 4 ( 9.1) | 6 ( 13.6) |
| Blood and lymphatic system disorders | 10 ( 22.7) | 14 ( 31.8) | 33 ( 75.0) | 33 ( 75.0) |
| Neutropenia | 2 ( 4.5) | 8 ( 18.2) | 21 ( 47.7) | 22 ( 50.0) |
| Anaemia | 6 ( 13.6) | 3 ( 6.8) | 23 ( 52.3) | 23 ( 52.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Thrombocytopenia | 4 ( 9.1) | 6 ( 13.6) | 16 ( 36.4) | 18 ( 40.9) |
| Leukopenia | 0 | 8 ( 18.2) | 13 ( 29.5) | 13 ( 29.5) |
| Lymphopenia | 1 ( 2.3) | 1 ( 2.3) | 6 ( 13.6) | 6 ( 13.6) |
| General disorders and administration site conditions | 6 ( 13.6) | 12 ( 27.3) | 35 ( 79.5) | 37 ( 84.1) |
| Fatigue | 4 ( 9.1) | 7 ( 15.9) | 18 ( 40.9) | 22 ( 50.0) |
| Pyrexia | 1 ( 2.3) | 3 ( 6.8) | 15 ( 34.1) | 16 ( 36.4) |
| Oedema peripheral | 1 ( 2.3) | 2 ( 4.5) | 10 ( 22.7) | 10 ( 22.7) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Asthenia | 0 | 2 ( 4.5) | 4 ( 9.1) | 6 ( 13.6) |
| Chills | 0 | 1 ( 2.3) | 5 ( 11.4) | 6 ( 13.6) |
| Metabolism and nutrition disorders | 6 ( 13.6) | 16 ( 36.4) | 36 ( 81.8) | 38 ( 86.4) |
| Hypokalaemia | 2 ( 4.5) | 4 ( 9.1) | 14 ( 31.8) | 17 ( 38.6) |
| Hypocalcaemia | 1 ( 2.3) | 1 ( 2.3) | 11 ( 25.0) | 11 ( 25.0) |
| Hypomagnesaemia | 0 | 4 ( 9.1) | 11 ( 25.0) | 11 ( 25.0) |
| Decreased appetite | 0 | 7 ( 15.9) | 13 ( 29.5) | 16 ( 36.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypophosphataemia | 1 ( 2.3) | 1 ( 2.3) | 9 ( 20.5) | 10 ( 22.7) |
| Hyponatraemia | 1 ( 2.3) | 2 ( 4.5) | 9 ( 20.5) | 9 ( 20.5) |
| Hypoalbuminaemia | 1 ( 2.3) | 2 ( 4.5) | 8 ( 18.2) | 10 ( 22.7) |
| Hypercalcaemia | 0 | 0 | 3 ( 6.8) | 3 ( 6.8) |
| Hyperglycaemia | 0 | 2 ( 4.5) | 3 ( 6.8) | 5 ( 11.4) |
| Hyperuricaemia | 2 ( 4.5) | 2 ( 4.5) | 2 ( 4.5) | 4 ( 9.1) |
| Infections and infestations | 0 | 2 ( 4.5) | 22 ( 50.0) | 22 ( 50.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Upper respiratory tract infection | 0 | 0 | 5 ( 11.4) | 5 ( 11.4) |
| Pneumonia | 0 | 0 | 4 ( 9.1) | 4 ( 9.1) |
| Nasopharyngitis | 0 | 0 | 2 ( 4.5) | 2 ( 4.5) |
| Musculoskeletal and connective tissue disorders | 3 ( 6.8) | 7 ( 15.9) | 29 ( 65.9) | 31 ( 70.5) |
| Back pain | 1 ( 2.3) | 4 ( 9.1) | 5 ( 11.4) | 8 ( 18.2) |
| Arthralgia | 1 ( 2.3) | 0 | 6 ( 13.6) | 6 ( 13.6) |
| Bone pain | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Musculoskeletal chest pain | 1 ( 2.3) | 1 ( 2.3) | 3 ( 6.8) | 3 ( 6.8) |
| Musculoskeletal pain | 0 | 1 ( 2.3) | 5 ( 11.4) | 6 ( 13.6) |
| Myalgia | 0 | 0 | 4 ( 9.1) | 4 ( 9.1) |
| Pain in extremity | 0 | 1 ( 2.3) | 4 ( 9.1) | 5 ( 11.4) |
| Investigations | 4 ( 9.1) | 6 ( 13.6) | 25 ( 56.8) | 25 ( 56.8) |
| Aspartate aminotransferase increased | 1 ( 2.3) | 0 | 8 ( 18.2) | 8 ( 18.2) |
| Weight decreased | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Alanine aminotransferase increased | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |
| Blood alkaline phosphatase increased | 1 ( 2.3) | 0 | 6 ( 13.6) | 6 ( 13.6) |
| C-reactive protein increased | 0 | 0 | 3 ( 6.8) | 3 ( 6.8) |
| Weight increased | 0 | 1 ( 2.3) | 3 ( 6.8) | 3 ( 6.8) |
| Blood creatinine increased | 0 | 3 ( 6.8) | 3 ( 6.8) | 3 ( 6.8) |
| Nervous system disorders | 1 ( 2.3) | 11 ( 25.0) | 24 ( 54.5) | 28 ( 63.6) |
| Headache | 0 | 7 ( 15.9) | 6 ( 13.6) | 13 ( 29.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dizziness | 0 | 2 ( 4.5) | 7 ( 15.9) | 9 ( 20.5) |
| Tremor | 0 | 1 ( 2.3) | 5 ( 11.4) | 6 ( 13.6) |
| Aphasia | 0 | 0 | 4 ( 9.1) | 4 ( 9.1) |
| Somnolence | 0 | 0 | 1 ( 2.3) | 1 ( 2.3) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 4.5) | 3 ( 6.8) | 22 ( 50.0) | 24 ( 54.5) |
| Cough | 0 | 1 ( 2.3) | 8 ( 18.2) | 9 ( 20.5) |
| Nasal congestion | 0 | 0 | 3 ( 6.8) | 3 ( 6.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dyspnoea | 1 ( 2.3) | 2 ( 4.5) | 3 ( 6.8) | 4 ( 9.1) |
| Oropharyngeal pain | 0 | 0 | 3 ( 6.8) | 3 ( 6.8) |
| Epistaxis | 1 ( 2.3) | 0 | 0 | 0 |
| Psychiatric disorders | 2 ( 4.5) | 2 ( 4.5) | 19 ( 43.2) | 20 ( 45.5) |
| Confusional state | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |
| Anxiety | 0 | 1 ( 2.3) | 5 ( 11.4) | 6 ( 13.6) |
| Insomnia | 0 | 1 ( 2.3) | 5 ( 11.4) | 6 ( 13.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Skin and subcutaneous tissue disorders | 0 | 0 | 15 ( 34.1) | 15 ( 34.1) |
| Alopecia | 0 | 0 | 5 ( 11.4) | 5 ( 11.4) |
| Rash | 0 | 0 | 4 ( 9.1) | 4 ( 9.1) |
| Vascular disorders | 0 | 4 ( 9.1) | 18 ( 40.9) | 19 ( 43.2) |
| Hypotension | 0 | 3 ( 6.8) | 9 ( 20.5) | 11 ( 25.0) |
| Hypertension | 0 | 1 ( 2.3) | 7 ( 15.9) | 7 ( 15.9) |
| Cardiac disorders | 1 ( 2.3) | 2 ( 4.5) | 14 ( 31.8) | 14 ( 31.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Tachycardia | 0 | 1 ( 2.3) | 9 ( 20.5) | 9 ( 20.5) |
| Renal and urinary disorders | 2 ( 4.5) | 3 ( 6.8) | 12 ( 27.3) | 14 ( 31.8) |
| Acute kidney injury | 0 | 3 ( 6.8) | 2 ( 4.5) | 4 ( 9.1) |
| Injury, poisoning and procedural complications | 0 | 1 ( 2.3) | 9 ( 20.5) | 10 ( 22.7) |
| Infusion related reaction | 0 | 0 | 3 ( 6.8) | 3 ( 6.8) |
| Eye disorders | 0 | 1 ( 2.3) | 3 ( 6.8) | 4 ( 9.1) |
| Diplopia | 0 | 0 | 1 ( 2.3) | 1 ( 2.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 5 ( 11.4) | 5 ( 11.4) |
| Reproductive system and breast disorders | 0 | 0 | 5 ( 11.4) | 5 ( 11.4) |
| Hepatobiliary disorders | 1 ( 2.3) | 0 | 3 ( 6.8) | 3 ( 6.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE | 45 ( 40.9) | 92 ( 83.6) | 110 (100.0) | 110 (100.0) |
| Immune system disorders | 0 | 1 ( 0.9) | 94 ( 85.5) | 94 ( 85.5) |
| Cytokine release syndrome | 0 | 0 | 92 ( 83.6) | 92 ( 83.6) |
| Hypogammaglobulinaemia | 0 | 1 ( 0.9) | 20 ( 18.2) | 21 ( 19.1) |
| Gastrointestinal disorders | 13 ( 11.8) | 61 ( 55.5) | 83 ( 75.5) | 99 ( 90.0) |
| Diarrhoea | 2 ( 1.8) | 11 ( 10.0) | 39 ( 35.5) | 47 ( 42.7) |
| Nausea | 6 ( 5.5) | 41 ( 37.3) | 32 ( 29.1) | 63 ( 57.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Constipation | 2 ( 1.8) | 16 ( 14.5) | 19 ( 17.3) | 32 ( 29.1) |
| Vomiting | 2 ( 1.8) | 5 ( 4.5) | 17 ( 15.5) | 21 ( 19.1) |
| Dry mouth | 0 | 1 ( 0.9) | 8 ( 7.3) | 8 ( 7.3) |
| Dyspepsia | 0 | 2 ( 1.8) | 6 ( 5.5) | 8 ( 7.3) |
| Blood and lymphatic system disorders | 23 ( 20.9) | 37 ( 33.6) | 84 ( 76.4) | 85 ( 77.3) |
| Neutropenia | 5 ( 4.5) | 13 ( 11.8) | 59 ( 53.6) | 60 ( 54.5) |
| Anaemia | 14 ( 12.7) | 17 ( 15.5) | 52 ( 47.3) | 52 ( 47.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Thrombocytopenia | 11 ( 10.0) | 15 ( 13.6) | 41 ( 37.3) | 45 ( 40.9) |
| Leukopenia | 1 ( 0.9) | 17 ( 15.5) | 31 ( 28.2) | 31 ( 28.2) |
| Lymphopenia | 1 ( 0.9) | 3 ( 2.7) | 19 ( 17.3) | 19 ( 17.3) |
| General disorders and administration site conditions | 11 ( 10.0) | 21 ( 19.1) | 84 ( 76.4) | 88 ( 80.0) |
| Fatigue | 5 ( 4.5) | 10 ( 9.1) | 39 ( 35.5) | 44 ( 40.0) |
| Pyrexia | 3 ( 2.7) | 5 ( 4.5) | 27 ( 24.5) | 31 ( 28.2) |
| Oedema peripheral | 4 ( 3.6) | 3 ( 2.7) | 15 ( 13.6) | 16 ( 14.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Asthenia | 1 ( 0.9) | 4 ( 3.6) | 15 ( 13.6) | 19 ( 17.3) |
| Chills | 1 ( 0.9) | 2 ( 1.8) | 12 ( 10.9) | 14 ( 12.7) |
| Metabolism and nutrition disorders | 11 ( 10.0) | 30 ( 27.3) | 84 ( 76.4) | 88 ( 80.0) |
| Hypokalaemia | 2 ( 1.8) | 9 ( 8.2) | 39 ( 35.5) | 44 ( 40.0) |
| Hypocalcaemia | 3 ( 2.7) | 5 ( 4.5) | 29 ( 26.4) | 30 ( 27.3) |
| Hypomagnesaemia | 0 | 5 ( 4.5) | 27 ( 24.5) | 28 ( 25.5) |
| Decreased appetite | 1 ( 0.9) | 10 ( 9.1) | 25 ( 22.7) | 31 ( 28.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypophosphataemia | 3 ( 2.7) | 2 ( 1.8) | 25 ( 22.7) | 27 ( 24.5) |
| Hyponatraemia | 2 ( 1.8) | 3 ( 2.7) | 20 ( 18.2) | 21 ( 19.1) |
| Hypoalbuminaemia | 2 ( 1.8) | 6 ( 5.5) | 16 ( 14.5) | 18 ( 16.4) |
| Hypercalcaemia | 1 ( 0.9) | 0 | 8 ( 7.3) | 8 ( 7.3) |
| Hyperglycaemia | 1 ( 0.9) | 2 ( 1.8) | 6 ( 5.5) | 8 ( 7.3) |
| Hyperuricaemia | 4 ( 3.6) | 4 ( 3.6) | 4 ( 3.6) | 8 ( 7.3) |
| Infections and infestations | 6 ( 5.5) | 5 ( 4.5) | 70 ( 63.6) | 71 ( 64.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Upper respiratory tract infection | 1 ( 0.9) | 0 | 18 ( 16.4) | 18 ( 16.4) |
| Pneumonia | 0 | 0 | 9 ( 8.2) | 9 ( 8.2) |
| Nasopharyngitis | 0 | 0 | 7 ( 6.4) | 7 ( 6.4) |
| Musculoskeletal and connective tissue disorders | 10 ( 9.1) | 12 ( 10.9) | 64 ( 58.2) | 67 ( 60.9) |
| Back pain | 3 ( 2.7) | 4 ( 3.6) | 15 ( 13.6) | 18 ( 16.4) |
| Arthralgia | 1 ( 0.9) | 3 ( 2.7) | 15 ( 13.6) | 18 ( 16.4) |
| Bone pain | 1 ( 0.9) | 0 | 11 ( 10.0) | 11 ( 10.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Musculoskeletal chest pain | 2 ( 1.8) | 1 ( 0.9) | 7 ( 6.4) | 7 ( 6.4) |
| Musculoskeletal pain | 0 | 2 ( 1.8) | 7 ( 6.4) | 8 ( 7.3) |
| Myalgia | 0 | 0 | 8 ( 7.3) | 8 ( 7.3) |
| Pain in extremity | 2 ( 1.8) | 2 ( 1.8) | 7 ( 6.4) | 9 ( 8.2) |
| Investigations | 9 ( 8.2) | 14 ( 12.7) | 62 ( 56.4) | 63 ( 57.3) |
| Aspartate aminotransferase increased | 1 ( 0.9) | 2 ( 1.8) | 21 ( 19.1) | 22 ( 20.0) |
| Weight decreased | 1 ( 0.9) | 0 | 16 ( 14.5) | 16 ( 14.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Alanine aminotransferase increased | 0 | 1 ( 0.9) | 16 ( 14.5) | 16 ( 14.5) |
| Blood alkaline phosphatase increased | 2 ( 1.8) | 1 ( 0.9) | 15 ( 13.6) | 15 ( 13.6) |
| C-reactive protein increased | 0 | 1 ( 0.9) | 12 ( 10.9) | 12 ( 10.9) |
| Weight increased | 0 | 1 ( 0.9) | 8 ( 7.3) | 8 ( 7.3) |
| Blood creatinine increased | 1 ( 0.9) | 5 ( 4.5) | 5 ( 4.5) | 7 ( 6.4) |
| Nervous system disorders | 4 ( 3.6) | 22 ( 20.0) | 61 ( 55.5) | 66 ( 60.0) |
| Headache | 1 ( 0.9) | 14 ( 12.7) | 26 ( 23.6) | 38 ( 34.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dizziness | 0 | 3 ( 2.7) | 15 ( 13.6) | 18 ( 16.4) |
| Tremor | 0 | 1 ( 0.9) | 8 ( 7.3) | 9 ( 8.2) |
| Aphasia | 0 | 0 | 7 ( 6.4) | 7 ( 6.4) |
| Somnolence | 0 | 1 ( 0.9) | 7 ( 6.4) | 8 ( 7.3) |
| Respiratory, thoracic and mediastinal disorders | 4 ( 3.6) | 5 ( 4.5) | 57 ( 51.8) | 59 ( 53.6) |
| Cough | 2 ( 1.8) | 2 ( 1.8) | 23 ( 20.9) | 24 ( 21.8) |
| Nasal congestion | 0 | 0 | 9 ( 8.2) | 9 ( 8.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dyspnoea | 1 ( 0.9) | 2 ( 1.8) | 8 ( 7.3) | 9 ( 8.2) |
| Oropharyngeal pain | 0 | 0 | 9 ( 8.2) | 9 ( 8.2) |
| Epistaxis | 1 ( 0.9) | 0 | 6 ( 5.5) | 6 ( 5.5) |
| Psychiatric disorders | 3 ( 2.7) | 9 ( 8.2) | 42 ( 38.2) | 48 ( 43.6) |
| Confusional state | 0 | 0 | 15 ( 13.6) | 15 ( 13.6) |
| Anxiety | 1 ( 0.9) | 5 ( 4.5) | 11 ( 10.0) | 16 ( 14.5) |
| Insomnia | 0 | 3 ( 2.7) | 11 ( 10.0) | 13 ( 11.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Skin and subcutaneous tissue disorders | 1 ( 0.9) | 4 ( 3.6) | 37 ( 33.6) | 41 ( 37.3) |
| Alopecia | 0 | 0 | 10 ( 9.1) | 10 ( 9.1) |
| Rash | 0 | 0 | 7 ( 6.4) | 7 ( 6.4) |
| Vascular disorders | 2 ( 1.8) | 5 ( 4.5) | 32 ( 29.1) | 34 ( 30.9) |
| Hypotension | 0 | 4 ( 3.6) | 19 ( 17.3) | 22 ( 20.0) |
| Hypertension | 0 | 1 ( 0.9) | 10 ( 9.1) | 10 ( 9.1) |
| Cardiac disorders | 4 ( 3.6) | 6 ( 5.5) | 29 ( 26.4) | 30 ( 27.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Tachycardia | 0 | 3 ( 2.7) | 17 ( 15.5) | 18 ( 16.4) |
| Renal and urinary disorders | 3 ( 2.7) | 4 ( 3.6) | 25 ( 22.7) | 27 ( 24.5) |
| Acute kidney injury | 0 | 2 ( 1.8) | 5 ( 4.5) | 6 ( 5.5) |
| Injury, poisoning and procedural complications | 2 ( 1.8) | 1 ( 0.9) | 20 ( 18.2) | 21 ( 19.1) |
| Infusion related reaction | 0 | 0 | 7 ( 6.4) | 7 ( 6.4) |
| Eye disorders | 1 ( 0.9) | 2 ( 1.8) | 16 ( 14.5) | 18 ( 16.4) |
| Diplopia | 0 | 1 ( 0.9) | 4 ( 3.6) | 5 ( 4.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 1 ( 0.9) | 10 ( 9.1) | 10 ( 9.1) |
| Reproductive system and breast disorders | 0 | 0 | 8 ( 7.3) | 8 ( 7.3) |
| Hepatobiliary disorders | 1 ( 0.9) | 0 | 7 ( 6.4) | 7 ( 6.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE | 5 ( 35.7) | 8 ( 57.1) | 14 (100.0) | 14 (100.0) |
| Immune system disorders | 0 | 0 | 13 ( 92.9) | 13 ( 92.9) |
| Cytokine release syndrome | 0 | 0 | 12 ( 85.7) | 12 ( 85.7) |
| Hypogammaglobulinaemia | 0 | 0 | 3 ( 21.4) | 3 ( 21.4) |
| Gastrointestinal disorders | 0 | 6 ( 42.9) | 11 ( 78.6) | 12 ( 85.7) |
| Diarrhoea | 0 | 0 | 4 ( 28.6) | 4 ( 28.6) |
| Nausea | 0 | 3 ( 21.4) | 4 ( 28.6) | 7 ( 50.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Constipation | 0 | 3 ( 21.4) | 2 ( 14.3) | 4 ( 28.6) |
| Vomiting | 0 | 2 ( 14.3) | 3 ( 21.4) | 5 ( 35.7) |
| Dry mouth | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Dyspepsia | 0 | 0 | 3 ( 21.4) | 3 ( 21.4) |
| Blood and lymphatic system disorders | 2 ( 14.3) | 2 ( 14.3) | 9 ( 64.3) | 9 ( 64.3) |
| Neutropenia | 1 ( 7.1) | 2 ( 14.3) | 6 ( 42.9) | 6 ( 42.9) |
| Anaemia | 0 | 0 | 3 ( 21.4) | 3 ( 21.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Thrombocytopenia | 1 ( 7.1) | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Leukopenia | 0 | 0 | 0 | 0 |
| Lymphopenia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| General disorders and administration site conditions | 1 ( 7.1) | 3 ( 21.4) | 9 ( 64.3) | 9 ( 64.3) |
| Fatigue | 0 | 1 ( 7.1) | 1 ( 7.1) | 2 ( 14.3) |
| Pyrexia | 1 ( 7.1) | 1 ( 7.1) | 3 ( 21.4) | 3 ( 21.4) |
| Oedema peripheral | 0 | 1 ( 7.1) | 3 ( 21.4) | 3 ( 21.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Asthenia | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Chills | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Metabolism and nutrition disorders | 1 ( 7.1) | 2 ( 14.3) | 9 ( 64.3) | 9 ( 64.3) |
| Hypokalaemia | 0 | 0 | 5 ( 35.7) | 5 ( 35.7) |
| Hypocalcaemia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Hypomagnesaemia | 1 ( 7.1) | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Decreased appetite | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypophosphataemia | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Hyponatraemia | 0 | 1 ( 7.1) | 1 ( 7.1) | 1 ( 7.1) |
| Hypoalbuminaemia | 0 | 1 ( 7.1) | 2 ( 14.3) | 2 ( 14.3) |
| Hypercalcaemia | 0 | 0 | 0 | 0 |
| Hyperglycaemia | 0 | 0 | 0 | 0 |
| Hyperuricaemia | 0 | 0 | 0 | 0 |
| Infections and infestations | 1 ( 7.1) | 0 | 9 ( 64.3) | 9 ( 64.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Upper respiratory tract infection | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Pneumonia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Nasopharyngitis | 0 | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 1 ( 7.1) | 2 ( 14.3) | 7 ( 50.0) | 8 ( 57.1) |
| Back pain | 0 | 1 ( 7.1) | 2 ( 14.3) | 3 ( 21.4) |
| Arthralgia | 1 ( 7.1) | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Bone pain | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Musculoskeletal chest pain | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Musculoskeletal pain | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Myalgia | 0 | 0 | 0 | 0 |
| Pain in extremity | 0 | 1 ( 7.1) | 0 | 1 ( 7.1) |
| Investigations | 1 ( 7.1) | 1 ( 7.1) | 5 ( 35.7) | 5 ( 35.7) |
| Aspartate aminotransferase increased | 1 ( 7.1) | 0 | 0 | 0 |
| Weight decreased | 0 | 1 ( 7.1) | 1 ( 7.1) | 1 ( 7.1) |

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AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Alanine aminotransferase increased | 1 ( 7.1) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | 0 | 0 | 0 | 0 |
| C-reactive protein increased | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Weight increased | 0 | 0 | 0 | 0 |
| Blood creatinine increased | 0 | 0 | 0 | 0 |
| Nervous system disorders | 1 ( 7.1) | 1 ( 7.1) | 4 ( 28.6) | 5 ( 35.7) |
| Headache | 1 ( 7.1) | 0 | 0 | 0 |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dizziness | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Tremor | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Aphasia | 0 | 0 | 0 | 0 |
| Somnolence | 0 | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 0 | 1 ( 7.1) | 3 ( 21.4) | 3 ( 21.4) |
| Cough | 0 | 0 | 0 | 0 |
| Nasal congestion | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |

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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dyspnoea | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Oropharyngeal pain | 0 | 0 | 0 | 0 |
| Epistaxis | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Psychiatric disorders | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Confusional state | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Anxiety | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Insomnia | 0 | 0 | 0 | 0 |

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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Skin and subcutaneous tissue disorders | 0 | 0 | 5 ( 35.7) | 5 ( 35.7) |
| Alopecia | 0 | 0 | 0 | 0 |
| Rash | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Vascular disorders | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Hypotension | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Hypertension | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Cardiac disorders | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |

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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Tachycardia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Renal and urinary disorders | 0 | 1 ( 7.1) | 0 | 1 ( 7.1) |
| Acute kidney injury | 0 | 1 ( 7.1) | 0 | 1 ( 7.1) |
| Injury, poisoning and procedural complications | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Infusion related reaction | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Eye disorders | 0 | 1 ( 7.1) | 2 ( 14.3) | 3 ( 21.4) |
| Diplopia | 0 | 1 ( 7.1) | 1 ( 7.1) | 2 ( 14.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 7.1) | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Reproductive system and breast disorders | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Hepatobiliary disorders | 0 | 0 | 0 | 0 |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE | 15 ( 46.9) | 30 ( 93.8) | 32 (100.0) | 32 (100.0) |
| Immune system disorders | 0 | 0 | 24 ( 75.0) | 24 ( 75.0) |
| Cytokine release syndrome | 0 | 0 | 23 ( 71.9) | 23 ( 71.9) |
| Hypogammaglobulinaemia | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Gastrointestinal disorders | 3 ( 9.4) | 24 ( 75.0) | 28 ( 87.5) | 31 ( 96.9) |
| Diarrhoea | 0 | 5 ( 15.6) | 7 ( 21.9) | 11 ( 34.4) |
| Nausea | 1 ( 3.1) | 16 ( 50.0) | 11 ( 34.4) | 22 ( 68.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Constipation | 0 | 5 ( 15.6) | 8 ( 25.0) | 12 ( 37.5) |
| Vomiting | 0 | 4 ( 12.5) | 7 ( 21.9) | 10 ( 31.3) |
| Dry mouth | 0 | 1 ( 3.1) | 3 ( 9.4) | 3 ( 9.4) |
| Dyspepsia | 0 | 1 ( 3.1) | 3 ( 9.4) | 4 ( 12.5) |
| Blood and lymphatic system disorders | 9 ( 28.1) | 11 ( 34.4) | 27 ( 84.4) | 27 ( 84.4) |
| Neutropenia | 2 ( 6.3) | 4 ( 12.5) | 18 ( 56.3) | 19 ( 59.4) |
| Anaemia | 6 ( 18.8) | 4 ( 12.5) | 15 ( 46.9) | 15 ( 46.9) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Thrombocytopenia | 2 ( 6.3) | 3 ( 9.4) | 17 ( 53.1) | 18 ( 56.3) |
| Leukopenia | 1 ( 3.1) | 8 ( 25.0) | 13 ( 40.6) | 13 ( 40.6) |
| Lymphopenia | 0 | 1 ( 3.1) | 8 ( 25.0) | 8 ( 25.0) |
| General disorders and administration site conditions | 2 ( 6.3) | 9 ( 28.1) | 24 ( 75.0) | 25 ( 78.1) |
| Fatigue | 1 ( 3.1) | 3 ( 9.4) | 13 ( 40.6) | 13 ( 40.6) |
| Pyrexia | 1 ( 3.1) | 3 ( 9.4) | 7 ( 21.9) | 9 ( 28.1) |
| Oedema peripheral | 1 ( 3.1) | 1 ( 3.1) | 4 ( 12.5) | 4 ( 12.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Asthenia | 0 | 1 ( 3.1) | 3 ( 9.4) | 4 ( 12.5) |
| Chills | 0 | 1 ( 3.1) | 5 ( 15.6) | 6 ( 18.8) |
| Metabolism and nutrition disorders | 3 ( 9.4) | 11 ( 34.4) | 23 ( 71.9) | 24 ( 75.0) |
| Hypokalaemia | 1 ( 3.1) | 3 ( 9.4) | 9 ( 28.1) | 11 ( 34.4) |
| Hypocalcaemia | 1 ( 3.1) | 1 ( 3.1) | 7 ( 21.9) | 7 ( 21.9) |
| Hypomagnesaemia | 0 | 3 ( 9.4) | 7 ( 21.9) | 8 ( 25.0) |
| Decreased appetite | 0 | 3 ( 9.4) | 9 ( 28.1) | 11 ( 34.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Hypophosphataemia | 1 ( 3.1) | 1 ( 3.1) | 4 ( 12.5) | 5 ( 15.6) |
| Hyponatraemia | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Hypoalbuminaemia | 1 ( 3.1) | 4 ( 12.5) | 5 ( 15.6) | 7 ( 21.9) |
| Hypercalcaemia | 1 ( 3.1) | 0 | 1 ( 3.1) | 1 ( 3.1) |
| Hyperglycaemia | 0 | 1 ( 3.1) | 2 ( 6.3) | 3 ( 9.4) |
| Hyperuricaemia | 1 ( 3.1) | 1 ( 3.1) | 0 | 1 ( 3.1) |
| Infections and infestations | 2 ( 6.3) | 0 | 19 ( 59.4) | 19 ( 59.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Upper respiratory tract infection | 0 | 0 | 6 ( 18.8) | 6 ( 18.8) |
| Pneumonia | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Nasopharyngitis | 0 | 0 | 1 ( 3.1) | 1 ( 3.1) |
| Musculoskeletal and connective tissue disorders | 2 ( 6.3) | 7 ( 21.9) | 23 ( 71.9) | 25 ( 78.1) |
| Back pain | 1 ( 3.1) | 3 ( 9.4) | 9 ( 28.1) | 12 ( 37.5) |
| Arthralgia | 0 | 2 ( 6.3) | 4 ( 12.5) | 6 ( 18.8) |
| Bone pain | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Musculoskeletal chest pain | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |
| Musculoskeletal pain | 0 | 1 ( 3.1) | 2 ( 6.3) | 3 ( 9.4) |
| Myalgia | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Pain in extremity | 0 | 1 ( 3.1) | 2 ( 6.3) | 3 ( 9.4) |
| Investigations | 4 ( 12.5) | 6 ( 18.8) | 21 ( 65.6) | 22 ( 68.8) |
| Aspartate aminotransferase increased | 1 ( 3.1) | 0 | 8 ( 25.0) | 8 ( 25.0) |
| Weight decreased | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Alanine aminotransferase increased | 0 | 0 | 6 ( 18.8) | 6 ( 18.8) |
| Blood alkaline phosphatase increased | 2 ( 6.3) | 0 | 8 ( 25.0) | 8 ( 25.0) |
| C-reactive protein increased | 0 | 1 ( 3.1) | 4 ( 12.5) | 4 ( 12.5) |
| Weight increased | 0 | 0 | 1 ( 3.1) | 1 ( 3.1) |
| Blood creatinine increased | 0 | 3 ( 9.4) | 2 ( 6.3) | 3 ( 9.4) |
| Nervous system disorders | 1 ( 3.1) | 9 ( 28.1) | 18 ( 56.3) | 19 ( 59.4) |
| Headache | 1 ( 3.1) | 4 ( 12.5) | 11 ( 34.4) | 14 ( 43.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dizziness | 0 | 2 ( 6.3) | 5 ( 15.6) | 7 ( 21.9) |
| Tremor | 0 | 1 ( 3.1) | 4 ( 12.5) | 5 ( 15.6) |
| Aphasia | 0 | 0 | 1 ( 3.1) | 1 ( 3.1) |
| Somnolence | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Respiratory, thoracic and mediastinal disorders | 3 ( 9.4) | 2 ( 6.3) | 16 ( 50.0) | 17 ( 53.1) |
| Cough | 2 ( 6.3) | 1 ( 3.1) | 8 ( 25.0) | 8 ( 25.0) |
| Nasal congestion | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dyspnoea | 0 | 1 ( 3.1) | 3 ( 9.4) | 4 ( 12.5) |
| Oropharyngeal pain | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Epistaxis | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |
| Psychiatric disorders | 1 ( 3.1) | 3 ( 9.4) | 9 ( 28.1) | 12 ( 37.5) |
| Confusional state | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Anxiety | 1 ( 3.1) | 1 ( 3.1) | 4 ( 12.5) | 5 ( 15.6) |
| Insomnia | 0 | 1 ( 3.1) | 1 ( 3.1) | 2 ( 6.3) |

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[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Skin and subcutaneous tissue disorders | 0 | 2 ( 6.3) | 11 ( 34.4) | 13 ( 40.6) |
| Alopecia | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |
| Rash | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Vascular disorders | 2 ( 6.3) | 2 ( 6.3) | 10 ( 31.3) | 11 ( 34.4) |
| Hypotension | 0 | 2 ( 6.3) | 5 ( 15.6) | 7 ( 21.9) |
| Hypertension | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |
| Cardiac disorders | 2 ( 6.3) | 3 ( 9.4) | 10 ( 31.3) | 11 ( 34.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Tachycardia | 0 | 2 ( 6.3) | 7 ( 21.9) | 8 ( 25.0) |
| Renal and urinary disorders | 1 ( 3.1) | 2 ( 6.3) | 6 ( 18.8) | 8 ( 25.0) |
| Acute kidney injury | 0 | 1 ( 3.1) | 1 ( 3.1) | 2 ( 6.3) |
| Injury, poisoning and procedural complications | 1 ( 3.1) | 1 ( 3.1) | 6 ( 18.8) | 7 ( 21.9) |
| Infusion related reaction | 0 | 0 | 1 ( 3.1) | 1 ( 3.1) |
| Eye disorders | 1 ( 3.1) | 0 | 6 ( 18.8) | 6 ( 18.8) |
| Diplopia | 0 | 0 | 1 ( 3.1) | 1 ( 3.1) |

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[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Reproductive system and breast disorders | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |
| Hepatobiliary disorders | 0 | 0 | 1 ( 3.1) | 1 ( 3.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one Grade 1 or 2 AE | 35 ( 38.0) | 70 ( 76.1) | 92 (100.0) | 92 (100.0) |
| Immune system disorders | 0 | 1 ( 1.1) | 83 ( 90.2) | 83 ( 90.2) |
| Cytokine release syndrome | 0 | 0 | 81 ( 88.0) | 81 ( 88.0) |
| Hypogammaglobulinaemia | 0 | 1 ( 1.1) | 19 ( 20.7) | 20 ( 21.7) |
| Gastrointestinal disorders | 10 ( 10.9) | 43 ( 46.7) | 66 ( 71.7) | 80 ( 87.0) |
| Diarrhoea | 2 ( 2.2) | 6 ( 6.5) | 36 ( 39.1) | 40 ( 43.5) |
| Nausea | 5 ( 5.4) | 28 ( 30.4) | 25 ( 27.2) | 48 ( 52.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Constipation | 2 ( 2.2) | 14 ( 15.2) | 13 ( 14.1) | 24 ( 26.1) |
| Vomiting | 2 ( 2.2) | 3 ( 3.3) | 13 ( 14.1) | 16 ( 17.4) |
| Dry mouth | 0 | 0 | 6 ( 6.5) | 6 ( 6.5) |
| Dyspepsia | 0 | 1 ( 1.1) | 6 ( 6.5) | 7 ( 7.6) |
| Blood and lymphatic system disorders | 16 ( 17.4) | 28 ( 30.4) | 66 ( 71.7) | 67 ( 72.8) |
| Neutropenia | 4 ( 4.3) | 11 ( 12.0) | 47 ( 51.1) | 47 ( 51.1) |
| Anaemia | 8 ( 8.7) | 13 ( 14.1) | 40 ( 43.5) | 40 ( 43.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Thrombocytopenia | 10 ( 10.9) | 12 ( 13.0) | 25 ( 27.2) | 28 ( 30.4) |
| Leukopenia | 0 | 9 ( 9.8) | 18 ( 19.6) | 18 ( 19.6) |
| Lymphopenia | 1 ( 1.1) | 2 ( 2.2) | 12 ( 13.0) | 12 ( 13.0) |
| General disorders and administration site conditions | 10 ( 10.9) | 15 ( 16.3) | 69 ( 75.0) | 72 ( 78.3) |
| Fatigue | 4 ( 4.3) | 8 ( 8.7) | 27 ( 29.3) | 33 ( 35.9) |
| Pyrexia | 3 ( 3.3) | 3 ( 3.3) | 23 ( 25.0) | 25 ( 27.2) |
| Oedema peripheral | 3 ( 3.3) | 3 ( 3.3) | 14 ( 15.2) | 15 ( 16.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Asthenia | 1 ( 1.1) | 3 ( 3.3) | 14 ( 15.2) | 17 ( 18.5) |
| Chills | 1 ( 1.1) | 1 ( 1.1) | 8 ( 8.7) | 9 ( 9.8) |
| Metabolism and nutrition disorders | 9 ( 9.8) | 21 ( 22.8) | 70 ( 76.1) | 73 ( 79.3) |
| Hypokalaemia | 1 ( 1.1) | 6 ( 6.5) | 35 ( 38.0) | 38 ( 41.3) |
| Hypocalcaemia | 2 ( 2.2) | 4 ( 4.3) | 23 ( 25.0) | 24 ( 26.1) |
| Hypomagnesaemia | 1 ( 1.1) | 2 ( 2.2) | 22 ( 23.9) | 22 ( 23.9) |
| Decreased appetite | 1 ( 1.1) | 7 ( 7.6) | 18 ( 19.6) | 22 ( 23.9) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypophosphataemia | 2 ( 2.2) | 1 ( 1.1) | 23 ( 25.0) | 24 ( 26.1) |
| Hyponatraemia | 2 ( 2.2) | 4 ( 4.3) | 17 ( 18.5) | 18 ( 19.6) |
| Hypoalbuminaemia | 1 ( 1.1) | 3 ( 3.3) | 13 ( 14.1) | 13 ( 14.1) |
| Hypercalcaemia | 0 | 0 | 7 ( 7.6) | 7 ( 7.6) |
| Hyperglycaemia | 1 ( 1.1) | 1 ( 1.1) | 4 ( 4.3) | 5 ( 5.4) |
| Hyperuricaemia | 3 ( 3.3) | 3 ( 3.3) | 4 ( 4.3) | 7 ( 7.6) |
| Infections and infestations | 5 ( 5.4) | 5 ( 5.4) | 60 ( 65.2) | 61 ( 66.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Upper respiratory tract infection | 1 ( 1.1) | 0 | 13 ( 14.1) | 13 ( 14.1) |
| Pneumonia | 0 | 0 | 8 ( 8.7) | 8 ( 8.7) |
| Nasopharyngitis | 0 | 0 | 6 ( 6.5) | 6 ( 6.5) |
| Musculoskeletal and connective tissue disorders | 9 ( 9.8) | 7 ( 7.6) | 48 ( 52.2) | 50 ( 54.3) |
| Back pain | 2 ( 2.2) | 2 ( 2.2) | 8 ( 8.7) | 9 ( 9.8) |
| Arthralgia | 2 ( 2.2) | 1 ( 1.1) | 12 ( 13.0) | 13 ( 14.1) |
| Bone pain | 1 ( 1.1) | 0 | 9 ( 9.8) | 9 ( 9.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Musculoskeletal chest pain | 2 ( 2.2) | 1 ( 1.1) | 6 ( 6.5) | 6 ( 6.5) |
| Musculoskeletal pain | 0 | 1 ( 1.1) | 6 ( 6.5) | 6 ( 6.5) |
| Myalgia | 0 | 0 | 6 ( 6.5) | 6 ( 6.5) |
| Pain in extremity | 2 ( 2.2) | 2 ( 2.2) | 5 ( 5.4) | 7 ( 7.6) |
| Investigations | 6 ( 6.5) | 9 ( 9.8) | 46 ( 50.0) | 46 ( 50.0) |
| Aspartate aminotransferase increased | 1 ( 1.1) | 2 ( 2.2) | 13 ( 14.1) | 14 ( 15.2) |
| Weight decreased | 1 ( 1.1) | 1 ( 1.1) | 14 ( 15.2) | 14 ( 15.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Alanine aminotransferase increased | 1 ( 1.1) | 1 ( 1.1) | 10 ( 10.9) | 10 ( 10.9) |
| Blood alkaline phosphatase increased | 0 | 1 ( 1.1) | 7 ( 7.6) | 7 ( 7.6) |
| C-reactive protein increased | 0 | 0 | 9 ( 9.8) | 9 ( 9.8) |
| Weight increased | 0 | 1 ( 1.1) | 7 ( 7.6) | 7 ( 7.6) |
| Blood creatinine increased | 1 ( 1.1) | 2 ( 2.2) | 3 ( 3.3) | 4 ( 4.3) |
| Nervous system disorders | 4 ( 4.3) | 14 ( 15.2) | 47 ( 51.1) | 52 ( 56.5) |
| Headache | 1 ( 1.1) | 10 ( 10.9) | 15 ( 16.3) | 24 ( 26.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Dizziness | 0 | 1 ( 1.1) | 12 ( 13.0) | 13 ( 14.1) |
| Tremor | 0 | 0 | 5 ( 5.4) | 5 ( 5.4) |
| Aphasia | 0 | 0 | 6 ( 6.5) | 6 ( 6.5) |
| Somnolence | 0 | 1 ( 1.1) | 5 ( 5.4) | 6 ( 6.5) |
| Respiratory, thoracic and mediastinal disorders | 1 ( 1.1) | 4 ( 4.3) | 44 ( 47.8) | 45 ( 48.9) |
| Cough | 0 | 1 ( 1.1) | 15 ( 16.3) | 16 ( 17.4) |
| Nasal congestion | 0 | 0 | 7 ( 7.6) | 7 ( 7.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
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SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Dyspnoea | 1 ( 1.1) | 1 ( 1.1) | 6 ( 6.5) | 6 ( 6.5) |
| Oropharyngeal pain | 0 | 0 | 7 ( 7.6) | 7 ( 7.6) |
| Epistaxis | 1 ( 1.1) | 0 | 4 ( 4.3) | 4 ( 4.3) |
| Psychiatric disorders | 2 ( 2.2) | 6 ( 6.5) | 35 ( 38.0) | 38 ( 41.3) |
| Confusional state | 0 | 0 | 14 ( 15.2) | 14 ( 15.2) |
| Anxiety | 0 | 4 ( 4.3) | 8 ( 8.7) | 12 ( 13.0) |
| Insomnia | 0 | 2 ( 2.2) | 10 ( 10.9) | 11 ( 12.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Skin and subcutaneous tissue disorders | 1 ( 1.1) | 2 ( 2.2) | 31 ( 33.7) | 33 ( 35.9) |
| Alopecia | 0 | 0 | 7 ( 7.6) | 7 ( 7.6) |
| Rash | 0 | 0 | 6 ( 6.5) | 6 ( 6.5) |
| Vascular disorders | 0 | 3 ( 3.3) | 24 ( 26.1) | 25 ( 27.2) |
| Hypotension | 0 | 2 ( 2.2) | 15 ( 16.3) | 16 ( 17.4) |
| Hypertension | 0 | 1 ( 1.1) | 8 ( 8.7) | 8 ( 8.7) |
| Cardiac disorders | 2 ( 2.2) | 3 ( 3.3) | 21 ( 22.8) | 21 ( 22.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Tachycardia | 0 | 1 ( 1.1) | 11 ( 12.0) | 11 ( 12.0) |
| Renal and urinary disorders | 2 ( 2.2) | 3 ( 3.3) | 19 ( 20.7) | 20 ( 21.7) |
| Acute kidney injury | 0 | 2 ( 2.2) | 4 ( 4.3) | 5 ( 5.4) |
| Injury, poisoning and procedural complications | 1 ( 1.1) | 0 | 16 ( 17.4) | 16 ( 17.4) |
| Infusion related reaction | 0 | 0 | 7 ( 7.6) | 7 ( 7.6) |
| Eye disorders | 0 | 3 ( 3.3) | 12 ( 13.0) | 15 ( 16.3) |
| Diplopia | 0 | 2 ( 2.2) | 4 ( 4.3) | 6 ( 6.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 1.1) | 1 ( 1.1) | 8 ( 8.7) | 8 ( 8.7) |
| Reproductive system and breast disorders | 0 | 0 | 7 ( 7.6) | 7 ( 7.6) |
| Hepatobiliary disorders | 1 ( 1.1) | 0 | 6 ( 6.5) | 6 ( 6.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE | 22 ( 44.0) | 43 ( 86.0) | 50 (100.0) | 50 (100.0) |
| Immune system disorders | 0 | 0 | 41 ( 82.0) | 41 ( 82.0) |
| Cytokine release syndrome | 0 | 0 | 40 ( 80.0) | 40 ( 80.0) |
| Hypogammaglobulinaemia | 0 | 0 | 9 ( 18.0) | 9 ( 18.0) |
| Gastrointestinal disorders | 7 ( 14.0) | 26 ( 52.0) | 36 ( 72.0) | 43 ( 86.0) |
| Diarrhoea | 1 ( 2.0) | 6 ( 12.0) | 16 ( 32.0) | 19 ( 38.0) |
| Nausea | 3 ( 6.0) | 17 ( 34.0) | 10 ( 20.0) | 25 ( 50.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Constipation | 2 ( 4.0) | 6 ( 12.0) | 8 ( 16.0) | 12 ( 24.0) |
| Vomiting | 1 ( 2.0) | 4 ( 8.0) | 8 ( 16.0) | 12 ( 24.0) |
| Dry mouth | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Dyspepsia | 0 | 2 ( 4.0) | 3 ( 6.0) | 5 ( 10.0) |
| Blood and lymphatic system disorders | 11 ( 22.0) | 14 ( 28.0) | 36 ( 72.0) | 36 ( 72.0) |
| Neutropenia | 3 ( 6.0) | 6 ( 12.0) | 26 ( 52.0) | 27 ( 54.0) |
| Anaemia | 7 ( 14.0) | 6 ( 12.0) | 22 ( 44.0) | 22 ( 44.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Thrombocytopenia | 5 ( 10.0) | 6 ( 12.0) | 15 ( 30.0) | 17 ( 34.0) |
| Leukopenia | 0 | 5 ( 10.0) | 9 ( 18.0) | 9 ( 18.0) |
| Lymphopenia | 0 | 2 ( 4.0) | 5 ( 10.0) | 5 ( 10.0) |
| General disorders and administration site conditions | 6 ( 12.0) | 12 ( 24.0) | 35 ( 70.0) | 38 ( 76.0) |
| Fatigue | 1 ( 2.0) | 5 ( 10.0) | 13 ( 26.0) | 17 ( 34.0) |
| Pyrexia | 3 ( 6.0) | 3 ( 6.0) | 11 ( 22.0) | 12 ( 24.0) |
| Oedema peripheral | 3 ( 6.0) | 2 ( 4.0) | 9 ( 18.0) | 9 ( 18.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Asthenia | 0 | 3 ( 6.0) | 5 ( 10.0) | 8 ( 16.0) |
| Chills | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Metabolism and nutrition disorders | 7 ( 14.0) | 15 ( 30.0) | 38 ( 76.0) | 41 ( 82.0) |
| Hypokalaemia | 1 ( 2.0) | 4 ( 8.0) | 17 ( 34.0) | 20 ( 40.0) |
| Hypocalcaemia | 1 ( 2.0) | 2 ( 4.0) | 9 ( 18.0) | 9 ( 18.0) |
| Hypomagnesaemia | 1 ( 2.0) | 2 ( 4.0) | 11 ( 22.0) | 12 ( 24.0) |
| Decreased appetite | 1 ( 2.0) | 1 ( 2.0) | 11 ( 22.0) | 12 ( 24.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Hypophosphataemia | 2 ( 4.0) | 1 ( 2.0) | 11 ( 22.0) | 12 ( 24.0) |
| Hyponatraemia | 0 | 2 ( 4.0) | 6 ( 12.0) | 6 ( 12.0) |
| Hypoalbuminaemia | 2 ( 4.0) | 5 ( 10.0) | 8 ( 16.0) | 10 ( 20.0) |
| Hypercalcaemia | 1 ( 2.0) | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Hyperglycaemia | 0 | 1 ( 2.0) | 1 ( 2.0) | 2 ( 4.0) |
| Hyperuricaemia | 3 ( 6.0) | 3 ( 6.0) | 1 ( 2.0) | 4 ( 8.0) |
| Infections and infestations | 2 ( 4.0) | 2 ( 4.0) | 31 ( 62.0) | 31 ( 62.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Upper respiratory tract infection | 0 | 0 | 10 ( 20.0) | 10 ( 20.0) |
| Pneumonia | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Nasopharyngitis | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Musculoskeletal and connective tissue disorders | 5 ( 10.0) | 6 ( 12.0) | 26 ( 52.0) | 27 ( 54.0) |
| Back pain | 2 ( 4.0) | 3 ( 6.0) | 7 ( 14.0) | 9 ( 18.0) |
| Arthralgia | 1 ( 2.0) | 0 | 5 ( 10.0) | 5 ( 10.0) |
| Bone pain | 1 ( 2.0) | 0 | 6 ( 12.0) | 6 ( 12.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Musculoskeletal chest pain | 0 | 0 | 5 ( 10.0) | 5 ( 10.0) |
| Musculoskeletal pain | 0 | 1 ( 2.0) | 3 ( 6.0) | 3 ( 6.0) |
| Myalgia | 0 | 0 | 2 ( 4.0) | 2 ( 4.0) |
| Pain in extremity | 1 ( 2.0) | 2 ( 4.0) | 1 ( 2.0) | 3 ( 6.0) |
| Investigations | 2 ( 4.0) | 8 ( 16.0) | 27 ( 54.0) | 28 ( 56.0) |
| Aspartate aminotransferase increased | 1 ( 2.0) | 1 ( 2.0) | 7 ( 14.0) | 8 ( 16.0) |
| Weight decreased | 0 | 1 ( 2.0) | 10 ( 20.0) | 10 ( 20.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Alanine aminotransferase increased | 0 | 0 | 4 ( 8.0) | 4 ( 8.0) |
| Blood alkaline phosphatase increased | 1 ( 2.0) | 0 | 7 ( 14.0) | 7 ( 14.0) |
| C-reactive protein increased | 0 | 1 ( 2.0) | 7 ( 14.0) | 7 ( 14.0) |
| Weight increased | 0 | 0 | 4 ( 8.0) | 4 ( 8.0) |
| Blood creatinine increased | 0 | 2 ( 4.0) | 2 ( 4.0) | 2 ( 4.0) |
| Nervous system disorders | 3 ( 6.0) | 6 ( 12.0) | 25 ( 50.0) | 27 ( 54.0) |
| Headache | 1 ( 2.0) | 2 ( 4.0) | 8 ( 16.0) | 10 ( 20.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Dizziness | 0 | 3 ( 6.0) | 8 ( 16.0) | 11 ( 22.0) |
| Tremor | 0 | 0 | 4 ( 8.0) | 4 ( 8.0) |
| Aphasia | 0 | 0 | 1 ( 2.0) | 1 ( 2.0) |
| Somnolence | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 4.0) | 1 ( 2.0) | 21 ( 42.0) | 21 ( 42.0) |
| Cough | 1 ( 2.0) | 0 | 8 ( 16.0) | 8 ( 16.0) |
| Nasal congestion | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Dyspnoea | 1 ( 2.0) | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Oropharyngeal pain | 0 | 0 | 2 ( 4.0) | 2 ( 4.0) |
| Epistaxis | 1 ( 2.0) | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Psychiatric disorders | 2 ( 4.0) | 3 ( 6.0) | 18 ( 36.0) | 21 ( 42.0) |
| Confusional state | 0 | 0 | 5 ( 10.0) | 5 ( 10.0) |
| Anxiety | 1 ( 2.0) | 1 ( 2.0) | 5 ( 10.0) | 6 ( 12.0) |
| Insomnia | 0 | 1 ( 2.0) | 7 ( 14.0) | 8 ( 16.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Skin and subcutaneous tissue disorders | 1 ( 2.0) | 3 ( 6.0) | 15 ( 30.0) | 18 ( 36.0) |
| Alopecia | 0 | 0 | 4 ( 8.0) | 4 ( 8.0) |
| Rash | 0 | 0 | 2 ( 4.0) | 2 ( 4.0) |
| Vascular disorders | 1 ( 2.0) | 3 ( 6.0) | 13 ( 26.0) | 15 ( 30.0) |
| Hypotension | 0 | 3 ( 6.0) | 4 ( 8.0) | 7 ( 14.0) |
| Hypertension | 0 | 0 | 6 ( 12.0) | 6 ( 12.0) |
| Cardiac disorders | 1 ( 2.0) | 2 ( 4.0) | 13 ( 26.0) | 13 ( 26.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Tachycardia | 0 | 0 | 8 ( 16.0) | 8 ( 16.0) |
| Renal and urinary disorders | 1 ( 2.0) | 3 ( 6.0) | 8 ( 16.0) | 10 ( 20.0) |
| Acute kidney injury | 0 | 2 ( 4.0) | 2 ( 4.0) | 3 ( 6.0) |
| Injury, poisoning and procedural complications | 2 ( 4.0) | 1 ( 2.0) | 6 ( 12.0) | 7 ( 14.0) |
| Infusion related reaction | 0 | 0 | 4 ( 8.0) | 4 ( 8.0) |
| Eye disorders | 1 ( 2.0) | 1 ( 2.0) | 5 ( 10.0) | 6 ( 12.0) |
| Diplopia | 0 | 1 ( 2.0) | 2 ( 4.0) | 3 ( 6.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 2.0) | 1 ( 2.0) | 5 ( 10.0) | 5 ( 10.0) |
| Reproductive system and breast disorders | 0 | 0 | 5 ( 10.0) | 5 ( 10.0) |
| Hepatobiliary disorders | 1 ( 2.0) | 0 | 3 ( 6.0) | 3 ( 6.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE | 28 ( 37.8) | 57 ( 77.0) | 74 (100.0) | 74 (100.0) |
| Immune system disorders | 0 | 1 ( 1.4) | 66 ( 89.2) | 66 ( 89.2) |
| Cytokine release syndrome | 0 | 0 | 64 ( 86.5) | 64 ( 86.5) |
| Hypogammaglobulinaemia | 0 | 1 ( 1.4) | 14 ( 18.9) | 15 ( 20.3) |
| Gastrointestinal disorders | 6 ( 8.1) | 41 ( 55.4) | 58 ( 78.4) | 68 ( 91.9) |
| Diarrhoea | 1 ( 1.4) | 5 ( 6.8) | 27 ( 36.5) | 32 ( 43.2) |
| Nausea | 3 ( 4.1) | 27 ( 36.5) | 26 ( 35.1) | 45 ( 60.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Constipation | 0 | 13 ( 17.6) | 13 ( 17.6) | 24 ( 32.4) |
| Vomiting | 1 ( 1.4) | 3 ( 4.1) | 12 ( 16.2) | 14 ( 18.9) |
| Dry mouth | 0 | 1 ( 1.4) | 6 ( 8.1) | 6 ( 8.1) |
| Dyspepsia | 0 | 0 | 6 ( 8.1) | 6 ( 8.1) |
| Blood and lymphatic system disorders | 14 ( 18.9) | 25 ( 33.8) | 57 ( 77.0) | 58 ( 78.4) |
| Neutropenia | 3 ( 4.1) | 9 ( 12.2) | 39 ( 52.7) | 39 ( 52.7) |
| Anaemia | 7 ( 9.5) | 11 ( 14.9) | 33 ( 44.6) | 33 ( 44.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Thrombocytopenia | 7 ( 9.5) | 9 ( 12.2) | 27 ( 36.5) | 29 ( 39.2) |
| Leukopenia | 1 ( 1.4) | 12 ( 16.2) | 22 ( 29.7) | 22 ( 29.7) |
| Lymphopenia | 1 ( 1.4) | 1 ( 1.4) | 15 ( 20.3) | 15 ( 20.3) |
| General disorders and administration site conditions | 6 ( 8.1) | 12 ( 16.2) | 58 ( 78.4) | 59 ( 79.7) |
| Fatigue | 4 ( 5.4) | 6 ( 8.1) | 27 ( 36.5) | 29 ( 39.2) |
| Pyrexia | 1 ( 1.4) | 3 ( 4.1) | 19 ( 25.7) | 22 ( 29.7) |
| Oedema peripheral | 1 ( 1.4) | 2 ( 2.7) | 9 ( 12.2) | 10 ( 13.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
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bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Asthenia | 1 ( 1.4) | 1 ( 1.4) | 12 ( 16.2) | 13 ( 17.6) |
| Chills | 1 ( 1.4) | 2 ( 2.7) | 10 ( 13.5) | 12 ( 16.2) |
| Metabolism and nutrition disorders | 5 ( 6.8) | 17 ( 23.0) | 55 ( 74.3) | 56 ( 75.7) |
| Hypokalaemia | 1 ( 1.4) | 5 ( 6.8) | 27 ( 36.5) | 29 ( 39.2) |
| Hypocalcaemia | 2 ( 2.7) | 3 ( 4.1) | 21 ( 28.4) | 22 ( 29.7) |
| Hypomagnesaemia | 0 | 3 ( 4.1) | 18 ( 24.3) | 18 ( 24.3) |
| Decreased appetite | 0 | 9 ( 12.2) | 16 ( 21.6) | 21 ( 28.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Hypophosphataemia | 1 ( 1.4) | 1 ( 1.4) | 16 ( 21.6) | 17 ( 23.0) |
| Hyponatraemia | 2 ( 2.7) | 2 ( 2.7) | 15 ( 20.3) | 16 ( 21.6) |
| Hypoalbuminaemia | 0 | 2 ( 2.7) | 10 ( 13.5) | 10 ( 13.5) |
| Hypercalcaemia | 0 | 0 | 5 ( 6.8) | 5 ( 6.8) |
| Hyperglycaemia | 1 ( 1.4) | 1 ( 1.4) | 5 ( 6.8) | 6 ( 8.1) |
| Hyperuricaemia | 1 ( 1.4) | 1 ( 1.4) | 3 ( 4.1) | 4 ( 5.4) |
| Infections and infestations | 5 ( 6.8) | 3 ( 4.1) | 48 ( 64.9) | 49 ( 66.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Upper respiratory tract infection | 1 ( 1.4) | 0 | 9 ( 12.2) | 9 ( 12.2) |
| Pneumonia | 0 | 0 | 7 ( 9.5) | 7 ( 9.5) |
| Nasopharyngitis | 0 | 0 | 4 ( 5.4) | 4 ( 5.4) |
| Musculoskeletal and connective tissue disorders | 6 ( 8.1) | 8 ( 10.8) | 45 ( 60.8) | 48 ( 64.9) |
| Back pain | 1 ( 1.4) | 2 ( 2.7) | 10 ( 13.5) | 12 ( 16.2) |
| Arthralgia | 1 ( 1.4) | 3 ( 4.1) | 11 ( 14.9) | 14 ( 18.9) |
| Bone pain | 0 | 0 | 7 ( 9.5) | 7 ( 9.5) |

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AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Musculoskeletal chest pain | 2 ( 2.7) | 1 ( 1.4) | 4 ( 5.4) | 4 ( 5.4) |
| Musculoskeletal pain | 0 | 1 ( 1.4) | 5 ( 6.8) | 6 ( 8.1) |
| Myalgia | 0 | 0 | 6 ( 8.1) | 6 ( 8.1) |
| Pain in extremity | 1 ( 1.4) | 1 ( 1.4) | 6 ( 8.1) | 7 ( 9.5) |
| Investigations | 8 ( 10.8) | 7 ( 9.5) | 40 ( 54.1) | 40 ( 54.1) |
| Aspartate aminotransferase increased | 1 ( 1.4) | 1 ( 1.4) | 14 ( 18.9) | 14 ( 18.9) |
| Weight decreased | 1 ( 1.4) | 0 | 7 ( 9.5) | 7 ( 9.5) |

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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Alanine aminotransferase increased | 1 ( 1.4) | 1 ( 1.4) | 12 ( 16.2) | 12 ( 16.2) |
| Blood alkaline phosphatase increased | 1 ( 1.4) | 1 ( 1.4) | 8 ( 10.8) | 8 ( 10.8) |
| C-reactive protein increased | 0 | 0 | 6 ( 8.1) | 6 ( 8.1) |
| Weight increased | 0 | 1 ( 1.4) | 4 ( 5.4) | 4 ( 5.4) |
| Blood creatinine increased | 1 ( 1.4) | 3 ( 4.1) | 3 ( 4.1) | 5 ( 6.8) |
| Nervous system disorders | 2 ( 2.7) | 17 ( 23.0) | 40 ( 54.1) | 44 ( 59.5) |
| Headache | 1 ( 1.4) | 12 ( 16.2) | 18 ( 24.3) | 28 ( 37.8) |

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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dizziness | 0 | 0 | 9 ( 12.2) | 9 ( 12.2) |
| Tremor | 0 | 1 ( 1.4) | 5 ( 6.8) | 6 ( 8.1) |
| Aphasia | 0 | 0 | 6 ( 8.1) | 6 ( 8.1) |
| Somnolence | 0 | 1 ( 1.4) | 4 ( 5.4) | 5 ( 6.8) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 2.7) | 5 ( 6.8) | 39 ( 52.7) | 41 ( 55.4) |
| Cough | 1 ( 1.4) | 2 ( 2.7) | 15 ( 20.3) | 16 ( 21.6) |
| Nasal congestion | 0 | 0 | 7 ( 9.5) | 7 ( 9.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Dyspnoea | 0 | 2 ( 2.7) | 6 ( 8.1) | 7 ( 9.5) |
| Oropharyngeal pain | 0 | 0 | 7 ( 9.5) | 7 ( 9.5) |
| Epistaxis | 0 | 0 | 4 ( 5.4) | 4 ( 5.4) |
| Psychiatric disorders | 1 ( 1.4) | 6 ( 8.1) | 26 ( 35.1) | 29 ( 39.2) |
| Confusional state | 0 | 0 | 11 ( 14.9) | 11 ( 14.9) |
| Anxiety | 0 | 4 ( 5.4) | 7 ( 9.5) | 11 ( 14.9) |
| Insomnia | 0 | 2 ( 2.7) | 4 ( 5.4) | 5 ( 6.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
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infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
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SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Skin and subcutaneous tissue disorders | 0 | 1 ( 1.4) | 27 ( 36.5) | 28 ( 37.8) |
| Alopecia | 0 | 0 | 6 ( 8.1) | 6 ( 8.1) |
| Rash | 0 | 0 | 6 ( 8.1) | 6 ( 8.1) |
| Vascular disorders | 1 ( 1.4) | 2 ( 2.7) | 21 ( 28.4) | 21 ( 28.4) |
| Hypotension | 0 | 1 ( 1.4) | 16 ( 21.6) | 16 ( 21.6) |
| Hypertension | 0 | 1 ( 1.4) | 5 ( 6.8) | 5 ( 6.8) |
| Cardiac disorders | 3 ( 4.1) | 4 ( 5.4) | 18 ( 24.3) | 19 ( 25.7) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Tachycardia | 0 | 3 ( 4.1) | 10 ( 13.5) | 11 ( 14.9) |
| Renal and urinary disorders | 2 ( 2.7) | 2 ( 2.7) | 17 ( 23.0) | 18 ( 24.3) |
| Acute kidney injury | 0 | 1 ( 1.4) | 3 ( 4.1) | 4 ( 5.4) |
| Injury, poisoning and procedural complications | 0 | 0 | 16 ( 21.6) | 16 ( 21.6) |
| Infusion related reaction | 0 | 0 | 4 ( 5.4) | 4 ( 5.4) |
| Eye disorders | 0 | 2 ( 2.7) | 13 ( 17.6) | 15 ( 20.3) |
| Diplopia | 0 | 1 ( 1.4) | 3 ( 4.1) | 4 ( 5.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.4.1.1d
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 7 ( 9.5) | 7 ( 9.5) |
| Reproductive system and breast disorders | 0 | 0 | 5 ( 6.8) | 5 ( 6.8) |
| Hepatobiliary disorders | 0 | 0 | 4 ( 5.4) | 4 ( 5.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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### 8.3.4.2 UE Grad 3-5 nach SOC und PT



Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE | 26 ( 32.5) | 45 ( 56.3) | 79 ( 98.8) | 79 ( 98.8) |
| Blood and lymphatic system disorders | 18 ( 22.5) | 42 ( 52.5) | 75 ( 93.8) | 77 ( 96.3) |
| Neutropenia | 7 ( 8.8) | 20 ( 25.0) | 71 ( 88.8) | 73 ( 91.3) |
| Anaemia | 7 ( 8.8) | 17 ( 21.3) | 46 ( 57.5) | 50 ( 62.5) |
| Thrombocytopenia | 9 ( 11.3) | 15 ( 18.8) | 43 ( 53.8) | 45 ( 56.3) |
| Leukopenia | 4 ( 5.0) | 14 ( 17.5) | 30 ( 37.5) | 33 ( 41.3) |
| Lymphopenia | 4 ( 5.0) | 16 ( 20.0) | 22 ( 27.5) | 25 ( 31.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 2 ( 2.5) | 1 ( 1.3) | 13 ( 16.3) | 14 ( 17.5) |
| Metabolism and nutrition disorders | 4 ( 5.0) | 1 ( 1.3) | 25 ( 31.3) | 25 ( 31.3) |
| Hypophosphataemia | 1 ( 1.3) | 0 | 12 ( 15.0) | 12 ( 15.0) |
| Hypocalcaemia | 0 | 1 ( 1.3) | 5 ( 6.3) | 6 ( 7.5) |
| Hyponatraemia | 2 ( 2.5) | 0 | 5 ( 6.3) | 5 ( 6.3) |
| Infections and infestations | 5 ( 6.3) | 2 ( 2.5) | 21 ( 26.3) | 21 ( 26.3) |
| Pneumonia | 0 | 1 ( 1.3) | 5 ( 6.3) | 6 ( 7.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Analysis Plan: 12MAY2021 Confidential

Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Sepsis | 0 | 0 | 5 ( 6.3) | 5 ( 6.3) |
| General disorders and administration site conditions | 1 ( 1.3) | 1 ( 1.3) | 13 ( 16.3) | 13 ( 16.3) |
| General physical health deterioration | 0 | 0 | 12 ( 15.0) | 12 ( 15.0) |
| Investigations | 0 | 0 | 13 ( 16.3) | 13 ( 16.3) |
| Nervous system disorders | 1 ( 1.3) | 0 | 6 ( 7.5) | 6 ( 7.5) |
| Immune system disorders | 0 | 0 | 7 ( 8.8) | 7 ( 8.8) |
| Cytokine release syndrome | 0 | 0 | 5 ( 6.3) | 5 ( 6.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Respiratory, thoracic and mediastinal disorders | 1 ( 1.3) | 2 ( 2.5) | 6 ( 7.5) | 7 ( 8.8) |
| Vascular disorders | 0 | 1 ( 1.3) | 3 ( 3.8) | 4 ( 5.0) |
| Injury, poisoning and procedural complications | 0 | 1 ( 1.3) | 3 ( 3.8) | 4 ( 5.0) |
| Musculoskeletal and connective tissue disorders | 6 ( 7.5) | 0 | 2 ( 2.5) | 2 ( 2.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE | 13 ( 29.5) | 22 ( 50.0) | 44 (100.0) | 44 (100.0) |
| Blood and lymphatic system disorders | 10 ( 22.7) | 21 ( 47.7) | 44 (100.0) | 44 (100.0) |
| Neutropenia | 1 ( 2.3) | 8 ( 18.2) | 39 ( 88.6) | 40 ( 90.9) |
| Anaemia | 5 ( 11.4) | 8 ( 18.2) | 28 ( 63.6) | 29 ( 65.9) |
| Thrombocytopenia | 2 ( 4.5) | 4 ( 9.1) | 21 ( 47.7) | 21 ( 47.7) |
| Leukopenia | 1 ( 2.3) | 9 ( 20.5) | 18 ( 40.9) | 18 ( 40.9) |
| Lymphopenia | 4 ( 9.1) | 9 ( 20.5) | 11 ( 25.0) | 11 ( 25.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 0 | 0 | 5 ( 11.4) | 5 ( 11.4) |
| Metabolism and nutrition disorders | 1 ( 2.3) | 2 ( 4.5) | 17 ( 38.6) | 18 ( 40.9) |
| Hypophosphataemia | 0 | 0 | 8 ( 18.2) | 8 ( 18.2) |
| Hypocalcaemia | 0 | 0 | 5 ( 11.4) | 5 ( 11.4) |
| Hyponatraemia | 1 ( 2.3) | 0 | 2 ( 4.5) | 2 ( 4.5) |
| Infections and infestations | 0 | 1 ( 2.3) | 12 ( 27.3) | 12 ( 27.3) |
| Pneumonia | 0 | 0 | 4 ( 9.1) | 4 ( 9.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Sepsis | 0 | 0 | 2 ( 4.5) | 2 ( 4.5) |
| General disorders and administration site conditions | 0 | 0 | 12 ( 27.3) | 12 ( 27.3) |
| General physical health deterioration | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |
| Investigations | 2 ( 4.5) | 2 ( 4.5) | 7 ( 15.9) | 7 ( 15.9) |
| Nervous system disorders | 0 | 0 | 6 ( 13.6) | 6 ( 13.6) |
| Immune system disorders | 0 | 0 | 3 ( 6.8) | 3 ( 6.8) |
| Cytokine release syndrome | 0 | 0 | 2 ( 4.5) | 2 ( 4.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0 | 2 ( 4.5) | 2 ( 4.5) |
| Vascular disorders | 0 | 1 ( 2.3) | 4 ( 9.1) | 4 ( 9.1) |
| Injury, poisoning and procedural complications | 0 | 0 | 3 ( 6.8) | 3 ( 6.8) |
| Musculoskeletal and connective tissue disorders | 1 ( 2.3) | 1 ( 2.3) | 1 ( 2.3) | 2 ( 4.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one Grade 3-5 AE | 36 ( 32.7) | 63 ( 57.3) | 110 (100.0) | 110 (100.0) |
| Blood and lymphatic system disorders | 25 ( 22.7) | 61 ( 55.5) | 107 ( 97.3) | 109 ( 99.1) |
| Neutropenia | 7 ( 6.4) | 26 ( 23.6) | 99 ( 90.0) | 102 ( 92.7) |
| Anaemia | 11 ( 10.0) | 24 ( 21.8) | 69 ( 62.7) | 74 ( 67.3) |
| Thrombocytopenia | 10 ( 9.1) | 17 ( 15.5) | 56 ( 50.9) | 58 ( 52.7) |
| Leukopenia | 5 ( 4.5) | 22 ( 20.0) | 45 ( 40.9) | 47 ( 42.7) |
| Lymphopenia | 8 ( 7.3) | 25 ( 22.7) | 32 ( 29.1) | 35 ( 31.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 2 ( 1.8) | 1 ( 0.9) | 16 ( 14.5) | 17 ( 15.5) |
| Metabolism and nutrition disorders | 5 ( 4.5) | 3 ( 2.7) | 40 ( 36.4) | 41 ( 37.3) |
| Hypophosphataemia | 1 ( 0.9) | 0 | 20 ( 18.2) | 20 ( 18.2) |
| Hypocalcaemia | 0 | 1 ( 0.9) | 10 ( 9.1) | 11 ( 10.0) |
| Hyponatraemia | 3 ( 2.7) | 0 | 6 ( 5.5) | 6 ( 5.5) |
| Infections and infestations | 5 ( 4.5) | 2 ( 1.8) | 27 ( 24.5) | 27 ( 24.5) |
| Pneumonia | 0 | 1 ( 0.9) | 8 ( 7.3) | 9 ( 8.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Sepsis | 0 | 0 | 7 ( 6.4) | 7 ( 6.4) |
| General disorders and administration site conditions | 1 ( 0.9) | 1 ( 0.9) | 23 ( 20.9) | 23 ( 20.9) |
| General physical health deterioration | 0 | 0 | 18 ( 16.4) | 18 ( 16.4) |
| Investigations | 2 ( 1.8) | 2 ( 1.8) | 18 ( 16.4) | 18 ( 16.4) |
| Nervous system disorders | 1 ( 0.9) | 0 | 10 ( 9.1) | 10 ( 9.1) |
| Immune system disorders | 0 | 0 | 9 ( 8.2) | 9 ( 8.2) |
| Cytokine release syndrome | 0 | 0 | 7 ( 6.4) | 7 ( 6.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 1 ( 0.9) | 1 ( 0.9) | 5 ( 4.5) | 6 ( 5.5) |
| Vascular disorders | 0 | 2 ( 1.8) | 5 ( 4.5) | 6 ( 5.5) |
| Injury, poisoning and procedural complications | 0 | 1 ( 0.9) | 6 ( 5.5) | 7 ( 6.4) |
| Musculoskeletal and connective tissue disorders | 6 ( 5.5) | 1 ( 0.9) | 3 ( 2.7) | 4 ( 3.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE | 3 ( 21.4) | 4 ( 28.6) | 13 ( 92.9) | 13 ( 92.9) |
| Blood and lymphatic system disorders | 3 ( 21.4) | 2 ( 14.3) | 12 ( 85.7) | 12 ( 85.7) |
| Neutropenia | 1 ( 7.1) | 2 ( 14.3) | 11 ( 78.6) | 11 ( 78.6) |
| Anaemia | 1 ( 7.1) | 1 ( 7.1) | 5 ( 35.7) | 5 ( 35.7) |
| Thrombocytopenia | 1 ( 7.1) | 2 ( 14.3) | 8 ( 57.1) | 8 ( 57.1) |
| Leukopenia | 0 | 1 ( 7.1) | 3 ( 21.4) | 4 ( 28.6) |
| Lymphopenia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Metabolism and nutrition disorders | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Hypophosphataemia | 0 | 0 | 0 | 0 |
| Hypocalcaemia | 0 | 0 | 0 | 0 |
| Hyponatraemia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Infections and infestations | 0 | 1 ( 7.1) | 6 ( 42.9) | 6 ( 42.9) |
| Pneumonia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Sepsis | 0 | 0 | 0 | 0 |
| General disorders and administration site conditions | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| General physical health deterioration | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Investigations | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Nervous system disorders | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Immune system disorders | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Cytokine release syndrome | 0 | 0 | 0 | 0 |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 0 | 1 ( 7.1) | 3 ( 21.4) | 3 ( 21.4) |
| Vascular disorders | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Injury, poisoning and procedural complications | 0 | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 1 ( 7.1) | 0 | 0 | 0 |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE | 11 ( 34.4) | 23 ( 71.9) | 32 (100.0) | 32 (100.0) |
| Blood and lymphatic system disorders | 8 ( 25.0) | 23 ( 71.9) | 30 ( 93.8) | 32 (100.0) |
| Neutropenia | 1 ( 3.1) | 8 ( 25.0) | 28 ( 87.5) | 29 ( 90.6) |
| Anaemia | 4 ( 12.5) | 8 ( 25.0) | 20 ( 62.5) | 22 ( 68.8) |
| Thrombocytopenia | 2 ( 6.3) | 2 ( 6.3) | 13 ( 40.6) | 13 ( 40.6) |
| Leukopenia | 2 ( 6.3) | 8 ( 25.0) | 15 ( 46.9) | 16 ( 50.0) |
| Lymphopenia | 4 ( 12.5) | 10 ( 31.3) | 13 ( 40.6) | 13 ( 40.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 0 | 1 ( 3.1) | 4 ( 12.5) | 5 ( 15.6) |
| Metabolism and nutrition disorders | 1 ( 3.1) | 1 ( 3.1) | 10 ( 31.3) | 10 ( 31.3) |
| Hypophosphataemia | 0 | 0 | 5 ( 15.6) | 5 ( 15.6) |
| Hypocalcaemia | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |
| Hyponatraemia | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Infections and infestations | 3 ( 9.4) | 0 | 7 ( 21.9) | 7 ( 21.9) |
| Pneumonia | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Sepsis | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| General disorders and administration site conditions | 1 ( 3.1) | 1 ( 3.1) | 5 ( 15.6) | 5 ( 15.6) |
| General physical health deterioration | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Investigations | 1 ( 3.1) | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Nervous system disorders | 0 | 0 | 0 | 0 |
| Immune system disorders | 0 | 0 | 1 ( 3.1) | 1 ( 3.1) |
| Cytokine release syndrome | 0 | 0 | 1 ( 3.1) | 1 ( 3.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 1 ( 3.1) | 1 ( 3.1) | 0 | 1 ( 3.1) |
| Vascular disorders | 0 | 1 ( 3.1) | 1 ( 3.1) | 1 ( 3.1) |
| Injury, poisoning and procedural complications | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Musculoskeletal and connective tissue disorders | 0 | 1 ( 3.1) | 0 | 1 ( 3.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE | 28 ( 30.4) | 44 ( 47.8) | 91 ( 98.9) | 91 ( 98.9) |
| Blood and lymphatic system disorders | 20 ( 21.7) | 40 ( 43.5) | 89 ( 96.7) | 89 ( 96.7) |
| Neutropenia | 7 ( 7.6) | 20 ( 21.7) | 82 ( 89.1) | 84 ( 91.3) |
| Anaemia | 8 ( 8.7) | 17 ( 18.5) | 54 ( 58.7) | 57 ( 62.0) |
| Thrombocytopenia | 9 ( 9.8) | 17 ( 18.5) | 51 ( 55.4) | 53 ( 57.6) |
| Leukopenia | 3 ( 3.3) | 15 ( 16.3) | 33 ( 35.9) | 35 ( 38.0) |
| Lymphopenia | 4 ( 4.3) | 15 ( 16.3) | 20 ( 21.7) | 23 ( 25.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 2 ( 2.2) | 0 | 14 ( 15.2) | 14 ( 15.2) |
| Metabolism and nutrition disorders | 4 ( 4.3) | 2 ( 2.2) | 32 ( 34.8) | 33 ( 35.9) |
| Hypophosphataemia | 1 ( 1.1) | 0 | 15 ( 16.3) | 15 ( 16.3) |
| Hypocalcaemia | 0 | 1 ( 1.1) | 7 ( 7.6) | 8 ( 8.7) |
| Hyponatraemia | 3 ( 3.3) | 0 | 5 ( 5.4) | 5 ( 5.4) |
| Infections and infestations | 2 ( 2.2) | 3 ( 3.3) | 26 ( 28.3) | 26 ( 28.3) |
| Pneumonia | 0 | 1 ( 1.1) | 6 ( 6.5) | 7 ( 7.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Sepsis | 0 | 0 | 5 ( 5.4) | 5 ( 5.4) |
| General disorders and administration site conditions | 0 | 0 | 20 ( 21.7) | 20 ( 21.7) |
| General physical health deterioration | 0 | 0 | 15 ( 16.3) | 15 ( 16.3) |
| Investigations | 1 ( 1.1) | 2 ( 2.2) | 16 ( 17.4) | 16 ( 17.4) |
| Nervous system disorders | 1 ( 1.1) | 0 | 12 ( 13.0) | 12 ( 13.0) |
| Immune system disorders | 0 | 0 | 9 ( 9.8) | 9 ( 9.8) |
| Cytokine release syndrome | 0 | 0 | 6 ( 6.5) | 6 ( 6.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 0 | 1 ( 1.1) | 8 ( 8.7) | 8 ( 8.7) |
| Vascular disorders | 0 | 1 ( 1.1) | 6 ( 6.5) | 7 ( 7.6) |
| Injury, poisoning and procedural complications | 0 | 1 ( 1.1) | 4 ( 4.3) | 5 ( 5.4) |
| Musculoskeletal and connective tissue disorders | 7 ( 7.6) | 0 | 3 ( 3.3) | 3 ( 3.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE | 21 ( 42.0) | 29 ( 58.0) | 50 (100.0) | 50 (100.0) |
| Blood and lymphatic system disorders | 16 ( 32.0) | 27 ( 54.0) | 48 ( 96.0) | 50 (100.0) |
| Neutropenia | 5 ( 10.0) | 11 ( 22.0) | 44 ( 88.0) | 45 ( 90.0) |
| Anaemia | 6 ( 12.0) | 13 ( 26.0) | 26 ( 52.0) | 30 ( 60.0) |
| Thrombocytopenia | 6 ( 12.0) | 10 ( 20.0) | 23 ( 46.0) | 24 ( 48.0) |
| Leukopenia | 2 ( 4.0) | 6 ( 12.0) | 17 ( 34.0) | 18 ( 36.0) |
| Lymphopenia | 3 ( 6.0) | 8 ( 16.0) | 11 ( 22.0) | 13 ( 26.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 1 ( 2.0) | 1 ( 2.0) | 6 ( 12.0) | 7 ( 14.0) |
| Metabolism and nutrition disorders | 1 ( 2.0) | 1 ( 2.0) | 17 ( 34.0) | 18 ( 36.0) |
| Hypophosphataemia | 0 | 0 | 5 ( 10.0) | 5 ( 10.0) |
| Hypocalcaemia | 0 | 0 | 2 ( 4.0) | 2 ( 4.0) |
| Hyponatraemia | 0 | 0 | 2 ( 4.0) | 2 ( 4.0) |
| Infections and infestations | 3 ( 6.0) | 1 ( 2.0) | 15 ( 30.0) | 15 ( 30.0) |
| Pneumonia | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Sepsis | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |
| General disorders and administration site conditions | 1 ( 2.0) | 1 ( 2.0) | 10 ( 20.0) | 10 ( 20.0) |
| General physical health deterioration | 0 | 0 | 10 ( 20.0) | 10 ( 20.0) |
| Investigations | 2 ( 4.0) | 2 ( 4.0) | 9 ( 18.0) | 9 ( 18.0) |
| Nervous system disorders | 1 ( 2.0) | 0 | 1 ( 2.0) | 1 ( 2.0) |
| Immune system disorders | 0 | 0 | 4 ( 8.0) | 4 ( 8.0) |
| Cytokine release syndrome | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 1 ( 2.0) | 2 ( 4.0) | 6 ( 12.0) | 7 ( 14.0) |
| Vascular disorders | 0 | 2 ( 4.0) | 3 ( 6.0) | 4 ( 8.0) |
| Injury, poisoning and procedural complications | 0 | 1 ( 2.0) | 1 ( 2.0) | 2 ( 4.0) |
| Musculoskeletal and connective tissue disorders | 6 ( 12.0) | 1 ( 2.0) | 0 | 1 ( 2.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE | 18 ( 24.3) | 38 ( 51.4) | 73 ( 98.6) | 73 ( 98.6) |
| Blood and lymphatic system disorders | 12 ( 16.2) | 36 ( 48.6) | 71 ( 95.9) | 71 ( 95.9) |
| Neutropenia | 3 ( 4.1) | 17 ( 23.0) | 66 ( 89.2) | 68 ( 91.9) |
| Anaemia | 6 ( 8.1) | 12 ( 16.2) | 48 ( 64.9) | 49 ( 66.2) |
| Thrombocytopenia | 5 ( 6.8) | 9 ( 12.2) | 41 ( 55.4) | 42 ( 56.8) |
| Leukopenia | 3 ( 4.1) | 17 ( 23.0) | 31 ( 41.9) | 33 ( 44.6) |
| Lymphopenia | 5 ( 6.8) | 17 ( 23.0) | 22 ( 29.7) | 23 ( 31.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Febrile neutropenia | 1 ( 1.4) | 0 | 12 ( 16.2) | 12 ( 16.2) |
| Metabolism and nutrition disorders | 4 ( 5.4) | 2 ( 2.7) | 25 ( 33.8) | 25 ( 33.8) |
| Hypophosphataemia | 1 ( 1.4) | 0 | 15 ( 20.3) | 15 ( 20.3) |
| Hypocalcaemia | 0 | 1 ( 1.4) | 8 ( 10.8) | 9 ( 12.2) |
| Hyponatraemia | 3 ( 4.1) | 0 | 5 ( 6.8) | 5 ( 6.8) |
| Infections and infestations | 2 ( 2.7) | 2 ( 2.7) | 18 ( 24.3) | 18 ( 24.3) |
| Pneumonia | 0 | 1 ( 1.4) | 6 ( 8.1) | 7 ( 9.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Sepsis | 0 | 0 | 4 ( 5.4) | 4 ( 5.4) |
| General disorders and administration site conditions | 0 | 0 | 15 ( 20.3) | 15 ( 20.3) |
| General physical health deterioration | 0 | 0 | 9 ( 12.2) | 9 ( 12.2) |
| Investigations | 0 | 0 | 11 ( 14.9) | 11 ( 14.9) |
| Nervous system disorders | 0 | 0 | 11 ( 14.9) | 11 ( 14.9) |
| Immune system disorders | 0 | 0 | 6 ( 8.1) | 6 ( 8.1) |
| Cytokine release syndrome | 0 | 0 | 4 ( 5.4) | 4 ( 5.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.3.1.1d
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0 | 2 ( 2.7) | 2 ( 2.7) |
| Vascular disorders | 0 | 0 | 4 ( 5.4) | 4 ( 5.4) |
| Injury, poisoning and procedural complications | 0 | 0 | 5 ( 6.8) | 5 ( 6.8) |
| Musculoskeletal and connective tissue disorders | 1 ( 1.4) | 0 | 3 ( 4.1) | 3 ( 4.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class at the maximum severity. AEs are graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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### 8.3.4.3 SUE nach SOC und PT



Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one SAE | 15 ( 18.8) | 6 ( 7.5) | 51 ( 63.8) | 51 ( 63.8) |
| Infections and infestations | 5 ( 6.3) | 2 ( 2.5) | 23 ( 28.8) | 23 ( 28.8) |
| Pneumonia | 0 | 1 ( 1.3) | 8 ( 10.0) | 9 ( 11.3) |
| Sepsis | 0 | 0 | 5 ( 6.3) | 5 ( 6.3) |
| General disorders and administration site conditions | 2 ( 2.5) | 0 | 14 ( 17.5) | 14 ( 17.5) |
| General physical health deterioration | 0 | 0 | 12 ( 15.0) | 12 ( 15.0) |
| Immune system disorders | 0 | 0 | 14 ( 17.5) | 14 ( 17.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Cytokine release syndrome | 0 | 0 | 14 ( 17.5) | 14 ( 17.5) |
| Blood and lymphatic system disorders | 2 ( 2.5) | 1 ( 1.3) | 14 ( 17.5) | 14 ( 17.5) |
| Febrile neutropenia | 2 ( 2.5) | 0 | 6 ( 7.5) | 6 ( 7.5) |
| Thrombocytopenia | 0 | 1 ( 1.3) | 4 ( 5.0) | 5 ( 6.3) |
| Nervous system disorders | 1 ( 1.3) | 0 | 8 ( 10.0) | 8 ( 10.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 6 ( 7.5) | 6 ( 7.5) |
| Respiratory, thoracic and mediastinal disorders | 1 ( 1.3) | 1 ( 1.3) | 7 ( 8.8) | 8 ( 10.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age <65 years

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=80) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Gastrointestinal disorders | 0 | 1 ( 1.3) | 5 ( 6.3) | 6 ( 7.5) |
| Injury, poisoning and procedural complications | 0 | 1 ( 1.3) | 3 ( 3.8) | 4 ( 5.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one SAE | 7 ( 15.9) | 2 ( 4.5) | 35 ( 79.5) | 35 ( 79.5) |
| Infections and infestations | 0 | 1 ( 2.3) | 12 ( 27.3) | 12 ( 27.3) |
| Pneumonia | 0 | 0 | 4 ( 9.1) | 4 ( 9.1) |
| Sepsis | 0 | 0 | 2 ( 4.5) | 2 ( 4.5) |
| General disorders and administration site conditions | 0 | 0 | 13 ( 29.5) | 13 ( 29.5) |
| General physical health deterioration | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |
| Immune system disorders | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Cytokine release syndrome | 0 | 0 | 6 ( 13.6) | 6 ( 13.6) |
| Blood and lymphatic system disorders | 0 | 0 | 4 ( 9.1) | 4 ( 9.1) |
| Febrile neutropenia | 0 | 0 | 1 ( 2.3) | 1 ( 2.3) |
| Thrombocytopenia | 0 | 0 | 2 ( 4.5) | 2 ( 4.5) |
| Nervous system disorders | 0 | 0 | 7 ( 15.9) | 7 ( 15.9) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 5 ( 11.4) | 5 ( 11.4) |
| Respiratory, thoracic and mediastinal disorders | 1 ( 2.3) | 0 | 2 ( 4.5) | 2 ( 4.5) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Age >=65 years

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=44) | | | |
|---|---|---|---|---|
| | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Gastrointestinal disorders | 0 | 0 | 1 ( 2.3) | 1 ( 2.3) |
| Injury, poisoning and procedural complications | 0 | 0 | 3 ( 6.8) | 3 ( 6.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one SAE | 21 ( 19.1) | 6 ( 5.5) | 73 ( 66.4) | 73 ( 66.4) |
| Infections and infestations | 5 ( 4.5) | 2 ( 1.8) | 29 ( 26.4) | 29 ( 26.4) |
| Pneumonia | 0 | 1 ( 0.9) | 10 ( 9.1) | 11 ( 10.0) |
| Sepsis | 0 | 0 | 7 ( 6.4) | 7 ( 6.4) |
| General disorders and administration site conditions | 2 ( 1.8) | 0 | 25 ( 22.7) | 25 ( 22.7) |
| General physical health deterioration | 0 | 0 | 18 ( 16.4) | 18 ( 16.4) |
| Immune system disorders | 0 | 0 | 18 ( 16.4) | 18 ( 16.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Cytokine release syndrome | 0 | 0 | 17 ( 15.5) | 17 ( 15.5) |
| Blood and lymphatic system disorders | 2 ( 1.8) | 1 ( 0.9) | 15 ( 13.6) | 15 ( 13.6) |
| Febrile neutropenia | 2 ( 1.8) | 0 | 6 ( 5.5) | 6 ( 5.5) |
| Thrombocytopenia | 0 | 1 ( 0.9) | 5 ( 4.5) | 6 ( 5.5) |
| Nervous system disorders | 1 ( 0.9) | 0 | 13 ( 11.8) | 13 ( 11.8) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 8 ( 7.3) | 8 ( 7.3) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 1.8) | 1 ( 0.9) | 6 ( 5.5) | 7 ( 6.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=110)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Gastrointestinal disorders | 0 | 0 | 5 ( 4.5) | 5 ( 4.5) |
| Injury, poisoning and procedural complications | 0 | 1 ( 0.9) | 6 ( 5.5) | 7 ( 6.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one SAE | 1 ( 7.1) | 2 ( 14.3) | 13 ( 92.9) | 13 ( 92.9) |
| Infections and infestations | 0 | 1 ( 7.1) | 6 ( 42.9) | 6 ( 42.9) |
| Pneumonia | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Sepsis | 0 | 0 | 0 | 0 |
| General disorders and administration site conditions | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| General physical health deterioration | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Immune system disorders | 0 | 0 | 3 ( 21.4) | 3 ( 21.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Cytokine release syndrome | 0 | 0 | 3 ( 21.4) | 3 ( 21.4) |
| Blood and lymphatic system disorders | 0 | 0 | 3 ( 21.4) | 3 ( 21.4) |
| Febrile neutropenia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Thrombocytopenia | 0 | 0 | 1 ( 7.1) | 1 ( 7.1) |
| Nervous system disorders | 0 | 0 | 2 ( 14.3) | 2 ( 14.3) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 3 ( 21.4) | 3 ( 21.4) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0 | 3 ( 21.4) | 3 ( 21.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Double Refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=14) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Gastrointestinal disorders | 0 | 1 ( 7.1) | 1 ( 7.1) | 2 ( 14.3) |
| Injury, poisoning and procedural complications | 0 | 0 | 0 | 0 |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one SAE | 7 ( 21.9) | 2 ( 6.3) | 19 ( 59.4) | 19 ( 59.4) |
| Infections and infestations | 3 ( 9.4) | 0 | 7 ( 21.9) | 7 ( 21.9) |
| Pneumonia | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Sepsis | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| General disorders and administration site conditions | 1 ( 3.1) | 0 | 5 ( 15.6) | 5 ( 15.6) |
| General physical health deterioration | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Immune system disorders | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Cytokine release syndrome | 0 | 0 | 3 ( 9.4) | 3 ( 9.4) |
| Blood and lymphatic system disorders | 0 | 0 | 4 ( 12.5) | 4 ( 12.5) |
| Febrile neutropenia | 0 | 0 | 1 ( 3.1) | 1 ( 3.1) |
| Thrombocytopenia | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Nervous system disorders | 0 | 0 | 1 ( 3.1) | 1 ( 3.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 6.3) | 1 ( 3.1) | 0 | 1 ( 3.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=32) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Gastrointestinal disorders | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |
| Injury, poisoning and procedural complications | 0 | 0 | 2 ( 6.3) | 2 ( 6.3) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one SAE | 15 ( 16.3) | 6 ( 6.5) | 67 ( 72.8) | 67 ( 72.8) |
| Infections and infestations | 2 ( 2.2) | 3 ( 3.3) | 28 ( 30.4) | 28 ( 30.4) |
| Pneumonia | 0 | 1 ( 1.1) | 8 ( 8.7) | 9 ( 9.8) |
| Sepsis | 0 | 0 | 5 ( 5.4) | 5 ( 5.4) |
| General disorders and administration site conditions | 1 ( 1.1) | 0 | 22 ( 23.9) | 22 ( 23.9) |
| General physical health deterioration | 0 | 0 | 15 ( 16.3) | 15 ( 16.3) |
| Immune system disorders | 0 | 0 | 18 ( 19.6) | 18 ( 19.6) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
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Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Cytokine release syndrome | 0 | 0 | 17 ( 18.5) | 17 ( 18.5) |
| Blood and lymphatic system disorders | 2 ( 2.2) | 1 ( 1.1) | 14 ( 15.2) | 14 ( 15.2) |
| Febrile neutropenia | 2 ( 2.2) | 0 | 6 ( 6.5) | 6 ( 6.5) |
| Thrombocytopenia | 0 | 1 ( 1.1) | 4 ( 4.3) | 5 ( 5.4) |
| Nervous system disorders | 1 ( 1.1) | 0 | 14 ( 15.2) | 14 ( 15.2) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 9 ( 9.8) | 9 ( 9.8) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0 | 9 ( 9.8) | 9 ( 9.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Penta-refractory=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=92) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Gastrointestinal disorders | 0 | 1 ( 1.1) | 4 ( 4.3) | 5 ( 5.4) |
| Injury, poisoning and procedural complications | 0 | 1 ( 1.1) | 4 ( 4.3) | 5 ( 5.4) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Number of subjects with at least one SAE | 13 ( 26.0) | 5 ( 10.0) | 37 ( 74.0) | 37 ( 74.0) |
| Infections and infestations | 3 ( 6.0) | 1 ( 2.0) | 15 ( 30.0) | 15 ( 30.0) |
| Pneumonia | 0 | 0 | 4 ( 8.0) | 4 ( 8.0) |
| Sepsis | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |
| General disorders and administration site conditions | 1 ( 2.0) | 0 | 12 ( 24.0) | 12 ( 24.0) |
| General physical health deterioration | 0 | 0 | 10 ( 20.0) | 10 ( 20.0) |
| Immune system disorders | 0 | 0 | 9 ( 18.0) | 9 ( 18.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Cytokine release syndrome | 0 | 0 | 9 ( 18.0) | 9 ( 18.0) |
| Blood and lymphatic system disorders | 1 ( 2.0) | 0 | 8 ( 16.0) | 8 ( 16.0) |
| Febrile neutropenia | 1 ( 2.0) | 0 | 4 ( 8.0) | 4 ( 8.0) |
| Thrombocytopenia | 0 | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Nervous system disorders | 1 ( 2.0) | 0 | 3 ( 6.0) | 3 ( 6.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 5 ( 10.0) | 5 ( 10.0) |
| Respiratory, thoracic and mediastinal disorders | 1 ( 2.0) | 1 ( 2.0) | 6 ( 12.0) | 7 ( 14.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=Yes

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=50) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Gastrointestinal disorders | 0 | 1 ( 2.0) | 4 ( 8.0) | 5 ( 10.0) |
| Injury, poisoning and procedural complications | 0 | 1 ( 2.0) | 1 ( 2.0) | 2 ( 4.0) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects (Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Number of subjects with at least one SAE | 9 ( 12.2) | 3 ( 4.1) | 49 ( 66.2) | 49 ( 66.2) |
| Infections and infestations | 2 ( 2.7) | 2 ( 2.7) | 20 ( 27.0) | 20 ( 27.0) |
| Pneumonia | 0 | 1 ( 1.4) | 8 ( 10.8) | 9 ( 12.2) |
| Sepsis | 0 | 0 | 4 ( 5.4) | 4 ( 5.4) |
| General disorders and administration site conditions | 1 ( 1.4) | 0 | 15 ( 20.3) | 15 ( 20.3) |
| General physical health deterioration | 0 | 0 | 9 ( 12.2) | 9 ( 12.2) |
| Immune system disorders | 0 | 0 | 12 ( 16.2) | 12 ( 16.2) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74)<br>Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
|---|---|---|---|---|
| Cytokine release syndrome | 0 | 0 | 11 ( 14.9) | 11 ( 14.9) |
| Blood and lymphatic system disorders | 1 ( 1.4) | 1 ( 1.4) | 10 ( 13.5) | 10 ( 13.5) |
| Febrile neutropenia | 1 ( 1.4) | 0 | 3 ( 4.1) | 3 ( 4.1) |
| Thrombocytopenia | 0 | 1 ( 1.4) | 3 ( 4.1) | 4 ( 5.4) |
| Nervous system disorders | 0 | 0 | 12 ( 16.2) | 12 ( 16.2) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 6 ( 8.1) | 6 ( 8.1) |
| Respiratory, thoracic and mediastinal disorders | 1 ( 1.4) | 0 | 3 ( 4.1) | 3 ( 4.1) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

Table 9.2.1.1d
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
(Including Neurotoxicity Signs or Symptoms), Overall and by Subgroup
bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells, Presence of Extramedullary Plasmacytoma=No

| | bb2121-Treated Population excluding subjects receiving 150 x 10^6 CAR T cells (N=74) | | | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | Leukapheresis to LD-Chemo [b]<br>n (%) | LD-Chemo to bb2121 Infusion<br>n (%) | On or After bb2121 Infusion<br>n (%) | LD-Chemo to End of Follow-up<br>n (%) |
| Gastrointestinal disorders | 0 | 0 | 2 ( 2.7) | 2 ( 2.7) |
| Injury, poisoning and procedural complications | 0 | 0 | 5 ( 6.8) | 5 ( 6.8) |

[a] Coded using MedDRA version 22.0. A subject is counted only once for multiple events within preferred term/system organ class.
[b] Only AEs related to protocol-mandated procedures and all serious adverse events are collected from Leukapheresis to LD-chemo.
AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of on or after bb2121
infusion, based on the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one
treatment period based on the 'Overall' analysis.
SOURCE: X:\Numerus\Studies\CLG\CLG104\Analysis\Prod\Progs\Tab_9_1_1_1.SAS
Date/time of run: 29JUN2021 09:26
Analysis Plan: 12MAY2021 Confidential

## II. Studie CRB-401

# 9. Gesamtüberleben

## 9.1 Datenschnitt vom 22.07.2019

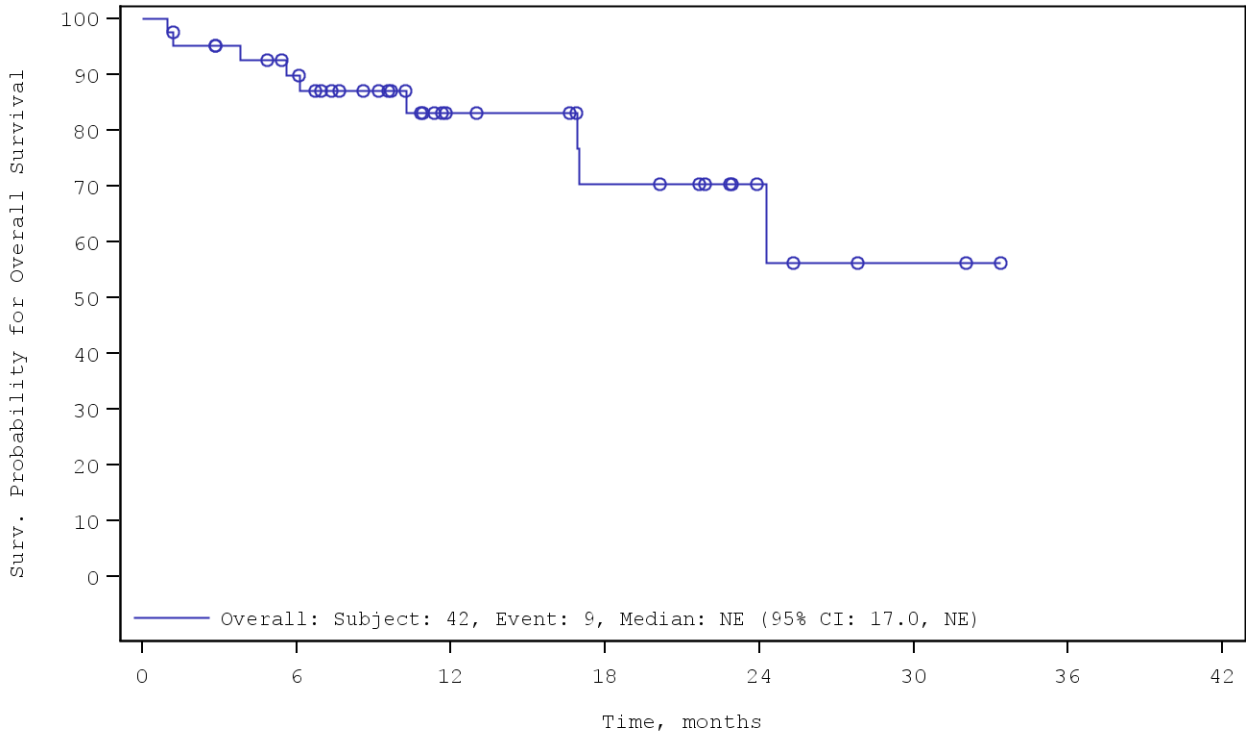
Table 1.2.1a
Summary of Overall Survival
Enrolled Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=19) | 450x10^6 (N=42) | Combined RP2D (150-450)x10^6 (N=61) |
| Overall Survival | N | 19 | 42 | 61 |
| Censored | n (%) | 12 ( 63.2) | 33 ( 78.6) | 45 ( 73.8) |
| Died | n (%) | 7 ( 36.8) | 9 ( 21.4) | 16 ( 26.2) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | 11.9 ( 2.8, 20.2) | 17.0 ( 6.1, NE ) | 16.9 ( 6.1, 24.3) |
| | Median (95% CI) | 20.2 (11.9, NE ) | NE (17.0, NE ) | NE (17.0, NE ) |
| | 75th Pcnt. (95% CI) | NE (20.2, NE ) | NE (24.3, NE ) | NE |
| 6 Months Event-Free | % (SE) | 83.3 ( 8.8) | 89.9 ( 4.8) | 87.9 ( 4.3) |
| 12 Months Event-Free | % (SE) | 71.3 (10.9) | 83.1 ( 6.5) | 78.7 ( 5.9) |
| 18 Months Event-Free | % (SE) | 61.1 (13.3) | 70.3 (10.0) | 66.9 ( 8.0) |
| 24 Months Event-Free | % (SE) | 45.8 (16.6) | 70.3 (10.0) | 62.1 ( 8.8) |
| 30 Months Event-Free | % (SE) | 45.8 (16.6) | 56.3 (14.9) | 53.2 (11.1) |
| 36 Months Event-Free | % (SE) | 45.8 (16.6) | NE | 53.2 (11.1) |
| 42 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable. Pcnt.=Percentile.
Subjects who did not die in CRB-401 study and the long-term follow-up studies are censored on last known alive date or current data cut-off date, whichever is earlier.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_1_1_1.SAS
Date/time of run: 09NOV2020 15:02
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401 Cut-off date: 22JUL2019

Figure 1.2.1a
Kaplan-Meier Curve of Overall Survival
Enrolled Population including only subjects receiving 450x10^6 CAR T cells
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Overall: | 42 | 33 | 16 | 11 | 5 | 2 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. Source Table: Table 1.2.1a.
SOURCE: X:\Numerus\Studies\CLG\CLG105\Analysis\Prod\Progs\Fig_1_1_1.SAS
Date/time of run: 19FEB2021 11:08
Analysis Plan: 21JAN2021 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 22JUL2019

Table 1.1.1a
Summary of Overall Survival
bb2121-Treated Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=18) | 450x10^6 (N=38) | Combined RP2D (150-450)x10^6 (N=56) |
| Overall Survival | N | 18 | 38 | 56 |
| Censored | n (%) | 11 ( 61.1) | 31 ( 81.6) | 42 ( 75.0) |
| Died | n (%) | 7 ( 38.9) | 7 ( 18.4) | 14 ( 25.0) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | 10.8 ( 1.7, 19.1) | 15.9 ( 9.1, NE ) | 15.9 ( 6.2, 23.2) |
| | Median (95% CI) | 19.1 (10.8, NE ) | NE (15.9, NE ) | NE (19.1, NE ) |
| | 75th Pcnt. (95% CI) | NE (19.1, NE ) | NE (23.2, NE ) | NE |
| 6 Months Event-Free | % (SE) | 83.3 ( 8.8) | 91.5 ( 4.7) | 88.9 ( 4.3) |
| 12 Months Event-Free | % (SE) | 71.3 (10.9) | 87.3 ( 6.1) | 81.2 ( 5.8) |
| 18 Months Event-Free | % (SE) | 61.1 (13.3) | 73.9 (10.1) | 69.1 ( 8.1) |
| 24 Months Event-Free | % (SE) | 45.8 (16.6) | 59.1 (15.5) | 55.0 (11.4) |
| 30 Months Event-Free | % (SE) | 45.8 (16.6) | 59.1 (15.5) | 55.0 (11.4) |
| 36 Months Event-Free | % (SE) | 45.8 (16.6) | NE | 55.0 (11.4) |
| 42 Months Event-Free | % (SE) | NE | NE | NE |

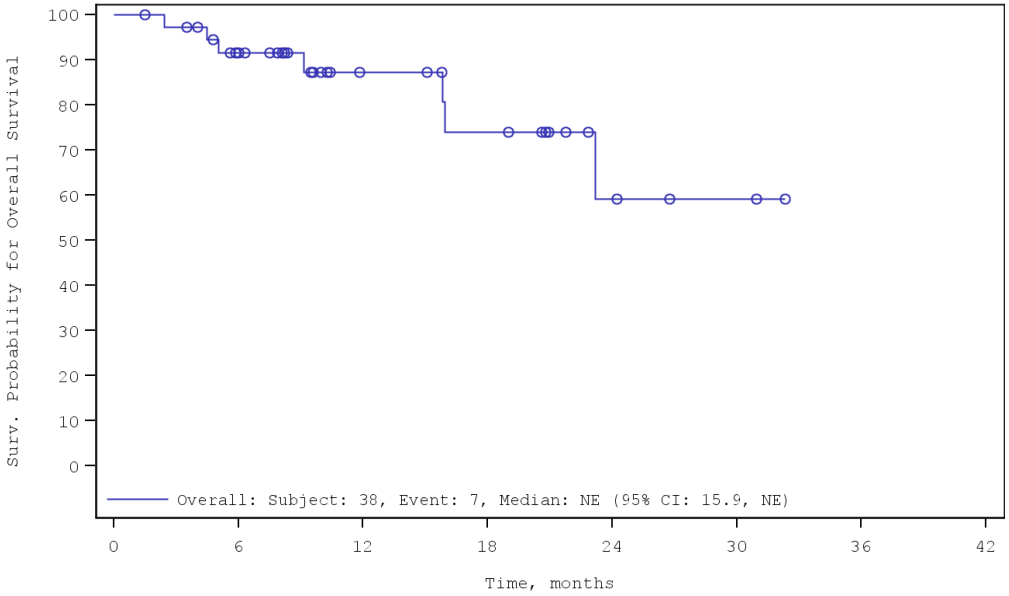
Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable. Pcnt.=Percentile.
Subjects who did not die in CRB-401 study and the long-term follow-up studies are censored on last known alive date or current data cut-off date, whichever is earlier.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_1_1_1.SAS
Date/time of run: 09NOV2020 15:02
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401

Page 1 of 1
Cut-off date: 22JUL2019

Figure 1.1.1a
Kaplan-Meier Curve of Overall Survival
bb2121-Treated Population including only subjects receiving 450x10^6 CAR T cells
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Overall: | 38 | 29 | 15 | 11 | 4 | 2 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. Source Table: Table 1.1.1a.
SOURCE: X:\Numerus\Studies\CLG\CLG105\Analysis\Prod\Progs\Fig_1_1_1.SAS
Date/time of run: 06APR2021 16:52
Analysis Plan: 21JAN2021 Confidential

## 9.2 Datenschnitt vom 14.01.2020

Celgene Corporation
Protocol: CRB-401


Cut-off date: 14JAN2020

Table 1.2.1b
Summary of Overall Survival
Enrolled Population

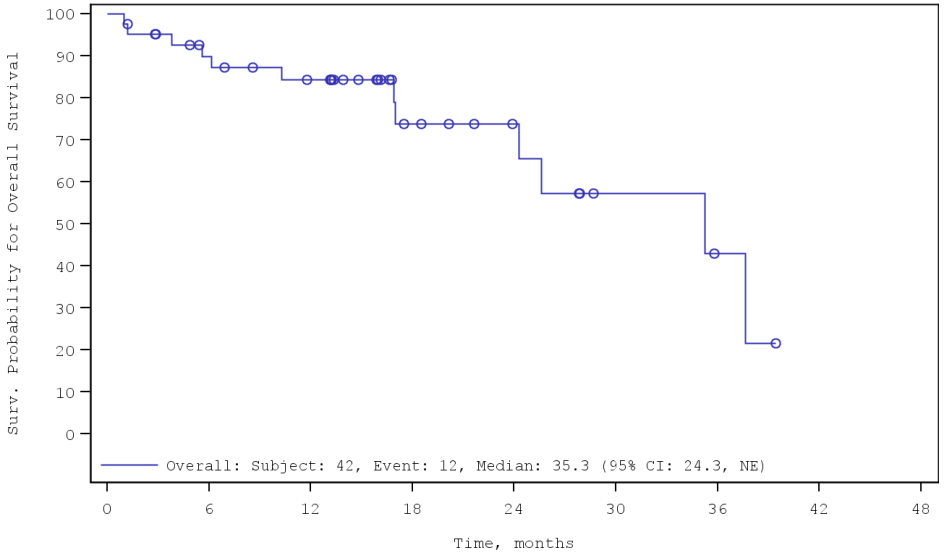
| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=19) | 450x10^6 (N=42) | Combined RP2D (150-450)x10^6 (N=61) |
| Overall Survival | N | 19 | 42 | 61 |
| Censored | n (%) | 12 ( 63.2) | 30 ( 71.4) | 42 ( 68.9) |
| Died | n (%) | 7 ( 36.8) | 12 ( 28.6) | 19 ( 31.1) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | 11.9 ( 2.8, NE ) | 17.0 ( 6.1, 35.3) | 17.0 ( 6.1, 25.6) |
| | Median (95% CI) | NE (11.9, NE ) | 35.3 (24.3, NE ) | 35.3 (20.2, NE ) |
| | 75th Pcnt. (95% CI) | NE (20.2, NE ) | 37.7 (35.3, NE ) | NE (35.3, NE ) |
| 6 Months Event-Free | % (SE) | 83.3 ( 8.8) | 89.9 ( 4.8) | 87.9 ( 4.3) |
| 12 Months Event-Free | % (SE) | 71.3 (10.9) | 84.3 ( 5.9) | 80.1 ( 5.4) |
| 18 Months Event-Free | % (SE) | 62.4 (12.7) | 73.7 ( 8.7) | 70.1 ( 7.2) |
| 24 Months Event-Free | % (SE) | 53.5 (13.6) | 73.7 ( 8.7) | 66.2 ( 7.8) |
| 30 Months Event-Free | % (SE) | 53.5 (13.6) | 57.3 (12.2) | 54.6 ( 9.8) |
| 36 Months Event-Free | % (SE) | 53.5 (13.6) | 43.0 (15.4) | 45.5 (11.7) |
| 42 Months Event-Free | % (SE) | 53.5 (13.6) | NE | 34.1 (13.2) |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable. Pcnt.=Percentile.
Subjects who did not die in CRB-401 study and the long-term follow-up studies are censored on last known alive date or current data cut-off date, whichever is earlier.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_1_1_1.SAS
Date/time of run: 05NOV2020 15:53
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401

Page 1 of 1
Cut-off date: 14JAN2020

Figure 1.2.1b
Kaplan-Meier Curve of Overall Survival
Enrolled Population including only subjects receiving 450x10^6 CAR T cells
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Overall: | 42 | 33 | 28 | 13 | 9 | 4 | 2 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. Source Table: Table 1.2.1b.
SOURCE: X:\Numerus\Studies\CLG\CLG105\Analysis\Prod\Progs\Fig_1_1_1.SAS
Date/time of run: 19FEB2021 11:08
Analysis Plan: 21JAN2021 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 14JAN2020

Table 1.1.1b
Summary of Overall Survival
bb2121-Treated Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=18) | 450x10^6 (N=38) | Combined RP2D (150-450)x10^6 (N=56) |
| Overall Survival | N | 18 | 38 | 56 |
| Censored | n (%) | 11 ( 61.1) | 28 ( 73.7) | 39 ( 69.6) |
| Died | n (%) | 7 ( 38.9) | 10 ( 26.3) | 17 ( 30.4) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | 10.8 ( 1.7, NE ) | 23.2 ( 9.1, 34.2) | 16.0 ( 6.2, 24.5) |
| | Median (95% CI) | NE (10.8, NE ) | 34.2 (23.2, NE ) | 34.2 (23.2, NE ) |
| | 75th Pcnt. (95% CI) | NE (19.1, NE ) | 36.6 (34.2, NE ) | NE (34.2, NE ) |
| 6 Months Event-Free | % (SE) | 83.3 ( 8.8) | 91.6 ( 4.7) | 88.9 ( 4.3) |
| 12 Months Event-Free | % (SE) | 71.3 (10.9) | 88.5 ( 5.4) | 82.8 ( 5.2) |
| 18 Months Event-Free | % (SE) | 62.4 (12.7) | 77.5 ( 8.7) | 72.4 ( 7.2) |
| 24 Months Event-Free | % (SE) | 53.5 (13.6) | 68.9 (11.2) | 62.7 ( 9.0) |
| 30 Months Event-Free | % (SE) | 53.5 (13.6) | 60.2 (12.7) | 56.4 (10.1) |
| 36 Months Event-Free | % (SE) | 53.5 (13.6) | 45.2 (16.1) | 47.0 (12.0) |
| 42 Months Event-Free | % (SE) | NE | NE | NE |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

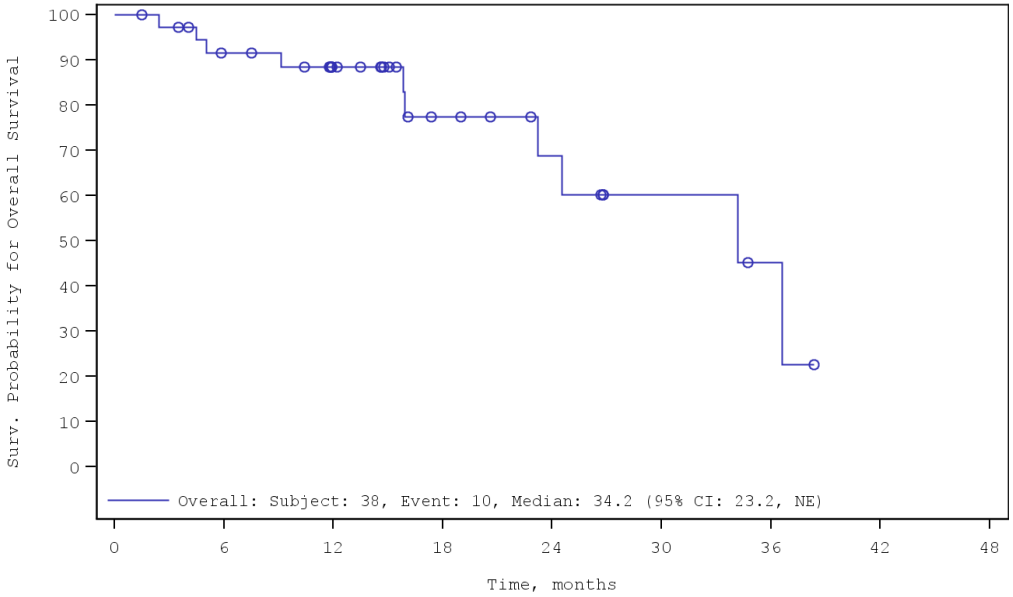
Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable. Pcnt.=Percentile.
Subjects who did not die in CRB-401 study and the long-term follow-up studies are censored on last known alive date or current data cut-off date, whichever is earlier.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_1_1_1.SAS
Date/time of run: 05NOV2020 15:53
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 14JAN2020

Figure 1.1.1b
Kaplan-Meier Curve of Overall Survival
bb2121-Treated Population including only subjects receiving 450x10^6 CAR T cells
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Overall: | 38 | 31 | 23 | 12 | 8 | 4 | 2 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. Source Table: Table 1.1.1b.
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Date/time of run: 06APR2021 16:57
Analysis Plan: 21JAN2021 Confidential

## 9.3 Datenschnitt vom 07.04.2020

Celgene Corporation
Protocol: CRB-401

Data cutoff date: 07APR2020
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Table 14.2.2.1
Summary of Overall Survival
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | | | | |
|---|---|---|---|---|---|---|
| | 50x10^6 (N=3) | 150x10^6 (N=18) | 450x10^6 (N=38) | 800x10^6 (N=3) | Combined RP2D (150-450)x10^6 (N=56) | Total Study (N=62) |
| Overall Survival | | | | | | |
| Censored - n (%) | 0 | 11 ( 61.1) | 28 ( 73.7) | 1 ( 33.3) | 39 ( 69.6) | 40 ( 64.5) |
| Died - n (%) | 3 (100.0) | 7 ( 38.9) | 10 ( 26.3) | 2 ( 66.7) | 17 ( 30.4) | 22 ( 35.5) |
| Overall Survival (months) | | | | | | |
| Median [a] | 6.0 | NE | 34.2 | 21.2 | 36.6 | 34.2 |
| 95% CI | (5.1, 9.3) | (10.8, NE) | (23.2, NE) | (19.2, NE) | (23.2, NE) | (19.2, NE) |
| Event-Free Rate %(SE) | | | | | | |
| 6 months | 33.3 (27.2) | 83.3 (8.8) | 91.6 (4.7) | 100.0 (0.0) | 88.9 (4.3) | 86.6 (4.4) |
| 12 months | 0.0 | 71.3 (10.9) | 88.5 (5.4) | 100.0 (0.0) | 82.7 (5.3) | 79.2 (5.4) |
| 18 months | 0.0 | 62.4 (12.7) | 80.5 (7.3) | 100.0 (0.0) | 74.5 (6.6) | 72.0 (6.3) |
| 24 months | 0.0 | 53.5 (13.6) | 71.5 (10.7) | 33.3 (27.2) | 65.7 (8.3) | 57.7 (8.2) |
| 30 months | 0.0 | 53.5 (13.6) | 62.6 (12.5) | 33.3 (27.2) | 60.2 (9.2) | 53.3 (8.7) |
| 36 months | 0.0 | 53.5 (13.6) | 46.9 (16.5) | 33.3 (27.2) | 50.2 (12.0) | 45.6 (10.3) |
| 42 months | 0.0 | 53.5 (13.6) | NE | NE | 37.6 (14.1) | 36.5 (11.6) |
| 48 months | 0.0 | NE | NE | NE | NE | NE |

Note: One subject dosed at 205 x 10^6 cells in Part B Cohort 1 and one subject dosed at 305 x 10^6 cells in Part B Cohort 3 are included under target dose of 450 x 10^6 cells. RP2D = Recommended phase 2 dose.
CI=Confidence interval; SE=Standard error; SD=Standard deviation; Min=Minimum; Max=Maximum; NE=Not estimable; N/A=Not available.
Subjects who did not die in CRB-401 study and the long-term follow-up studies are censored on last known alive date or current data cut-off date, whichever is earlier.
[a] The median and event-free rate are based on Kaplan-Meier estimate.
[b] The summary statistics are univariate statistics without adjusting for censoring.
[c] Ongoing subjects include those who are still ongoing in CRB-401 study, or those who have discontinued from CRB-401 study, but are still ongoing in long term follow-up studies.

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Celgene Corporation

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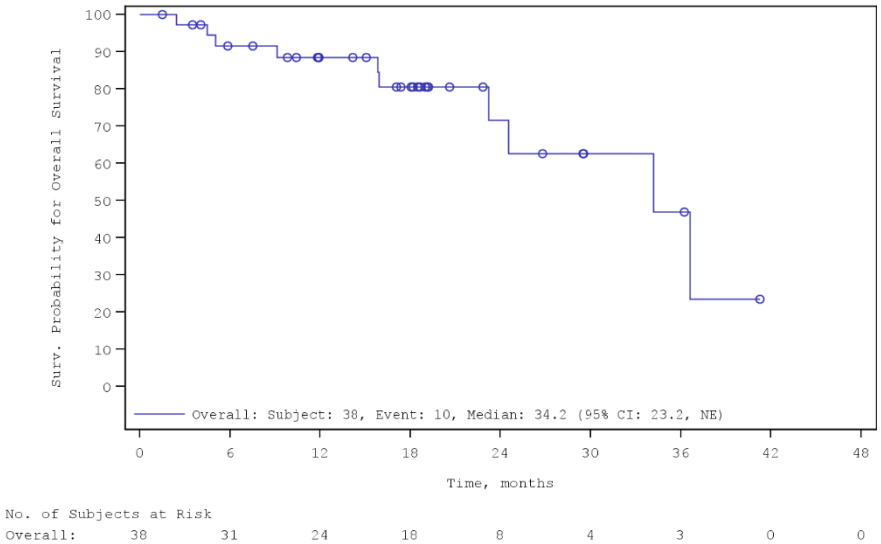
Protocol: CRB-401 Cut-off date: 07APR2020

Figure 1.1.1c
Kaplan-Meier Curve of Overall Survival
bb2121-Treated Population including only subjects receiving 450x10^6 CAR T cells
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]




Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. Source Table: Table 1.1.1c.
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Date/time of run: 06APR2021 16:59
Analysis Plan: 21JAN2021 Confidential

# 10. Ansprechen (Datenschnitt vom 07.04.2020)

Celgene Corporation
Protocol: CRB-401

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Cut-off date: 07APR2020

Table 4.1c
Summary of Response Rate by IRC Assessment - Overall
bb2121-Treated Population

| | 150x10^6 (N=18) | 450x10^6 (N=38) | Combined RP2D (150-450)x10^6 (N=56) |
|---|---|---|---|
| Best Overall Response - n (%) | | | |
| Stringent Complete Response (sCR) | 6 ( 33.3) | 15 ( 39.5) | 21 ( 37.5) |
| Very Good Partial Response (VGPR) | 1 ( 5.6) | 11 ( 28.9) | 12 ( 21.4) |
| Partial Response (PR) | 3 ( 16.7) | 6 ( 15.8) | 9 ( 16.1) |
| Minimal Response (MR) | 1 ( 5.6) | 1 ( 2.6) | 2 ( 3.6) |
| Stable Disease (SD) | 4 ( 22.2) | 3 ( 7.9) | 7 ( 12.5) |
| Progressive Disease (PD) | 3 ( 16.7) | 2 ( 5.3) | 5 ( 8.9) |
| Inevaluable for Response (IE) [a] | 0 | 0 | 0 |
| Overall Response Rate - n (%) [b] | 10 ( 55.6) | 32 ( 84.2) | 42 ( 75.0) |
| 95% CI [c] | 30.8, 78.5 | 68.7, 94.0 | 61.6, 85.6 |
| 90% CI [c] | 34.1, 75.6 | 71.2, 92.9 | 63.7, 84.2 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

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Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.1c
Summary of Response Rate by IRC Assessment - Overall
bb2121-Treated Population

| | 150x10^6 (N=18) | 450x10^6 (N=38) | Combined RP2D (150-450)x10^6 (N=56) |
|---|---|---|---|
| Response Rate of VGPR or better - n (%) [b] | 7 ( 38.9) | 26 ( 68.4) | 33 ( 58.9) |
| 95% CI [c] | 17.3, 64.3 | 51.3, 82.5 | 45.0, 71.9 |
| 90% CI [c] | 19.9, 60.8 | 53.9, 80.7 | 47.1, 70.1 |
| Complete Response Rate - n (%) [b] | 6 ( 33.3) | 15 ( 39.5) | 21 ( 37.5) |
| 95% CI [c] | 13.3, 59.0 | 24.0, 56.6 | 24.9, 51.5 |
| 90% CI [c] | 15.6, 55.4 | 26.1, 54.1 | 26.7, 49.3 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

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Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 11.1.1c
Summary of Time to Response and Duration of Response for Subjects Who Achieved Partial Response (PR) or Better by IRC Assessment (FDA Censoring Rules), bb2121-Treated Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=10) | 450x10^6 (N=32) | Combined RP2D (150-450)x10^6 (N=42) |
| Time to First Response of Partial Response or Better (months) [a] | n | 10 | 32 | 42 |
| | Mean | 1.25 | 1.29 | 1.28 |
| | SD | 0.745 | 0.536 | 0.583 |
| | Median | 0.99 | 1.02 | 1.02 |
| | Min, Max | 0.7, 3.1 | 1.0, 3.0 | 0.7, 3.1 |
| Time to Response (months) [a] [b] | | | | |
| <= 1 | n (%) | 8 ( 80.0) | 23 ( 71.9) | 31 ( 73.8) |
| > 1 - <= 2 | n (%) | 1 ( 10.0) | 7 ( 21.9) | 8 ( 19.0) |
| > 2 - <= 3 | n (%) | 1 ( 10.0) | 2 ( 6.3) | 3 ( 7.1) |
| > 3 - <= 4 | n (%) | 0 | 0 | 0 |
| > 4 - <= 6 | n (%) | 0 | 0 | 0 |
| > 6 | n (%) | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. SD=Standard deviation. Min=Minimum. Max=Maximum. SE=Standard error.
[a] Only responses of designated category are considered.
[b] The time to response category is based on protocol planned visit time plus the allowed window.
[c] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
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Date/time of run: 12NOV2020 16:08
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 11.1.1c
Summary of Time to Response and Duration of Response for Subjects Who Achieved Partial Response (PR) or Better by IRC Assessment (FDA Censoring Rules), bb2121-Treated Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=10) | 450x10^6 (N=32) | Combined RP2D (150-450)x10^6 (N=42) |
| Duration of Response [a] | N | 10 | 32 | 42 |
| Censored | n (%) | 3 ( 30.0) | 7 ( 21.9) | 10 ( 23.8) |
| Progressed/Died | n (%) | 7 ( 70.0) | 25 ( 78.1) | 32 ( 76.2) |
| Progressed | n (%) | 7 ( 70.0) | 24 ( 75.0) | 31 ( 73.8) |
| Died | n (%) | 0 | 1 ( 3.1) | 1 ( 2.4) |
| Duration Since Initial | 25th Pcnt. (95% CI) | 4.6 ( 2.1, 11.3) | 6.2 ( 1.9, 8.0) | 6.2 ( 2.9, 8.0) |
| Response (months) [a] [c] | Median (95% CI) | 10.8 ( 2.1, NE ) | 10.0 ( 7.2, 14.8) | 10.3 ( 7.4, 13.6) |
| | 75th Pcnt. (95% CI) | NE ( 10.3, NE ) | 17.0 ( 10.4, NE ) | 17.0 ( 12.5, NE ) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. SD=Standard deviation. Min=Minimum. Max=Maximum. SE=Standard error.
[a] Only responses of designated category are considered.
[b] The time to response category is based on protocol planned visit time plus the allowed window.
[c] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_11_1_1.SAS
Date/time of run: 12NOV2020 16:08
Analysis Plan: 30JUN2020 Confidential

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Protocol: CRB-401


Cut-off date: 07APR2020

Table 11.1.1c
Summary of Time to Response and Duration of Response for Subjects Who Achieved Partial Response (PR) or Better by IRC Assessment (FDA Censoring Rules), bb2121-Treated Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=10) | 450x10^6 (N=32) | Combined RP2D (150-450)x10^6 (N=42) |
| 6 Months Event-Free | % (SE) | 70.0 ( 14.5) | 77.1 ( 7.6) | 75.4 ( 6.8) |
| 12 Months Event-Free | % (SE) | 40.0 ( 15.5) | 40.2 ( 9.0) | 40.2 ( 7.8) |
| 18 Months Event-Free | % (SE) | 30.0 ( 14.5) | 21.1 ( 8.0) | 24.0 ( 7.0) |
| 24 Months Event-Free | % (SE) | 30.0 ( 14.5) | 10.6 ( 6.6) | 17.1 ( 6.5) |
| 30 Months Event-Free | % (SE) | 30.0 ( 14.5) | 10.6 ( 6.6) | 17.1 ( 6.5) |
| 36 Months Event-Free | % (SE) | 30.0 ( 14.5) | 10.6 ( 6.6) | 17.1 ( 6.5) |
| 42 Months Event-Free | % (SE) | NE | NE | NE |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. SD=Standard deviation. Min=Minimum. Max=Maximum. SE=Standard error.
[a] Only responses of designated category are considered.
[b] The time to response category is based on protocol planned visit time plus the allowed window.
[c] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
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Date/time of run: 12NOV2020 16:08
Analysis Plan: 30JUN2020 Confidential

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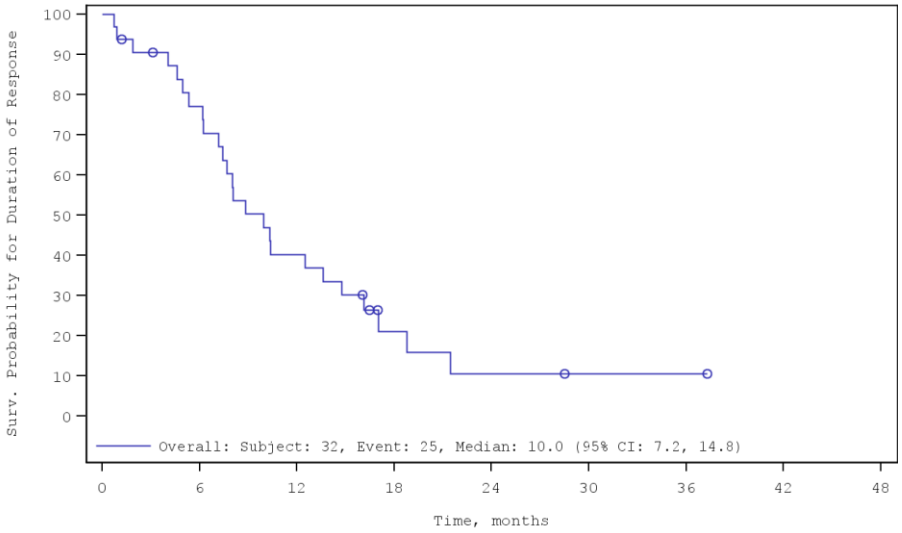
Protocol: CRB-401 Cut-off date: 07APR2020

Figure 11.1.1c
Kaplan-Meier Curve of Duration of Response for Subjects Who Achieved Partial Response (PR) or Better by IRC Assessment
(FDA Censoring Rules), bb2121-Treated Population including only subjects receiving 450x10^6 CAR T cells
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Overall: | 32 | 23 | 12 | 4 | 2 | 1 | 1 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. Source Table: Table 11.1.1c.
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Analysis Plan: 21JAN2021 Confidential
Celgene Corporation

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Protocol: CRB-401 Cut-off date: 07APR2020

Table 11.2.1c
Summary of Time to Response and Duration of Response for Subjects Who Achieved Complete Response (CR) or Better by IRC Assessment (FDA Censoring Rules), bb2121-Treated Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=6) | 450x10^6 (N=15) | Combined RP2D (150-450)x10^6 (N=21) |
| Time to First Response of Complete Response or Better (months) [a] | n | 6 | 15 | 21 |
| | Mean | 3.56 | 3.71 | 3.67 |
| | SD | 5.103 | 3.012 | 3.587 |
| | Median | 0.99 | 2.99 | 2.10 |
| | Min, Max | 1.0, 13.7 | 1.0, 9.0 | 1.0, 13.7 |
| Time to Response (months) [a] [b] | | | | |
| <= 1 | n (%) | 4 ( 66.7) | 5 ( 33.3) | 9 ( 42.9) |
| > 1 - <= 2 | n (%) | 0 | 2 ( 13.3) | 2 ( 9.5) |
| > 2 - <= 3 | n (%) | 0 | 2 ( 13.3) | 2 ( 9.5) |
| > 3 - <= 4 | n (%) | 1 ( 16.7) | 2 ( 13.3) | 3 ( 14.3) |
| > 4 - <= 6 | n (%) | 0 | 1 ( 6.7) | 1 ( 4.8) |
| > 6 | n (%) | 1 ( 16.7) | 3 ( 20.0) | 4 ( 19.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. SD=Standard deviation. Min=Minimum. Max=Maximum. SE=Standard error.
[a] Only responses of designated category are considered.
[b] The time to response category is based on protocol planned visit time plus the allowed window.
[c] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
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Date/time of run: 12NOV2020 16:08
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 11.2.1c
Summary of Time to Response and Duration of Response for Subjects Who Achieved Complete Response (CR) or Better by IRC Assessment (FDA Censoring Rules), bb2121-Treated Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=6) | 450x10^6 (N=15) | Combined RP2D (150-450)x10^6 (N=21) |
| Duration of Response [a] | N | 6 | 15 | 21 |
| Censored | n (%) | 2 ( 33.3) | 3 ( 20.0) | 5 ( 23.8) |
| Progressed/Died | n (%) | 4 ( 66.7) | 12 ( 80.0) | 16 ( 76.2) |
| Progressed | n (%) | 4 ( 66.7) | 11 ( 73.3) | 15 ( 71.4) |
| Died | n (%) | 0 | 1 ( 6.7) | 1 ( 4.8) |
| Duration Since Initial | 25th Pcnt. (95% CI) | 10.3 ( 8.0, 13.6) | 6.2 ( 4.1, 10.4) | 8.0 ( 4.1, 10.4) |
| Response (months) [a] [c] | Median (95% CI) | 12.4 ( 8.0, NE ) | 14.8 ( 5.3, 18.8) | 13.6 ( 8.0, 18.8) |
| | 75th Pcnt. (95% CI) | NE ( 10.3, NE ) | 18.8 ( 14.8, NE ) | 21.5 ( 14.8, NE ) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. SD=Standard deviation. Min=Minimum. Max=Maximum. SE=Standard error.
[a] Only responses of designated category are considered.
[b] The time to response category is based on protocol planned visit time plus the allowed window.
[c] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_11_1_1.SAS
Date/time of run: 12NOV2020 16:08
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 11.2.1c
Summary of Time to Response and Duration of Response for Subjects Who Achieved Complete Response (CR) or Better by IRC Assessment (FDA Censoring Rules), bb2121-Treated Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=6) | 450x10^6 (N=15) | Combined RP2D (150-450)x10^6 (N=21) |
| 6 Months Event-Free | % (SE) | 100.0 ( 0.0) | 80.0 ( 10.3) | 85.7 ( 7.6) |
| 12 Months Event-Free | % (SE) | 50.0 ( 20.4) | 53.3 ( 12.9) | 52.4 ( 10.9) |
| 18 Months Event-Free | % (SE) | 33.3 ( 19.2) | 30.0 ( 12.8) | 31.7 ( 10.6) |
| 24 Months Event-Free | % (SE) | 33.3 ( 19.2) | 10.0 ( 9.2) | 19.0 ( 9.4) |
| 30 Months Event-Free | % (SE) | 33.3 ( 19.2) | NE | 19.0 ( 9.4) |
| 36 Months Event-Free | % (SE) | 33.3 ( 19.2) | NE | 19.0 ( 9.4) |
| 42 Months Event-Free | % (SE) | NE | NE | NE |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. Pcnt.=Percentile. NE=Not Estimable. SD=Standard deviation. Min=Minimum. Max=Maximum. SE=Standard error.
[a] Only responses of designated category are considered.
[b] The time to response category is based on protocol planned visit time plus the allowed window.
[c] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_11_1_1.SAS
Date/time of run: 12NOV2020 16:08
Analysis Plan: 30JUN2020 Confidential

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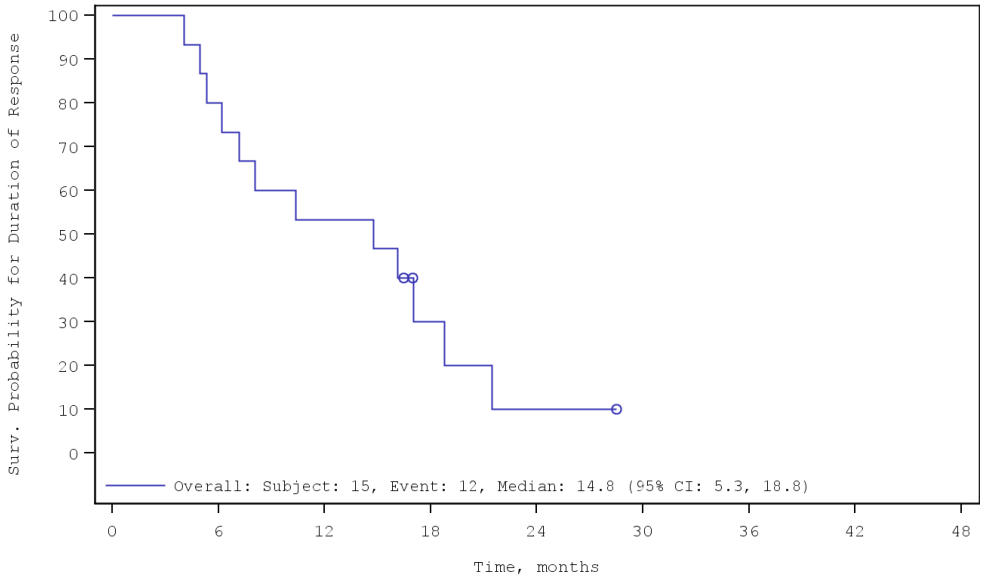
Protocol: CRB-401 Cut-off date: 07APR2020

Figure 11.2.1c
Kaplan-Meier Curve of Duration of Response for Subjects Who Achieved Complete Response (CR) or Better by IRC Assessment (FDA Censoring Rules), bb2121-Treated Population including only subjects receiving 450x10^6 CAR T cells For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Overall: | 15 | 12 | 8 | 3 | 1 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. Source Table: Table 11.2.1c.
SOURCE: X:\Numerus\Studies\CLG\CLG105\Analysis\Prod\Progs\Fig_11_1_1.SAS
Date/time of run: 12APR2021 10:54
Analysis Plan: 21JAN2021 Confidential

Celgene Corporation
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Table 14.2.1.5.3.3
Summary of Proportion of Subjects Who Achieved Complete Response (CR) and Minimal Residual Disease (MRD) Negativity
For Subjects Who Achieved CR or Better
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | | | | |
|---|---|---|---|---|---|---|
| MRD Negativity [a] | 50x10^6 (N=0) n (%) | 150x10^6 (N=7) n (%) | 450x10^6 (N=14) n (%) | 800x10^6 (N=3) n (%) | Combined RP2D (150-450)x10^6 (N=21) n (%) | Total Study (N=24) n (%) |
| Proportion of subjects who achieved CR or better and MRD negative status within 3 months prior to achieving CR or better until the time of progressive disease or death [b] | | | | | | |
| 10^(-4) Sensitivity | N/A | 5 ( 71.4) | 9 ( 64.3) | 1 ( 33.3) | 14 ( 66.7) | 15 ( 62.5) |
| 95% CI [b] | | 29.0, 96.3 | 35.1, 87.2 | 0.8, 90.6 | 43.0, 85.4 | 40.6, 81.2 |
| 10^(-5) Sensitivity | N/A | 5 ( 71.4) | 8 ( 57.1) | 1 ( 33.3) | 13 ( 61.9) | 14 ( 58.3) |
| 95% CI [b] | | 29.0, 96.3 | 28.9, 82.3 | 0.8, 90.6 | 38.4, 81.9 | 36.6, 77.9 |
| 10^(-6) Sensitivity | N/A | 4 ( 57.1) | 4 ( 28.6) | 0 | 8 ( 38.1) | 8 ( 33.3) |
| 95% CI [b] | | 18.4, 90.1 | 8.4, 58.1 | 0.0, 70.8 | 18.1, 61.6 | 15.6, 55.3 |

Note: One subject dosed at 205 x 10^6 cells in Part B Cohort 1 and one subject dosed at 305 x 10^6 cells in Part B Cohort 3 are included under target dose of 450 x 10^6 cells. RP2D = Recommended phase 2 dose; N/A=Not available.
[a] MRD negativity rate is the proportion of subjects who achieved CR or better and MRD negative status within 3 months prior to achieving CR or better until the time of progressive disease (PD) or death during initial treatment period with subjects who achieved CR or better in bb2121-treated population as the denominator. If a subject had no PD, the last response assessment date is used, and FDA progression free survival rules are used to determine progression and last assessment date.
[b] Only responses by investigator assessment confirmed by a consecutive assessment with the same response category or better are considered.
[c] Clopper-Pearson exact confidence interval (CI) for MRD negativity rate.

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Table 14.2.1.5.3.1
Summary of Proportion of Subjects Who Achieved Complete Response (CR) and Minimal Residual Disease (MRD) Negativity by Visit
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | | | | |
|---|---|---|---|---|---|---|
| MRD Negativity [a] | 50x10^6 (N=3) n (%) | 150x10^6 (N=18) n (%) | 450x10^6 (N=38) n (%) | 800x10^6 (N=3) n (%) | Combined RP2D (150-450)x10^6 (N=56) n (%) | Total Study (N=62) n (%) |
| Proportion of subjects who achieved CR or better and MRD negative status within 3 months prior to achieving CR or better until the time of progressive disease or death [b] | | | | | | |
| Any Timepoint | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 5 (27.8) | 9 (23.7) | 1 (33.3) | 14 (25.0) | 15 (24.2) |
| 95% CI [c] | 0.0, 70.8 | 9.7, 53.5 | 11.4, 40.2 | 0.8, 90.6 | 14.4, 38.4 | 14.2, 36.7 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 5 (27.8) | 8 (21.1) | 1 (33.3) | 13 (23.2) | 14 (22.6) |
| 95% CI [c] | 0.0, 70.8 | 9.7, 53.5 | 9.6, 37.3 | 0.8, 90.6 | 13.0, 36.4 | 12.9, 35.0 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 4 (22.2) | 4 (10.5) | 0 ( 0.0) | 8 (14.3) | 8 (12.9) |
| 95% CI [c] | 0.0, 70.8 | 6.4, 47.6 | 2.9, 24.8 | 0.0, 70.8 | 6.4, 26.2 | 5.7, 23.9 |
| Day 14 | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 5 (13.2) | 0 ( 0.0) | 6 (10.7) | 6 ( 9.7) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 4.4, 28.1 | 0.0, 70.8 | 4.0, 21.9 | 3.6, 19.9 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 2 ( 5.3) | 0 ( 0.0) | 3 ( 5.4) | 3 ( 4.8) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.6, 17.7 | 0.0, 70.8 | 1.1, 14.9 | 1.0, 13.5 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) |
| 95% CI [c] | 0.0, 70.8 | 0.0, 18.5 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 6.4 | 0.0, 5.8 |

Note: One subject dosed at 205 x 10^6 cells in Part B Cohort 1 and one subject dosed at 305 x 10^6 cells in Part B Cohort 3 are included under target dose of 450 x 10^6 cells. RP2D = Recommended phase 2 dose.
[a] MRD negativity rate is the proportion of subjects who achieved CR or better and MRD negative status within 3 months prior to achieving CR or better until the time of progressive disease (PD) or death during initial treatment period with bb2121-treated population as the denominator. If a subject had no PD, the last response assessment date is used, and FDA progression free survival rules are used to determine progression and last response assessment date.
[b] Only responses by investigator assessment confirmed by a consecutive assessment with the same response category or better are considered.
[c] Clopper-Pearson exact confidence interval (CI) for MRD negativity rate.

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Table 14.2.1.5.3.1
Summary of Proportion of Subjects Who Achieved Complete Response (CR) and Minimal Residual Disease (MRD) Negativity by Visit
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | | | | |
|---|---|---|---|---|---|---|
| MRD Negativity [a] | 50x10^6 (N=3) n (%) | 150x10^6 (N=18) n (%) | 450x10^6 (N=38) n (%) | 800x10^6 (N=3) n (%) | Combined RP2D (150-450)x10^6 (N=56) n (%) | Total Study (N=62) n (%) |
| Month 1 | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 2 (11.1) | 5 (13.2) | 0 ( 0.0) | 7 (12.5) | 7 (11.3) |
| 95% CI [c] | 0.0, 70.8 | 1.4, 34.7 | 4.4, 28.1 | 0.0, 70.8 | 5.2, 24.1 | 4.7, 21.9 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 3 (16.7) | 4 (10.5) | 0 ( 0.0) | 7 (12.5) | 7 (11.3) |
| 95% CI [c] | 0.0, 70.8 | 3.6, 41.4 | 2.9, 24.8 | 0.0, 70.8 | 5.2, 24.1 | 4.7, 21.9 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 0 ( 0.0) | 1 ( 2.6) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.0, 18.5 | 0.1, 13.8 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| Month 3 | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 3 (16.7) | 7 (18.4) | 1 (33.3) | 10 (17.9) | 11 (17.7) |
| 95% CI [c] | 0.0, 70.8 | 3.6, 41.4 | 7.7, 34.3 | 0.8, 90.6 | 8.9, 30.4 | 9.2, 29.5 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 2 (11.1) | 6 (15.8) | 1 (33.3) | 8 (14.3) | 9 (14.5) |
| 95% CI [c] | 0.0, 70.8 | 1.4, 34.7 | 6.0, 31.3 | 0.8, 90.6 | 6.4, 26.2 | 6.9, 25.8 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 2 (11.1) | 4 (10.5) | 0 ( 0.0) | 6 (10.7) | 6 ( 9.7) |
| 95% CI [c] | 0.0, 70.8 | 1.4, 34.7 | 2.9, 24.8 | 0.0, 70.8 | 4.0, 21.9 | 3.6, 19.9 |

Note: One subject dosed at 205 x 10^6 cells in Part B Cohort 1 and one subject dosed at 305 x 10^6 cells in Part B Cohort 3 are included under target dose of 450 x 10^6 cells. RP2D = Recommended phase 2 dose.
[a] MRD negativity rate is the proportion of subjects who achieved CR or better and MRD negative status within 3 months prior to achieving CR or better until the time of progressive disease (PD) or death during initial treatment period with bb2121-treated population as the denominator. If a subject had no PD, the last response assessment date is used, and FDA progression free survival rules are used to determine progression and last response assessment date.
[b] Only responses by investigator assessment confirmed by a consecutive assessment with the same response category or better are considered.
[c] Clopper-Pearson exact confidence interval (CI) for MRD negativity rate.

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Table 14.2.1.5.3.1
Summary of Proportion of Subjects Who Achieved Complete Response (CR) and Minimal Residual Disease (MRD) Negativity by Visit
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | | | | |
|---|---|---|---|---|---|---|
| MRD Negativity [a] | 50x10^6 (N=3) n (%) | 150x10^6 (N=18) n (%) | 450x10^6 (N=38) n (%) | 800x10^6 (N=3) n (%) | Combined RP2D (150-450)x10^6 (N=56) n (%) | Total Study (N=62) n (%) |
| Month 6 | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 2 (11.1) | 4 (10.5) | 0 ( 0.0) | 6 (10.7) | 6 ( 9.7) |
| 95% CI [c] | 0.0, 70.8 | 1.4, 34.7 | 2.9, 24.8 | 0.0, 70.8 | 4.0, 21.9 | 3.6, 19.9 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 2 (11.1) | 4 (10.5) | 0 ( 0.0) | 6 (10.7) | 6 ( 9.7) |
| 95% CI [c] | 0.0, 70.8 | 1.4, 34.7 | 2.9, 24.8 | 0.0, 70.8 | 4.0, 21.9 | 3.6, 19.9 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 3 ( 7.9) | 0 ( 0.0) | 4 ( 7.1) | 4 ( 6.5) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 1.7, 21.4 | 0.0, 70.8 | 2.0, 17.3 | 1.8, 15.7 |
| Month 9 | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 0 ( 0.0) | 1 ( 2.6) | 1 (33.3) | 1 ( 1.8) | 2 ( 3.2) |
| 95% CI [c] | 0.0, 70.8 | 0.0, 18.5 | 0.1, 13.8 | 0.8, 90.6 | 0.0, 9.6 | 0.4, 11.2 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 0 ( 0.0) | 1 ( 2.6) | 1 (33.3) | 1 ( 1.8) | 2 ( 3.2) |
| 95% CI [c] | 0.0, 70.8 | 0.0, 18.5 | 0.1, 13.8 | 0.8, 90.6 | 0.0, 9.6 | 0.4, 11.2 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 0 ( 0.0) | 1 ( 2.6) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.0, 18.5 | 0.1, 13.8 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |

Note: One subject dosed at 205 x 10^6 cells in Part B Cohort 1 and one subject dosed at 305 x 10^6 cells in Part B Cohort 3 are included under target dose of 450 x 10^6 cells. RP2D = Recommended phase 2 dose.
[a] MRD negativity rate is the proportion of subjects who achieved CR or better and MRD negative status within 3 months prior to achieving CR or better until the time of progressive disease (PD) or death during initial treatment period with bb2121-treated population as the denominator. If a subject had no PD, the last response assessment date is used, and FDA progression free survival rules are used to determine progression and last response assessment date.
[b] Only responses by investigator assessment confirmed by a consecutive assessment with the same response category or better are considered.
[c] Clopper-Pearson exact confidence interval (CI) for MRD negativity rate.

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Table 14.2.1.5.3.1
Summary of Proportion of Subjects Who Achieved Complete Response (CR) and Minimal Residual Disease (MRD) Negativity by Visit
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | | | | |
|---|---|---|---|---|---|---|
| MRD Negativity [a] | 50x10^6 (N=3) n (%) | 150x10^6 (N=18) n (%) | 450x10^6 (N=38) n (%) | 800x10^6 (N=3) n (%) | Combined RP2D (150-450)x10^6 (N=56) n (%) | Total Study (N=62) n (%) |
| Month 12 | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 0 ( 0.0) | 3 ( 7.9) | 0 ( 0.0) | 3 ( 5.4) | 3 ( 4.8) |
| 95% CI [c] | 0.0, 70.8 | 0.0, 18.5 | 1.7, 21.4 | 0.0, 70.8 | 1.1, 14.9 | 1.0, 13.5 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 0 ( 0.0) | 3 ( 7.9) | 0 ( 0.0) | 3 ( 5.4) | 3 ( 4.8) |
| 95% CI [c] | 0.0, 70.8 | 0.0, 18.5 | 1.7, 21.4 | 0.0, 70.8 | 1.1, 14.9 | 1.0, 13.5 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 0 ( 0.0) | 1 ( 2.6) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.0, 18.5 | 0.1, 13.8 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| Month 18 | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 0 ( 0.0) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 0 ( 0.0) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) |
| 95% CI [c] | 0.0, 70.8 | 0.0, 18.5 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 6.4 | 0.0, 5.8 |

Note: One subject dosed at 205 x 10^6 cells in Part B Cohort 1 and one subject dosed at 305 x 10^6 cells in Part B Cohort 3 are included under target dose of 450 x 10^6 cells. RP2D = Recommended phase 2 dose.
[a] MRD negativity rate is the proportion of subjects who achieved CR or better and MRD negative status within 3 months prior to achieving CR or better until the time of progressive disease (PD) or death during initial treatment period with bb2121-treated population as the denominator. If a subject had no PD, the last response assessment date is used, and FDA progression free survival rules are used to determine progression and last response assessment date.
[b] Only responses by investigator assessment confirmed by a consecutive assessment with the same response category or better are considered.
[c] Clopper-Pearson exact confidence interval (CI) for MRD negativity rate.

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Table 14.2.1.5.3.1
Summary of Proportion of Subjects Who Achieved Complete Response (CR) and Minimal Residual Disease (MRD) Negativity by Visit
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | | | | |
|---|---|---|---|---|---|---|
| MRD Negativity [a] | 50x10^6 (N=3) n (%) | 150x10^6 (N=18) n (%) | 450x10^6 (N=38) n (%) | 800x10^6 (N=3) n (%) | Combined RP2D (150-450)x10^6 (N=56) n (%) | Total Study (N=62) n (%) |
| Month 24 | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 0 ( 0.0) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 0 ( 0.0) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 0 ( 0.0) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| Month 30 | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 0 ( 0.0) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 0 ( 0.0) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 0 ( 0.0) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |

Note: One subject dosed at 205 x 10^6 cells in Part B Cohort 1 and one subject dosed at 305 x 10^6 cells in Part B Cohort 3 are included under target dose of 450 x 10^6 cells. RP2D = Recommended phase 2 dose.
[a] MRD negativity rate is the proportion of subjects who achieved CR or better and MRD negative status within 3 months prior to achieving CR or better until the time of progressive disease (PD) or death during initial treatment period with bb2121-treated population as the denominator. If a subject had no PD, the last response assessment date is used, and FDA progression free survival rules are used to determine progression and last response assessment date.
[b] Only responses by investigator assessment confirmed by a consecutive assessment with the same response category or better are considered.
[c] Clopper-Pearson exact confidence interval (CI) for MRD negativity rate.

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Table 14.2.1.5.3.1
Summary of Proportion of Subjects Who Achieved Complete Response (CR) and Minimal Residual Disease (MRD) Negativity by Visit
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | | | | |
|---|---|---|---|---|---|---|
| MRD Negativity [a] | 50x10^6 (N=3) n (%) | 150x10^6 (N=18) n (%) | 450x10^6 (N=38) n (%) | 800x10^6 (N=3) n (%) | Combined RP2D (150-450)x10^6 (N=56) n (%) | Total Study (N=62) n (%) |
| Month 36 | | | | | | |
| 10^(-4) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 0 ( 0.0) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| 10^(-5) Sensitivity | 0 ( 0.0) | 1 ( 5.6) | 0 ( 0.0) | 0 ( 0.0) | 1 ( 1.8) | 1 ( 1.6) |
| 95% CI [c] | 0.0, 70.8 | 0.1, 27.3 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 9.6 | 0.0, 8.7 |
| 10^(-6) Sensitivity | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) | 0 ( 0.0) |
| 95% CI [c] | 0.0, 70.8 | 0.0, 18.5 | 0.0, 9.3 | 0.0, 70.8 | 0.0, 6.4 | 0.0, 5.8 |

Note: One subject dosed at 205 x 10^6 cells in Part B Cohort 1 and one subject dosed at 305 x 10^6 cells in Part B Cohort 3 are included under target dose of 450 x 10^6 cells. RP2D = Recommended phase 2 dose.
[a] MRD negativity rate is the proportion of subjects who achieved CR or better and MRD negative status within 3 months prior to achieving CR or better until the time of progressive disease (PD) or death during initial treatment period with bb2121-treated population as the denominator. If a subject had no PD, the last response assessment date is used, and FDA progression free survival rules are used to determine progression and last response assessment date.
[b] Only responses by investigator assessment confirmed by a consecutive assessment with the same response category or better are considered.
[c] Clopper-Pearson exact confidence interval (CI) for MRD negativity rate.

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Version: 15+1 Run Date: 03AUG2020 12:17 Data extract date: 10JUL2020

# 11. Progressionsfreies Überleben (Datenschnitt vom 07.04.2020)

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Protocol: CRB-401 Cut-off date: 07APR2020

Table 2.2.1c
Summary of Progression-free Survival by IRC Assessment (FDA Censoring Rules)
Enrolled Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=19) | 450x10^6 (N=42) | Combined RP2D (150-450)x10^6 (N=61) |
| Progression-free Survival | N | 19 | 42 | 61 |
| Censored | n (%) | 4 ( 21.1) | 9 ( 21.4) | 13 ( 21.3) |
| Progressed/Died | n (%) | 15 ( 78.9) | 33 ( 78.6) | 48 ( 78.7) |
| Progressed | n (%) | 14 ( 73.7) | 30 ( 71.4) | 44 ( 72.1) |
| Died | n (%) | 1 ( 5.3) | 3 ( 7.1) | 4 ( 6.6) |
| Progression-free Survival Time (months) [a] | 25th Pcnt. (95% CI) | 3.1 ( 1.7, 4.2) | 6.1 ( 2.7, 8.8) | 4.2 ( 2.8, 6.7) |
| | Median (95% CI) | 5.6 ( 3.1, 12.0) | 10.1 ( 7.3, 12.9) | 9.5 ( 6.7, 12.1) |
| | 75th Pcnt. (95% CI) | 13.1 ( 6.2, NE ) | 18.8 (12.1, 23.5) | 16.7 (12.1, 23.5) |
| 6 Months Event-Free | % (SE) | 50.0 (11.8) | 77.3 ( 6.7) | 68.7 ( 6.1) |
| 12 Months Event-Free | % (SE) | 27.8 (10.6) | 42.6 ( 8.0) | 38.0 ( 6.5) |
| 18 Months Event-Free | % (SE) | 16.7 ( 8.8) | 26.6 ( 7.2) | 23.5 ( 5.7) |
| 24 Months Event-Free | % (SE) | 16.7 ( 8.8) | 8.5 ( 5.3) | 12.3 ( 4.7) |
| 30 Months Event-Free | % (SE) | 16.7 ( 8.8) | 8.5 ( 5.3) | 12.3 ( 4.7) |
| 36 Months Event-Free | % (SE) | 16.7 ( 8.8) | 8.5 ( 5.3) | 12.3 ( 4.7) |
| 42 Months Event-Free | % (SE) | 16.7 ( 8.8) | NE | 12.3 ( 4.7) |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable. Pcnt.=Percentile.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
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Date/time of run: 05NOV2020 15:56
Analysis Plan: 30JUN2020 Confidential
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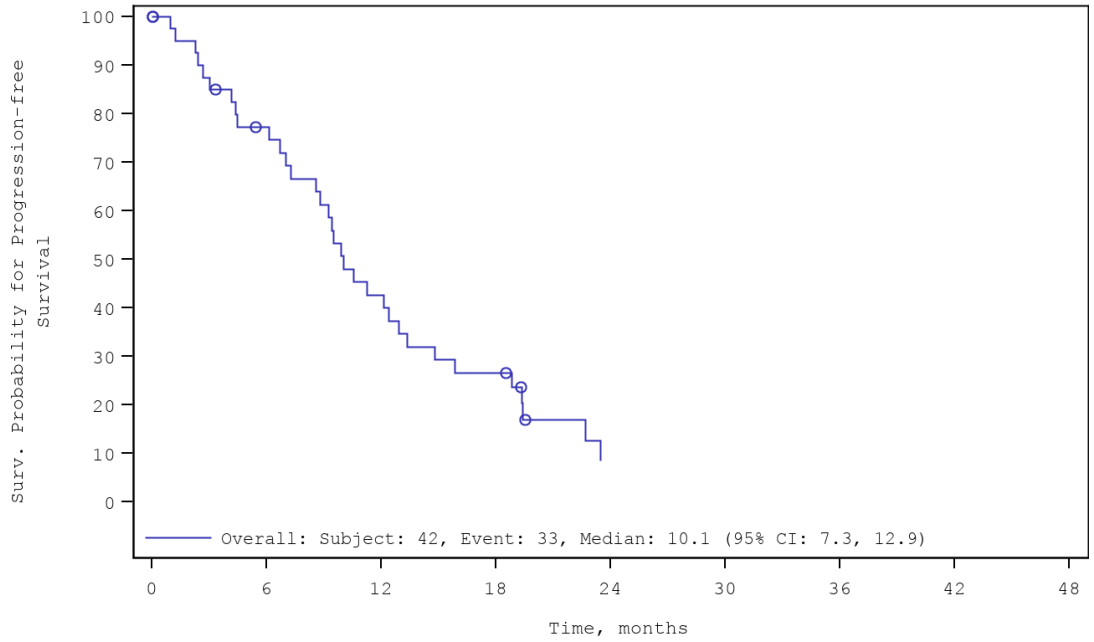
Protocol: CRB-401 Cut-off date: 07APR2020

Figure 2.2.1c
Kaplan-Meier Curve of Progression-free Survival by IRC Assessment (FDA Censoring Rules)
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Overall: | 42 | 29 | 16 | 10 | 2 | 2 | 1 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. Source Table: Table 2.2.1c.
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Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 3.1.1c
Summary of Progression-free Survival by IRC Assessment (EMA Censoring Rules)
bb2121-Treated Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=18) | 450x10^6 (N=38) | Combined RP2D (150-450)x10^6 (N=56) |
| Progression-free Survival | N | 18 | 38 | 56 |
| Censored | n (%) | 3 ( 16.7) | 6 ( 15.8) | 9 ( 16.1) |
| Progressed/Died | n (%) | 15 ( 83.3) | 32 ( 84.2) | 47 ( 83.9) |
| Progressed | n (%) | 14 ( 77.8) | 31 ( 81.6) | 45 ( 80.4) |
| Died | n (%) | 1 ( 5.6) | 1 ( 2.6) | 2 ( 3.6) |
| Progression-free Survival Time (months) [a] | 25th Pcnt. (95% CI) | 2.0 ( 0.6, 3.1) | 5.6 ( 1.9, 7.5) | 3.1 ( 1.9, 5.9) |
| | Median (95% CI) | 4.5 ( 2.0, 10.9) | 9.0 ( 7.2, 12.2) | 8.4 ( 5.9, 11.1) |
| | 75th Pcnt. (95% CI) | 12.0 ( 5.2, NE ) | 17.8 (11.3, 22.4) | 14.6 (11.1, 22.4) |
| 6 Months Event-Free | % (SE) | 44.4 (11.7) | 70.8 ( 7.4) | 62.3 ( 6.5) |
| 12 Months Event-Free | % (SE) | 27.8 (10.6) | 35.4 ( 7.9) | 33.0 ( 6.3) |
| 18 Months Event-Free | % (SE) | 16.7 ( 8.8) | 21.2 ( 6.8) | 19.9 ( 5.4) |
| 24 Months Event-Free | % (SE) | 16.7 ( 8.8) | 8.5 ( 5.4) | 12.4 ( 4.8) |
| 30 Months Event-Free | % (SE) | 16.7 ( 8.8) | 8.5 ( 5.4) | 12.4 ( 4.8) |
| 36 Months Event-Free | % (SE) | 16.7 ( 8.8) | 8.5 ( 5.4) | 12.4 ( 4.8) |
| 42 Months Event-Free | % (SE) | NE | NE | NE |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable. Pcnt.=Percentile.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
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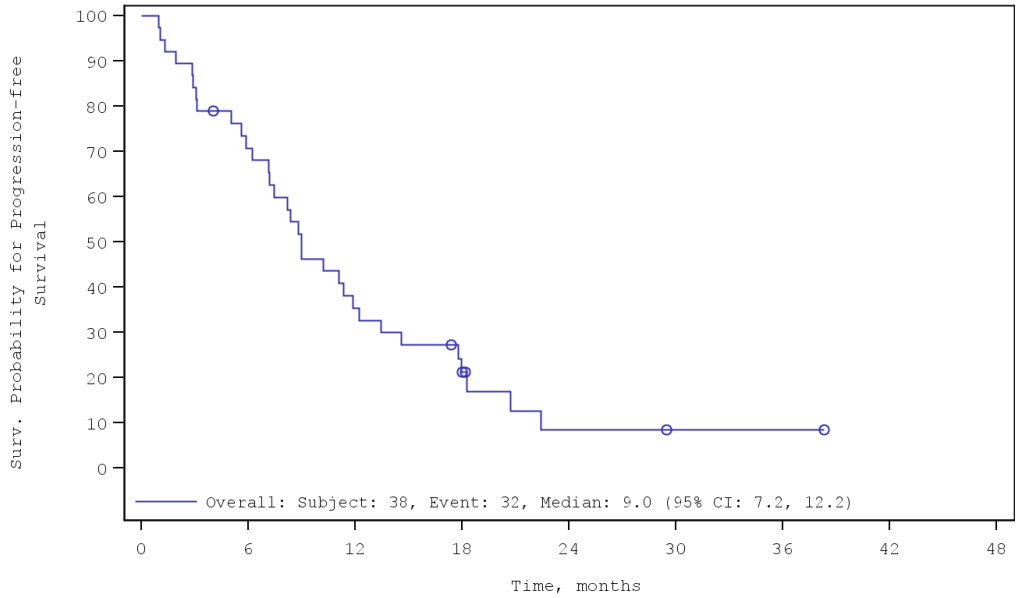
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401 Cut-off date: 07APR2020

Figure 3.1.1c
Kaplan-Meier Curve of Progression-free Survival by IRC Assessment (EMA Censoring Rules)
bb2121-Treated Population including only subjects receiving 450x10^6 CAR T cells
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Overall: | 38 | 26 | 13 | 7 | 2 | 1 | 1 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. Source Table: Table 3.1.1c.
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Table 2.1.1c
Summary of Progression-free Survival by IRC Assessment (FDA Censoring Rules)
bb2121-Treated Population

| | | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|---|
| | Statistics | 150x10^6 (N=18) | 450x10^6 (N=38) | Combined RP2D (150-450)x10^6 (N=56) |
| Progression-free Survival | N | 18 | 38 | 56 |
| Censored | n (%) | 3 ( 16.7) | 7 ( 18.4) | 10 ( 17.9) |
| Progressed/Died | n (%) | 15 ( 83.3) | 31 ( 81.6) | 46 ( 82.1) |
| Progressed | n (%) | 14 ( 77.8) | 30 ( 78.9) | 44 ( 78.6) |
| Died | n (%) | 1 ( 5.6) | 1 ( 2.6) | 2 ( 3.6) |
| Progression-free Survival Time (months) [a] | 25th Pcnt. (95% CI) | 2.0 ( 0.6, 3.1) | 5.9 ( 1.9, 8.2) | 3.1 ( 1.9, 5.9) |
| | Median (95% CI) | 4.5 ( 2.0, 10.9) | 9.0 ( 7.2, 12.2) | 8.8 ( 5.9, 11.3) |
| | 75th Pcnt. (95% CI) | 12.0 ( 5.2, NE ) | 17.8 (11.3, 22.4) | 14.6 (11.1, 22.4) |
| 6 Months Event-Free | % (SE) | 44.4 (11.7) | 72.9 ( 7.3) | 63.7 ( 6.5) |
| 12 Months Event-Free | % (SE) | 27.8 (10.6) | 36.5 ( 8.0) | 33.7 ( 6.4) |
| 18 Months Event-Free | % (SE) | 16.7 ( 8.8) | 21.8 ( 7.0) | 20.3 ( 5.5) |
| 24 Months Event-Free | % (SE) | 16.7 ( 8.8) | 8.7 ( 5.5) | 12.7 ( 4.9) |
| 30 Months Event-Free | % (SE) | 16.7 ( 8.8) | 8.7 ( 5.5) | 12.7 ( 4.9) |
| 36 Months Event-Free | % (SE) | 16.7 ( 8.8) | 8.7 ( 5.5) | 12.7 ( 4.9) |
| 42 Months Event-Free | % (SE) | NE | NE | NE |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable. Pcnt.=Percentile.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
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Date/time of run: 05NOV2020 15:56
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401

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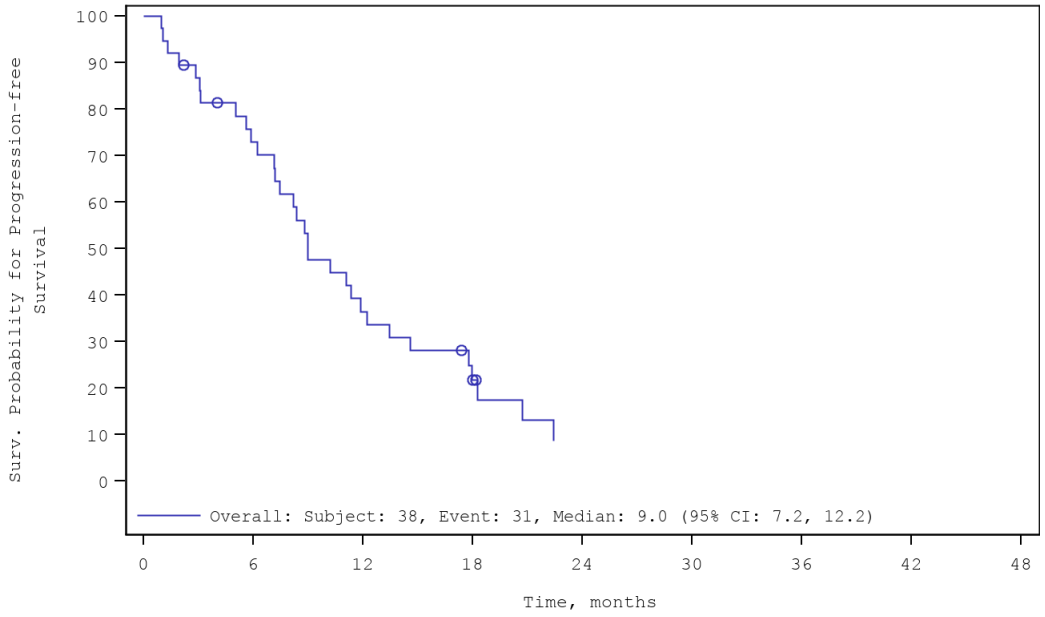
Cut-off date: 07APR2020

Figure 2.1.1c
Kaplan-Meier Curve of Progression-free Survival by IRC Assessment (FDA Censoring Rules)
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Overall: | 38 | 26 | 13 | 7 | 2 | 1 | 1 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. Source Table: Table 2.1.1c.
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Analysis Plan: 30JUN2020 Confidential

# 12. Verträglichkeit (Datenschnitt vom 07.04.2020)

## 12.1 UE Gesamtraten

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 5.2.3c
Overview of Adverse Events (AEs)
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Enrolled Population (N=42) | | | |
|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) |
| Subjects with at least one AE | 31 ( 73.8) | 37 ( 88.1) | 38 ( 90.5) | 38 ( 90.5) |
| Subjects with at least one AE attributed to LP | 3 ( 7.1) | 2 ( 4.8) | 1 ( 2.4) | 2 ( 4.8) |
| Subjects with at least one AE attributed to LD | 1 ( 2.4) | 30 ( 71.4) | 28 ( 66.7) | 33 ( 78.6) |
| Subjects with at least one AE related [a] to bb2121 | 0 | 3 ( 7.1) | 37 ( 88.1) | 37 ( 88.1) |
| Subjects with at least one serious AE | 7 ( 16.7) | 1 ( 2.4) | 29 ( 69.0) | 29 ( 69.0) |
| Subjects with at least one serious AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE attributed to LD | 0 | 1 ( 2.4) | 0 | 1 ( 2.4) |
| Subjects with at least one serious AE related [a] to bb2121 | 0 | 0 | 12 ( 28.6) | 12 ( 28.6) |
| Subjects with at least one grade 1 or 2 [b] AE | 29 ( 69.0) | 34 ( 81.0) | 38 ( 90.5) | 38 ( 90.5) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LP | 2 ( 4.8) | 1 ( 2.4) | 1 ( 2.4) | 2 ( 4.8) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LD | 1 ( 2.4) | 26 ( 61.9) | 23 ( 54.8) | 30 ( 71.4) |
| Subjects with at least one grade 1 or 2 [b] AE related [a] to bb2121 | 0 | 1 ( 2.4) | 37 ( 88.1) | 37 ( 88.1) |
| Subjects with at least one grade 3, 4 or 5 [b] AE | 13 ( 31.0) | 25 ( 59.5) | 37 ( 88.1) | 37 ( 88.1) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LP | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LD | 0 | 22 ( 52.4) | 26 ( 61.9) | 30 ( 71.4) |
| Subjects with at least one grade 3, 4 or 5 [b] AE related [a] to bb2121 | 0 | 2 ( 4.8) | 26 ( 61.9) | 26 ( 61.9) |

Note: Footnotes are displayed on the last page only.
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Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 5.1.3c
Overview of Adverse Events (AEs), Overall and by Subgroup
bb2121-Treated Population, Overall
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=38) | | | |
|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) |
| Subjects with at least one AE | 27 ( 71.1) | 37 ( 97.4) | 38 (100.0) | 38 (100.0) |
| Subjects with at least one AE attributed to LP | 3 ( 7.9) | 2 ( 5.3) | 1 ( 2.6) | 2 ( 5.3) |
| Subjects with at least one AE attributed to LD | 1 ( 2.6) | 30 ( 78.9) | 28 ( 73.7) | 33 ( 86.8) |
| Subjects with at least one AE related [a] to bb2121 | 0 | 3 ( 7.9) | 37 ( 97.4) | 37 ( 97.4) |
| Subjects with at least one serious AE | 3 ( 7.9) | 1 ( 2.6) | 29 ( 76.3) | 29 ( 76.3) |
| Subjects with at least one serious AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE attributed to LD | 0 | 1 ( 2.6) | 0 | 1 ( 2.6) |
| Subjects with at least one serious AE related [a] to bb2121 | 0 | 0 | 12 ( 31.6) | 12 ( 31.6) |
| Subjects with at least one grade 1 or 2 [b] AE | 26 ( 68.4) | 34 ( 89.5) | 38 (100.0) | 38 (100.0) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LP | 2 ( 5.3) | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LD | 1 ( 2.6) | 26 ( 68.4) | 23 ( 60.5) | 30 ( 78.9) |
| Subjects with at least one grade 1 or 2 [b] AE related [a] to bb2121 | 0 | 1 ( 2.6) | 37 ( 97.4) | 37 ( 97.4) |
| Subjects with at least one grade 3, 4 or 5 [b] AE | 10 ( 26.3) | 25 ( 65.8) | 37 ( 97.4) | 37 ( 97.4) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LP | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LD | 0 | 22 ( 57.9) | 26 ( 68.4) | 30 ( 78.9) |
| Subjects with at least one grade 3, 4 or 5 [b] AE related [a] to bb2121 | 0 | 2 ( 5.3) | 26 ( 68.4) | 26 ( 68.4) |

Note: Footnotes are displayed on the last page only.
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Analysis Plan: 30JUN2020 Confidential

## 12.2 UESI

Celgene Corporation

Protocol: CRB-401
Cut-off date: 07APR2020

Table 7.5c
Adverse Events of Special Interest (AESIs) and Selected AEs Summary, Overall and by Subgroup
bb2121-Treated Population, Overall
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI or Selected AE | 20 ( 52.6) | 30 ( 78.9) | 38 (100.0) | 38 (100.0) | 38 (100.0) |
| Subjects with at least one serious AESI or Selected AE | 3 ( 7.9) | 1 ( 2.6) | 22 ( 57.9) | 22 ( 57.9) | 23 ( 60.5) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI or Selected AE | 16 ( 42.1) | 24 ( 63.2) | 38 (100.0) | 38 (100.0) | 38 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI or Selected AE | 9 ( 23.7) | 24 ( 63.2) | 36 ( 94.7) | 36 ( 94.7) | 37 ( 97.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria
for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.

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Analysis Plan: 30JUN2020 Confidential

## 12.2 UE nach SOC und PT

### 12.2.1 UE Grad 1 und 2 nach SOC und PT

Table 6.4.1c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Number of subjects with at least one Grade 1 or 2 AE [b] | 26 ( 68.4) | 34 ( 89.5) | 38 (100.0) | 38 (100.0) | 38 (100.0) |
| Gastrointestinal disorders | 8 ( 21.1) | 20 ( 52.6) | 35 ( 92.1) | 36 ( 94.7) | 37 ( 97.4) |
| Nausea | 2 ( 5.3) | 16 ( 42.1) | 17 ( 44.7) | 27 ( 71.1) | 27 ( 71.1) |
| Diarrhoea | 2 ( 5.3) | 2 ( 5.3) | 18 ( 47.4) | 18 ( 47.4) | 19 ( 50.0) |
| Constipation | 3 ( 7.9) | 2 ( 5.3) | 13 ( 34.2) | 13 ( 34.2) | 14 ( 36.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_4.SAS
Date/time of run: 02OCT2020 16:07
Analysis Plan: 30JUN2020 Confidential

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Protocol: CRB-401 Cut-off date: 07APR2020

Table 6.4.1c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Vomiting | 1 ( 2.6) | 2 ( 5.3) | 12 ( 31.6) | 13 ( 34.2) | 13 ( 34.2) |
| Abdominal pain | 1 ( 2.6) | 1 ( 2.6) | 7 ( 18.4) | 8 ( 21.1) | 8 ( 21.1) |
| Abdominal discomfort | 0 | 1 ( 2.6) | 3 ( 7.9) | 4 ( 10.5) | 4 ( 10.5) |
| Abdominal distension | 0 | 1 ( 2.6) | 2 ( 5.3) | 3 ( 7.9) | 3 ( 7.9) |
| Dry mouth | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.

[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_4.SAS
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Table 6.4.1c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Dyspepsia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Gastrooesophageal reflux disease | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) |
| Stomatitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Dysphagia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Flatulence | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_4.SAS
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Table 6.4.1c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Pancreatitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Abdominal pain lower | 0 | 0 | 0 | 0 | 0 |
| Abdominal tenderness | 0 | 0 | 0 | 0 | 0 |
| Gingival swelling | 0 | 0 | 0 | 0 | 0 |
| Haemorrhoids | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.

[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.

[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.1c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Inguinal hernia | 0 | 0 | 0 | 0 | 0 |
| Paraesthesia oral | 0 | 0 | 0 | 0 | 0 |
| Retching | 0 | 0 | 0 | 0 | 0 |
| Toothache | 0 | 0 | 0 | 0 | 0 |
| Blood and lymphatic system disorders | 11 ( 28.9) | 19 ( 50.0) | 33 ( 86.8) | 33 ( 86.8) | 34 ( 89.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.1c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Neutropenia | 4 ( 10.5) | 6 ( 15.8) | 31 ( 81.6) | 31 ( 81.6) | 31 ( 81.6) |
| Anaemia | 7 ( 18.4) | 11 ( 28.9) | 27 ( 71.1) | 27 ( 71.1) | 28 ( 73.7) |
| Thrombocytopenia | 6 ( 15.8) | 5 ( 13.2) | 25 ( 65.8) | 25 ( 65.8) | 26 ( 68.4) |
| Leukopenia | 3 ( 7.9) | 10 ( 26.3) | 21 ( 55.3) | 21 ( 55.3) | 21 ( 55.3) |
| Lymphopenia | 3 ( 7.9) | 5 ( 13.2) | 14 ( 36.8) | 14 ( 36.8) | 14 ( 36.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.1c
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For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Febrile neutropenia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Erythropenia | 0 | 0 | 0 | 0 | 0 |
| General disorders and administration site conditions | 10 ( 26.3) | 10 ( 26.3) | 33 ( 86.8) | 34 ( 89.5) | 35 ( 92.1) |
| Fatigue | 5 ( 13.2) | 4 ( 10.5) | 19 ( 50.0) | 21 ( 55.3) | 23 ( 60.5) |
| Oedema peripheral | 1 ( 2.6) | 4 ( 10.5) | 13 ( 34.2) | 15 ( 39.5) | 16 ( 42.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Pyrexia | 2 ( 5.3) | 1 ( 2.6) | 14 ( 36.8) | 14 ( 36.8) | 15 ( 39.5) |
| Chills | 2 ( 5.3) | 0 | 10 ( 26.3) | 10 ( 26.3) | 12 ( 31.6) |
| Pain | 2 ( 5.3) | 1 ( 2.6) | 3 ( 7.9) | 4 ( 10.5) | 6 ( 15.8) |
| Asthenia | 0 | 0 | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |
| Gait disturbance | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Chest discomfort | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Malaise | 0 | 1 ( 2.6) | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |
| Influenza like illness | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Mass | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Oedema | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Chest pain | 0 | 0 | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 4 ( 10.5) | 5 ( 13.2) | 29 ( 76.3) | 31 ( 81.6) | 32 ( 84.2) |
| Arthralgia | 2 ( 5.3) | 2 ( 5.3) | 14 ( 36.8) | 15 ( 39.5) | 16 ( 42.1) |
| Back pain | 0 | 0 | 6 ( 15.8) | 6 ( 15.8) | 6 ( 15.8) |
| Musculoskeletal pain | 0 | 1 ( 2.6) | 5 ( 13.2) | 5 ( 13.2) | 5 ( 13.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Musculoskeletal chest pain | 1 ( 2.6) | 1 ( 2.6) | 3 ( 7.9) | 4 ( 10.5) | 5 ( 13.2) |
| Bone pain | 0 | 2 ( 5.3) | 2 ( 5.3) | 4 ( 10.5) | 4 ( 10.5) |
| Myalgia | 0 | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Pain in extremity | 0 | 0 | 5 ( 13.2) | 5 ( 13.2) | 5 ( 13.2) |
| Muscular weakness | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Musculoskeletal discomfort | 0 | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Muscle spasms | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Neck pain | 0 | 0 | 0 | 0 | 0 |
| Groin pain | 0 | 0 | 0 | 0 | 0 |
| Tendonitis | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Metabolism and nutrition disorders | 11 ( 28.9) | 19 ( 50.0) | 30 ( 78.9) | 31 ( 81.6) | 32 ( 84.2) |
| Hypokalaemia | 2 ( 5.3) | 8 ( 21.1) | 15 ( 39.5) | 19 ( 50.0) | 19 ( 50.0) |
| Hypophosphataemia | 0 | 2 ( 5.3) | 14 ( 36.8) | 14 ( 36.8) | 14 ( 36.8) |
| Hypocalcaemia | 2 ( 5.3) | 4 ( 10.5) | 12 ( 31.6) | 13 ( 34.2) | 13 ( 34.2) |
| Hypoalbuminaemia | 2 ( 5.3) | 5 ( 13.2) | 11 ( 28.9) | 12 ( 31.6) | 13 ( 34.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.1c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Hypomagnesaemia | 1 ( 2.6) | 2 ( 5.3) | 7 ( 18.4) | 8 ( 21.1) | 9 ( 23.7) |
| Decreased appetite | 0 | 4 ( 10.5) | 6 ( 15.8) | 8 ( 21.1) | 8 ( 21.1) |
| Hyperglycaemia | 1 ( 2.6) | 4 ( 10.5) | 7 ( 18.4) | 7 ( 18.4) | 7 ( 18.4) |
| Hyponatraemia | 0 | 0 | 7 ( 18.4) | 7 ( 18.4) | 7 ( 18.4) |
| Hyperuricaemia | 2 ( 5.3) | 0 | 1 ( 2.6) | 1 ( 2.6) | 3 ( 7.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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|---|---|---|---|---|---|
| Hypernatraemia | 0 | 1 ( 2.6) | 2 ( 5.3) | 3 ( 7.9) | 3 ( 7.9) |
| Dehydration | 1 ( 2.6) | 0 | 2 ( 5.3) | 2 ( 5.3) | 3 ( 7.9) |
| Fluid overload | 0 | 2 ( 5.3) | 2 ( 5.3) | 3 ( 7.9) | 3 ( 7.9) |
| Hyperkalaemia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Failure to thrive | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Hypercalcaemia | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) |
| Hypermagnesaemia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Hypoglycaemia | 0 | 0 | 0 | 0 | 0 |
| Infections and infestations | 2 ( 5.3) | 3 ( 7.9) | 28 ( 73.7) | 28 ( 73.7) | 29 ( 76.3) |
| Upper respiratory tract infection | 1 ( 2.6) | 0 | 12 ( 31.6) | 12 ( 31.6) | 13 ( 34.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
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Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Urinary tract infection | 0 | 0 | 7 ( 18.4) | 7 ( 18.4) | 7 ( 18.4) |
| Influenza | 0 | 0 | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |
| Respiratory syncytial virus infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Sinusitis | 0 | 0 | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |
| Nasopharyngitis | 0 | 1 ( 2.6) | 2 ( 5.3) | 3 ( 7.9) | 3 ( 7.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Bronchitis | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Clostridium difficile infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Ear infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Folliculitis | 0 | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) |
| Lung infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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|---|---|---|---|---|---|
| Parvovirus infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Pneumonia | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Rhinovirus infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Skin infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Tooth infection | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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|---|---|---|---|---|---|
| Acarodermatitis | 0 | 0 | 0 | 0 | 0 |
| Anal abscess | 0 | 0 | 0 | 0 | 0 |
| Device related infection | 0 | 0 | 0 | 0 | 0 |
| Hordeolum | 0 | 0 | 0 | 0 | 0 |
| Rhinitis | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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|---|---|---|---|---|---|
| Viral infection | 0 | 0 | 0 | 0 | 0 |
| Viral upper respiratory tract infection | 0 | 0 | 0 | 0 | 0 |
| Vulvovaginal mycotic infection | 0 | 0 | 0 | 0 | 0 |
| Immune system disorders | 2 ( 5.3) | 0 | 34 ( 89.5) | 34 ( 89.5) | 35 ( 92.1) |
| Cytokine release syndrome | 0 | 0 | 34 ( 89.5) | 34 ( 89.5) | 34 ( 89.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Hypogammaglobulinaemia | 1 ( 2.6) | 0 | 5 ( 13.2) | 5 ( 13.2) | 6 ( 15.8) |
| Seasonal allergy | 0 | 0 | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 6 ( 15.8) | 2 ( 5.3) | 29 ( 76.3) | 29 ( 76.3) | 31 ( 81.6) |
| Cough | 3 ( 7.9) | 0 | 17 ( 44.7) | 17 ( 44.7) | 18 ( 47.4) |
| Nasal congestion | 0 | 1 ( 2.6) | 10 ( 26.3) | 11 ( 28.9) | 11 ( 28.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Dyspnoea | 0 | 1 ( 2.6) | 6 ( 15.8) | 7 ( 18.4) | 7 ( 18.4) |
| Productive cough | 0 | 1 ( 2.6) | 6 ( 15.8) | 7 ( 18.4) | 7 ( 18.4) |
| Oropharyngeal pain | 1 ( 2.6) | 0 | 5 ( 13.2) | 5 ( 13.2) | 6 ( 15.8) |
| Dyspnoea exertional | 1 ( 2.6) | 0 | 2 ( 5.3) | 2 ( 5.3) | 3 ( 7.9) |
| Epistaxis | 1 ( 2.6) | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.1c
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bb2121-Treated Population
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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Hypoxia | 0 | 0 | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |
| Pneumonitis | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) |
| Rhinorrhoea | 0 | 1 ( 2.6) | 2 ( 5.3) | 3 ( 7.9) | 3 ( 7.9) |
| Upper-airway cough syndrome | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Wheezing | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Pleural effusion | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Pulmonary oedema | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Rales | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Rhinitis allergic | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Sinus congestion | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Throat tightness | 0 | 0 | 0 | 0 | 0 |
| Nervous system disorders | 6 ( 15.8) | 8 ( 21.1) | 25 ( 65.8) | 27 ( 71.1) | 28 ( 73.7) |
| Headache | 1 ( 2.6) | 6 ( 15.8) | 12 ( 31.6) | 14 ( 36.8) | 14 ( 36.8) |
| Dizziness | 0 | 0 | 8 ( 21.1) | 8 ( 21.1) | 8 ( 21.1) |
| Neurotoxicity | 0 | 0 | 5 ( 13.2) | 5 ( 13.2) | 5 ( 13.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Tremor | 2 ( 5.3) | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Hypoaesthesia | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) | 2 ( 5.3) |
| Paraesthesia | 2 ( 5.3) | 0 | 2 ( 5.3) | 2 ( 5.3) | 3 ( 7.9) |
| Disturbance in attention | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Dysgeusia | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Somnolence | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Syncope | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Aphasia | 0 | 0 | 0 | 0 | 0 |
| Dysgraphia | 0 | 0 | 0 | 0 | 0 |
| Facial paralysis | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Haemorrhage intracranial | 0 | 0 | 0 | 0 | 0 |
| Neuropathy peripheral | 0 | 0 | 0 | 0 | 0 |
| Investigations | 5 ( 13.2) | 5 ( 13.2) | 23 ( 60.5) | 24 ( 63.2) | 24 ( 63.2) |
| Blood alkaline phosphatase increased | 1 ( 2.6) | 0 | 7 ( 18.4) | 7 ( 18.4) | 8 ( 21.1) |
| Blood creatinine increased | 1 ( 2.6) | 1 ( 2.6) | 4 ( 10.5) | 5 ( 13.2) | 6 ( 15.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Transaminases increased | 0 | 1 ( 2.6) | 5 ( 13.2) | 5 ( 13.2) | 5 ( 13.2) |
| Weight increased | 0 | 1 ( 2.6) | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Weight decreased | 0 | 0 | 5 ( 13.2) | 5 ( 13.2) | 5 ( 13.2) |
| Blood bilirubin increased | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Activated partial thromboplastin time prolonged | 2 ( 5.3) | 1 ( 2.6) | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Aspartate aminotransferase increased | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Blood uric acid increased | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) |
| International normalised ratio increased | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Creatinine renal clearance abnormal | 0 | 0 | 0 | 0 | 0 |
| Heart rate irregular | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Skin and subcutaneous tissue disorders | 2 ( 5.3) | 3 ( 7.9) | 15 ( 39.5) | 18 ( 47.4) | 20 ( 52.6) |
| Pruritus | 1 ( 2.6) | 1 ( 2.6) | 3 ( 7.9) | 4 ( 10.5) | 5 ( 13.2) |
| Rash | 0 | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Alopecia | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) |
| Erythema | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Skin lesion | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Dry skin | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Ecchymosis | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) | 2 ( 5.3) |
| Rash maculo-papular | 0 | 0 | 0 | 0 | 0 |
| Skin disorder | 0 | 0 | 0 | 0 | 0 |

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| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Blister | 0 | 0 | 0 | 0 | 0 |
| Vascular disorders | 1 ( 2.6) | 1 ( 2.6) | 15 ( 39.5) | 15 ( 39.5) | 15 ( 39.5) |
| Hypotension | 0 | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Hypertension | 0 | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Hot flush | 0 | 0 | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.1c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Deep vein thrombosis | 0 | 0 | 0 | 0 | 0 |
| Psychiatric disorders | 0 | 1 ( 2.6) | 11 ( 28.9) | 12 ( 31.6) | 12 ( 31.6) |
| Insomnia | 0 | 1 ( 2.6) | 5 ( 13.2) | 6 ( 15.8) | 6 ( 15.8) |
| Confusional state | 0 | 0 | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |
| Anxiety | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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|---|---|---|---|---|---|
| Depression | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Delirium | 0 | 0 | 0 | 0 | 0 |
| Cardiac disorders | 1 ( 2.6) | 2 ( 5.3) | 12 ( 31.6) | 12 ( 31.6) | 13 ( 34.2) |
| Tachycardia | 0 | 2 ( 5.3) | 6 ( 15.8) | 6 ( 15.8) | 6 ( 15.8) |
| Sinus tachycardia | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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|---|---|---|---|---|---|
| Atrial fibrillation | 1 ( 2.6) | 0 | 3 ( 7.9) | 3 ( 7.9) | 4 ( 10.5) |
| Bradycardia | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Ventricular arrhythmia | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Sinus bradycardia | 0 | 0 | 0 | 0 | 0 |
| Ventricular extrasystoles | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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|---|---|---|---|---|---|
| Ventricular tachycardia | 0 | 0 | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 3 ( 7.9) | 0 | 9 ( 23.7) | 9 ( 23.7) | 11 ( 28.9) |
| Fall | 1 ( 2.6) | 0 | 2 ( 5.3) | 2 ( 5.3) | 3 ( 7.9) |
| Arthropod bite | 0 | 0 | 0 | 0 | 0 |
| Contusion | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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|---|---|---|---|---|---|
| Procedural pain | 0 | 0 | 0 | 0 | 0 |
| Rib fracture | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) |
| Skin laceration | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Infusion related reaction | 0 | 0 | 0 | 0 | 0 |
| Spinal fracture | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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|---|---|---|---|---|---|
| Eye disorders | 1 ( 2.6) | 1 ( 2.6) | 9 ( 23.7) | 9 ( 23.7) | 9 ( 23.7) |
| Lacrimation increased | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Visual impairment | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Dry eye | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Ocular hyperaemia | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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|---|---|---|---|---|---|
| Vision blurred | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Ear and labyrinth disorders | 0 | 1 ( 2.6) | 6 ( 15.8) | 7 ( 18.4) | 7 ( 18.4) |
| Ear pain | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Ear congestion | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) | 2 ( 5.3) |
| Tinnitus | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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|---|---|---|---|---|---|
| Deafness | 0 | 0 | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0 | 7 ( 18.4) | 7 ( 18.4) | 7 ( 18.4) |
| Bowen's disease | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Plasmacytoma | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Tumour pain | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Bone neoplasm | 0 | 0 | 0 | 0 | 0 |
| Renal and urinary disorders | 1 ( 2.6) | 0 | 7 ( 18.4) | 7 ( 18.4) | 7 ( 18.4) |
| Dysuria | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Pollakiuria | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Haematuria | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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|---|---|---|---|---|---|
| Urinary retention | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Nephrolithiasis | 0 | 0 | 0 | 0 | 0 |
| Proteinuria | 0 | 0 | 0 | 0 | 0 |
| Endocrine disorders | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) | 3 ( 7.9) |
| Hypothyroidism | 1 ( 2.6) | 1 ( 2.6) | 0 | 1 ( 2.6) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.1c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Reproductive system and breast disorders | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Vaginal discharge | 0 | 0 | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | 0 | 0 | 0 | 0 | 0 |
| Atrial septal defect | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_4.SAS
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE [b] | 29 ( 69.0) | 41 ( 97.6) |
| Gastrointestinal disorders | 8 ( 19.0) | 37 ( 88.1) |
| Nausea | 2 ( 4.8) | 27 ( 64.3) |
| Diarrhoea | 2 ( 4.8) | 19 ( 45.2) |
| Constipation | 3 ( 7.1) | 14 ( 33.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Vomiting | 1 ( 2.4) | 13 ( 31.0) |
| Abdominal pain | 1 ( 2.4) | 8 ( 19.0) |
| Abdominal discomfort | 0 | 4 ( 9.5) |
| Abdominal distension | 0 | 3 ( 7.1) |
| Dry mouth | 0 | 2 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_4.SAS
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Dyspepsia | 0 | 1 ( 2.4) |
| Gastrooesophageal reflux disease | 1 ( 2.4) | 2 ( 4.8) |
| Stomatitis | 0 | 1 ( 2.4) |
| Dysphagia | 0 | 1 ( 2.4) |
| Pancreatitis | 0 | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Abdominal pain lower | 0 | 0 |
| Abdominal tenderness | 0 | 0 |
| Gingival swelling | 0 | 0 |
| Haemorrhoids | 0 | 0 |
| Inguinal hernia | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Paraesthesia oral | 0 | 0 |
| Retching | 0 | 0 |
| Toothache | 0 | 0 |
| Blood and lymphatic system disorders | 12 ( 28.6) | 35 ( 83.3) |
| Neutropenia | 5 ( 11.9) | 32 ( 76.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Anaemia | 8 ( 19.0) | 29 ( 69.0) |
| Thrombocytopenia | 7 ( 16.7) | 27 ( 64.3) |
| Leukopenia | 3 ( 7.1) | 21 ( 50.0) |
| Lymphopenia | 3 ( 7.1) | 14 ( 33.3) |
| Febrile neutropenia | 0 | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Erythropenia | 0 | 0 |
| General disorders and administration site conditions | 11 ( 26.2) | 36 ( 85.7) |
| Fatigue | 5 ( 11.9) | 23 ( 54.8) |
| Pyrexia | 3 ( 7.1) | 16 ( 38.1) |
| Oedema peripheral | 1 ( 2.4) | 16 ( 38.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Chills | 2 ( 4.8) | 12 ( 28.6) |
| Pain | 2 ( 4.8) | 6 ( 14.3) |
| Asthenia | 0 | 3 ( 7.1) |
| Gait disturbance | 0 | 1 ( 2.4) |
| Chest discomfort | 0 | 2 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Malaise | 0 | 3 ( 7.1) |
| Influenza like illness | 0 | 1 ( 2.4) |
| Mass | 0 | 1 ( 2.4) |
| Chest pain | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 6 ( 14.3) | 34 ( 81.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Arthralgia | 2 ( 4.8) | 16 ( 38.1) |
| Back pain | 0 | 6 ( 14.3) |
| Musculoskeletal pain | 1 ( 2.4) | 6 ( 14.3) |
| Musculoskeletal chest pain | 1 ( 2.4) | 5 ( 11.9) |
| Bone pain | 0 | 4 ( 9.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Myalgia | 0 | 4 ( 9.5) |
| Pain in extremity | 1 ( 2.4) | 6 ( 14.3) |
| Muscular weakness | 0 | 1 ( 2.4) |
| Musculoskeletal discomfort | 0 | 4 ( 9.5) |
| Neck pain | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Groin pain | 0 | 0 |
| Tendonitis | 0 | 0 |
| Metabolism and nutrition disorders | 11 ( 26.2) | 32 ( 76.2) |
| Hypokalaemia | 2 ( 4.8) | 19 ( 45.2) |
| Hypophosphataemia | 0 | 14 ( 33.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_4.SAS

Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Hypocalcaemia | 2 ( 4.8) | 13 ( 31.0) |
| Hypoalbuminaemia | 2 ( 4.8) | 13 ( 31.0) |
| Hypomagnesaemia | 1 ( 2.4) | 9 ( 21.4) |
| Decreased appetite | 0 | 8 ( 19.0) |
| Hyperglycaemia | 1 ( 2.4) | 7 ( 16.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_4.SAS
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Hyponatraemia | 0 | 7 ( 16.7) |
| Hyperuricaemia | 2 ( 4.8) | 3 ( 7.1) |
| Hypernatraemia | 0 | 3 ( 7.1) |
| Dehydration | 1 ( 2.4) | 3 ( 7.1) |
| Fluid overload | 0 | 3 ( 7.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Hyperkalaemia | 0 | 1 ( 2.4) |
| Hypermagnesaemia | 0 | 1 ( 2.4) |
| Hypoglycaemia | 0 | 0 |
| Infections and infestations | 2 ( 4.8) | 29 ( 69.0) |
| Upper respiratory tract infection | 1 ( 2.4) | 13 ( 31.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Urinary tract infection | 0 | 7 ( 16.7) |
| Influenza | 0 | 3 ( 7.1) |
| Respiratory syncytial virus infection | 0 | 2 ( 4.8) |
| Sinusitis | 0 | 3 ( 7.1) |
| Nasopharyngitis | 0 | 3 ( 7.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Folliculitis | 0 | 1 ( 2.4) |
| Lung infection | 0 | 1 ( 2.4) |
| Parvovirus infection | 0 | 1 ( 2.4) |
| Skin infection | 0 | 1 ( 2.4) |
| Tooth infection | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Acarodermatitis | 0 | 0 |
| Anal abscess | 0 | 0 |
| Device related infection | 0 | 0 |
| Hordeolum | 0 | 0 |
| Rhinitis | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Viral infection | 0 | 0 |
| Viral upper respiratory tract infection | 0 | 0 |
| Vulvovaginal mycotic infection | 0 | 0 |
| Immune system disorders | 2 ( 4.8) | 35 ( 83.3) |
| Cytokine release syndrome | 0 | 34 ( 81.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Hypogammaglobulinaemia | 1 ( 2.4) | 6 ( 14.3) |
| Seasonal allergy | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 8 ( 19.0) | 33 ( 78.6) |
| Cough | 4 ( 9.5) | 19 ( 45.2) |
| Nasal congestion | 0 | 11 ( 26.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
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Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Dyspnoea | 1 ( 2.4) | 8 ( 19.0) |
| Productive cough | 0 | 7 ( 16.7) |
| Oropharyngeal pain | 1 ( 2.4) | 6 ( 14.3) |
| Dyspnoea exertional | 1 ( 2.4) | 3 ( 7.1) |
| Epistaxis | 1 ( 2.4) | 4 ( 9.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Hypoxia | 1 ( 2.4) | 4 ( 9.5) |
| Pneumonitis | 1 ( 2.4) | 2 ( 4.8) |
| Rhinorrhoea | 0 | 3 ( 7.1) |
| Upper-airway cough syndrome | 0 | 2 ( 4.8) |
| Wheezing | 0 | 2 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
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Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Pulmonary oedema | 0 | 1 ( 2.4) |
| Rhinitis allergic | 0 | 1 ( 2.4) |
| Throat tightness | 0 | 0 |
| Nervous system disorders | 7 ( 16.7) | 29 ( 69.0) |
| Headache | 1 ( 2.4) | 14 ( 33.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Dizziness | 0 | 8 ( 19.0) |
| Neurotoxicity | 0 | 5 ( 11.9) |
| Tremor | 2 ( 4.8) | 4 ( 9.5) |
| Paraesthesia | 2 ( 4.8) | 3 ( 7.1) |
| Hypoaesthesia | 0 | 2 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Neuropathy peripheral | 1 ( 2.4) | 1 ( 2.4) |
| Aphasia | 0 | 0 |
| Dysgraphia | 0 | 0 |
| Facial paralysis | 0 | 0 |
| Haemorrhage intracranial | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
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subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Investigations | 5 ( 11.9) | 24 ( 57.1) |
| Blood alkaline phosphatase increased | 1 ( 2.4) | 8 ( 19.0) |
| Blood creatinine increased | 1 ( 2.4) | 6 ( 14.3) |
| Transaminases increased | 0 | 5 ( 11.9) |
| Weight increased | 0 | 4 ( 9.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Weight decreased | 0 | 5 ( 11.9) |
| Blood bilirubin increased | 0 | 2 ( 4.8) |
| Creatinine renal clearance abnormal | 0 | 0 |
| Heart rate irregular | 0 | 0 |
| Skin and subcutaneous tissue disorders | 3 ( 7.1) | 21 ( 50.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Pruritus | 1 ( 2.4) | 5 ( 11.9) |
| Rash | 0 | 4 ( 9.5) |
| Alopecia | 1 ( 2.4) | 2 ( 4.8) |
| Erythema | 0 | 2 ( 4.8) |
| Skin lesion | 0 | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
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Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Dry skin | 0 | 1 ( 2.4) |
| Rash maculo-papular | 0 | 0 |
| Skin disorder | 0 | 0 |
| Blister | 0 | 0 |
| Vascular disorders | 1 ( 2.4) | 15 ( 35.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Hypotension | 0 | 4 ( 9.5) |
| Hypertension | 0 | 4 ( 9.5) |
| Hot flush | 0 | 3 ( 7.1) |
| Deep vein thrombosis | 0 | 0 |
| Psychiatric disorders | 1 ( 2.4) | 13 ( 31.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Insomnia | 0 | 6 ( 14.3) |
| Confusional state | 1 ( 2.4) | 4 ( 9.5) |
| Depression | 0 | 1 ( 2.4) |
| Delirium | 0 | 0 |
| Cardiac disorders | 1 ( 2.4) | 13 ( 31.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Tachycardia | 0 | 6 ( 14.3) |
| Sinus tachycardia | 0 | 2 ( 4.8) |
| Atrial fibrillation | 1 ( 2.4) | 4 ( 9.5) |
| Sinus bradycardia | 0 | 0 |
| Ventricular extrasystoles | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Ventricular tachycardia | 0 | 0 |
| Injury, poisoning and procedural complications | 4 ( 9.5) | 12 ( 28.6) |
| Contusion | 1 ( 2.4) | 2 ( 4.8) |
| Fall | 1 ( 2.4) | 3 ( 7.1) |
| Arthropod bite | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
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Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Procedural pain | 0 | 0 |
| Skin laceration | 0 | 1 ( 2.4) |
| Infusion related reaction | 0 | 0 |
| Spinal fracture | 0 | 0 |
| Eye disorders | 1 ( 2.4) | 9 ( 21.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Lacrimation increased | 0 | 1 ( 2.4) |
| Visual impairment | 0 | 2 ( 4.8) |
| Renal and urinary disorders | 3 ( 7.1) | 9 ( 21.4) |
| Dysuria | 0 | 2 ( 4.8) |
| Pollakiuria | 0 | 2 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Haematuria | 0 | 1 ( 2.4) |
| Urinary retention | 1 ( 2.4) | 1 ( 2.4) |
| Nephrolithiasis | 0 | 0 |
| Proteinuria | 0 | 0 |
| Ear and labyrinth disorders | 0 | 7 ( 16.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Ear pain | 0 | 2 ( 4.8) |
| Deafness | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 7 ( 16.7) |
| Bowen's disease | 0 | 1 ( 2.4) |
| Plasmacytoma | 0 | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Tumour pain | 0 | 1 ( 2.4) |
| Bone neoplasm | 0 | 0 |
| Endocrine disorders | 1 ( 2.4) | 3 ( 7.1) |
| Reproductive system and breast disorders | 0 | 1 ( 2.4) |
| Vaginal discharge | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_4.SAS
Date/time of run: 02OCT2020 16:07
Analysis Plan: 30JUN2020 Confidential

Table 6.4.3c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| System Organ Class<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | <br>Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|
| Congenital, familial and genetic disorders | 0 | 0 |
| Atrial septal defect | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC for column of treatment period A-F based on the combined RP2D. SOCs/PTs are presented only if at least 5% of
subjects reported an event for at least one treatment period in at least one treatment group.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_4.SAS
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### 12.2.2 UESI Grad 1 und 2 nach SOC und PT

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Cut-off date: 07APR2020

Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| AE Category<br>Preferred Term [a] | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Subjects with at least one grade 1 or 2 [b] AESI or selected AE [c] | 18 ( 42.9) | 24 ( 57.1) | 38 ( 90.5) | 38 ( 90.5) | 40 ( 95.2) |
| Cytopenia-Overall | 12 ( 28.6) | 19 ( 45.2) | 33 ( 78.6) | 33 ( 78.6) | 35 ( 83.3) |
| Neutropenia | 5 ( 11.9) | 6 ( 14.3) | 31 ( 73.8) | 31 ( 73.8) | 32 ( 76.2) |
| Anaemia | 8 ( 19.0) | 11 ( 26.2) | 27 ( 64.3) | 27 ( 64.3) | 29 ( 69.0) |
| Thrombocytopenia | 7 ( 16.7) | 5 ( 11.9) | 25 ( 59.5) | 25 ( 59.5) | 27 ( 64.3) |
| Leukopenia | 3 ( 7.1) | 10 ( 23.8) | 21 ( 50.0) | 21 ( 50.0) | 21 ( 50.0) |
| Lymphopenia | 3 ( 7.1) | 5 ( 11.9) | 14 ( 33.3) | 14 ( 33.3) | 14 ( 33.3) |
| Febrile neutropenia | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
Date/time of run: 23NOV2020 16:38
Analysis Plan: 30JUN2020 Confidential

Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Neutrophil count decreased | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Platelet count decreased | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Cytopenia-Neutropenia | 6 ( 14.3) | 13 ( 31.0) | 32 ( 76.2) | 32 ( 76.2) | 33 ( 78.6) |
| Neutropenia | 5 ( 11.9) | 6 ( 14.3) | 31 ( 73.8) | 31 ( 73.8) | 32 ( 76.2) |
| Leukopenia | 3 ( 7.1) | 10 ( 23.8) | 21 ( 50.0) | 21 ( 50.0) | 21 ( 50.0) |
| Febrile neutropenia | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Neutrophil count decreased | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Cytopenia-Anaemia | 8 ( 19.0) | 11 ( 26.2) | 27 ( 64.3) | 27 ( 64.3) | 29 ( 69.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
Date/time of run: 23NOV2020 16:38
Analysis Plan: 30JUN2020 Confidential

Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| AE Category<br>Preferred Term [a] | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Anaemia | 8 ( 19.0) | 11 ( 26.2) | 27 ( 64.3) | 27 ( 64.3) | 29 ( 69.0) |
| Cytopenia-Thrombocytopenia | 7 ( 16.7) | 5 ( 11.9) | 25 ( 59.5) | 25 ( 59.5) | 27 ( 64.3) |
| Thrombocytopenia | 7 ( 16.7) | 5 ( 11.9) | 25 ( 59.5) | 25 ( 59.5) | 27 ( 64.3) |
| Platelet count decreased | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Cytopenia-Lymphopenia | 3 ( 7.1) | 5 ( 11.9) | 14 ( 33.3) | 14 ( 33.3) | 14 ( 33.3) |
| Lymphopenia | 3 ( 7.1) | 5 ( 11.9) | 14 ( 33.3) | 14 ( 33.3) | 14 ( 33.3) |
| Neurologic Toxicity-Broad | 7 ( 16.7) | 9 ( 21.4) | 31 ( 73.8) | 33 ( 78.6) | 35 ( 83.3) |
| Headache | 1 ( 2.4) | 6 ( 14.3) | 18 ( 42.9) | 20 ( 47.6) | 20 ( 47.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Dizziness | 0 | 0 | 8 ( 19.0) | 8 ( 19.0) | 8 ( 19.0) |
| Confusional state | 1 ( 2.4) | 0 | 7 ( 16.7) | 7 ( 16.7) | 8 ( 19.0) |
| Insomnia | 0 | 1 ( 2.4) | 5 ( 11.9) | 6 ( 14.3) | 6 ( 14.3) |
| Neurotoxicity | 0 | 0 | 6 ( 14.3) | 6 ( 14.3) | 6 ( 14.3) |
| Tremor | 2 ( 4.8) | 0 | 4 ( 9.5) | 4 ( 9.5) | 4 ( 9.5) |
| Muscular weakness | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Somnolence | 0 | 0 | 4 ( 9.5) | 4 ( 9.5) | 4 ( 9.5) |
| Gait disturbance | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
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Protocol: CRB-401


Cut-off date: 07APR2020

Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Anxiety | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Depression | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Disturbance in attention | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Dysgeusia | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Failure to thrive | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Hypoaesthesia | 0 | 1 ( 2.4) | 1 ( 2.4) | 2 ( 4.8) | 2 ( 4.8) |
| Paraesthesia | 2 ( 4.8) | 0 | 2 ( 4.8) | 2 ( 4.8) | 3 ( 7.1) |
| Syncope | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Tinnitus | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Vision blurred | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Anal incontinence | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Aphasia | 0 | 0 | 0 | 0 | 0 |
| Bradyphrenia | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Brain oedema | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Cognitive disorder | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Delirium | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
Date/time of run: 23NOV2020 16:38
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Protocol: CRB-401


Cut-off date: 07APR2020

Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Depressed level of consciousness | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Diplopia | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Dysarthria | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Dysgraphia | 0 | 0 | 0 | 0 | 0 |
| Facial paralysis | 0 | 0 | 0 | 0 | 0 |
| Haemorrhage intracranial | 0 | 0 | 0 | 0 | 0 |
| Hallucination | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Incontinence | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
Date/time of run: 23NOV2020 16:38
Analysis Plan: 30JUN2020 Confidential

Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Language disorder | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Lethargy | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Memory impairment | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Mental impairment | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Muscle atrophy | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Neuropathy peripheral | 1 ( 2.4) | 0 | 0 | 0 | 1 ( 2.4) |
| Nystagmus | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Orthostatic hypotension | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
Date/time of run: 23NOV2020 16:38
Analysis Plan: 30JUN2020 Confidential

Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Photophobia | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Postural tremor | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Sleep disorder | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Throat tightness | 0 | 0 | 0 | 0 | 0 |
| Carpal tunnel syndrome | 0 | 1 ( 2.4) | 0 | 1 ( 2.4) | 1 ( 2.4) |
| Neuralgia | 1 ( 2.4) | 0 | 0 | 0 | 1 ( 2.4) |
| Paraesthesia oral | 0 | 0 | 0 | 0 | 0 |
| Peripheral sensory neuropathy | 0 | 1 ( 2.4) | 0 | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Presyncope | 1 ( 2.4) | 0 | 0 | 0 | 1 ( 2.4) |
| Urinary incontinence | 1 ( 2.4) | 0 | 0 | 0 | 1 ( 2.4) |
| Neurologic Toxicity-Focused | 3 ( 7.1) | 1 ( 2.4) | 20 ( 47.6) | 20 ( 47.6) | 21 ( 50.0) |
| Confusional state | 1 ( 2.4) | 0 | 7 ( 16.7) | 7 ( 16.7) | 8 ( 19.0) |
| Insomnia | 0 | 1 ( 2.4) | 5 ( 11.9) | 6 ( 14.3) | 6 ( 14.3) |
| Neurotoxicity | 0 | 0 | 6 ( 14.3) | 6 ( 14.3) | 6 ( 14.3) |
| Tremor | 2 ( 4.8) | 0 | 4 ( 9.5) | 4 ( 9.5) | 4 ( 9.5) |
| Somnolence | 0 | 0 | 4 ( 9.5) | 4 ( 9.5) | 4 ( 9.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
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Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Gait disturbance | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Disturbance in attention | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Aphasia | 0 | 0 | 0 | 0 | 0 |
| Bradyphrenia | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Brain oedema | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Cognitive disorder | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Delirium | 0 | 0 | 0 | 0 | 0 |
| Depressed level of consciousness | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Dysarthria | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Dysgraphia | 0 | 0 | 0 | 0 | 0 |
| Hallucination | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Lethargy | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Memory impairment | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Nystagmus | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Postural tremor | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Sleep disorder | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
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Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| AE Category<br>Preferred Term [a] | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Cytokine Release Syndrome | 0 | 0 | 34 ( 81.0) | 34 ( 81.0) | 34 ( 81.0) |
| Cytokine release syndrome | 0 | 0 | 34 ( 81.0) | 34 ( 81.0) | 34 ( 81.0) |
| Infections-Overall | 2 ( 4.8) | 3 ( 7.1) | 28 ( 66.7) | 28 ( 66.7) | 29 ( 69.0) |
| Upper respiratory tract infection | 1 ( 2.4) | 0 | 12 ( 28.6) | 12 ( 28.6) | 13 ( 31.0) |
| Urinary tract infection | 0 | 0 | 7 ( 16.7) | 7 ( 16.7) | 7 ( 16.7) |
| Respiratory syncytial virus infection | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Sinusitis | 0 | 0 | 3 ( 7.1) | 3 ( 7.1) | 3 ( 7.1) |
| Influenza | 0 | 0 | 3 ( 7.1) | 3 ( 7.1) | 3 ( 7.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Bronchitis | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Clostridium difficile infection | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Ear infection | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Lung infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Nasopharyngitis | 0 | 1 ( 2.4) | 2 ( 4.8) | 3 ( 7.1) | 3 ( 7.1) |
| Parvovirus infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Pneumonia | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Rhinovirus infection | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Skin infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Acarodermatitis | 0 | 0 | 0 | 0 | 0 |
| Anal abscess | 0 | 0 | 0 | 0 | 0 |
| Bronchiolitis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Chronic sinusitis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Conjunctivitis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Corona virus infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Diverticulitis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
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Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Enterovirus infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Folliculitis | 0 | 1 ( 2.4) | 0 | 1 ( 2.4) | 1 ( 2.4) |
| Gastroenteritis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Gastroenteritis viral | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Hordeolum | 0 | 0 | 0 | 0 | 0 |
| Otitis externa | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Paronychia | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Parotitis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
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Protocol: CRB-401


Cut-off date: 07APR2020

Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Rhinitis | 0 | 0 | 0 | 0 | 0 |
| Staphylococcal bacteraemia | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Staphylococcal infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Stitch abscess | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Tooth infection | 0 | 0 | 0 | 0 | 0 |
| Vaginal infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Vascular access site infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Vulvovaginal mycotic infection | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| AE Category<br>Preferred Term [a] | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Device related infection | 0 | 0 | 0 | 0 | 0 |
| Fungal infection | 0 | 1 ( 2.4) | 0 | 1 ( 2.4) | 1 ( 2.4) |
| Subcutaneous abscess | 1 ( 2.4) | 0 | 0 | 0 | 1 ( 2.4) |
| Viral infection | 0 | 0 | 0 | 0 | 0 |
| Viral upper respiratory tract infection | 0 | 0 | 0 | 0 | 0 |
| Infections-Pathogen Unspecified | 2 ( 4.8) | 2 ( 4.8) | 23 ( 54.8) | 23 ( 54.8) | 24 ( 57.1) |
| Upper respiratory tract infection | 1 ( 2.4) | 0 | 12 ( 28.6) | 12 ( 28.6) | 13 ( 31.0) |
| Urinary tract infection | 0 | 0 | 7 ( 16.7) | 7 ( 16.7) | 7 ( 16.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Sinusitis | 0 | 0 | 3 ( 7.1) | 3 ( 7.1) | 3 ( 7.1) |
| Bronchitis | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Ear infection | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Lung infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Nasopharyngitis | 0 | 1 ( 2.4) | 2 ( 4.8) | 3 ( 7.1) | 3 ( 7.1) |
| Pneumonia | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Skin infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Anal abscess | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Protocol: CRB-401


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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Chronic sinusitis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Conjunctivitis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Diverticulitis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Folliculitis | 0 | 1 ( 2.4) | 0 | 1 ( 2.4) | 1 ( 2.4) |
| Gastroenteritis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Hordeolum | 0 | 0 | 0 | 0 | 0 |
| Otitis externa | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Paronychia | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Parotitis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Rhinitis | 0 | 0 | 0 | 0 | 0 |
| Stitch abscess | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Tooth infection | 0 | 0 | 0 | 0 | 0 |
| Vaginal infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Vascular access site infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Device related infection | 0 | 0 | 0 | 0 | 0 |
| Subcutaneous abscess | 1 ( 2.4) | 0 | 0 | 0 | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
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Protocol: CRB-401


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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Infections-Viral | 0 | 0 | 9 ( 21.4) | 9 ( 21.4) | 9 ( 21.4) |
| Respiratory syncytial virus infection | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Influenza | 0 | 0 | 3 ( 7.1) | 3 ( 7.1) | 3 ( 7.1) |
| Parvovirus infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Rhinovirus infection | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Bronchiolitis | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Corona virus infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Enterovirus infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | Enrolled Population (N=42)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Gastroenteritis viral | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Viral infection | 0 | 0 | 0 | 0 | 0 |
| Viral upper respiratory tract infection | 0 | 0 | 0 | 0 | 0 |
| Infections-Bacterial | 0 | 0 | 4 ( 9.5) | 4 ( 9.5) | 4 ( 9.5) |
| Clostridium difficile infection | 0 | 0 | 2 ( 4.8) | 2 ( 4.8) | 2 ( 4.8) |
| Staphylococcal bacteraemia | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Staphylococcal infection | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Infections-Fungal | 0 | 1 ( 2.4) | 0 | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| AE Category<br>Preferred Term [a] | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Vulvovaginal mycotic infection | 0 | 0 | 0 | 0 | 0 |
| Fungal infection | 0 | 1 ( 2.4) | 0 | 1 ( 2.4) | 1 ( 2.4) |
| New Malignancy | 0 | 0 | 5 ( 11.9) | 5 ( 11.9) | 5 ( 11.9) |
| Bowen's disease | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Basal cell carcinoma | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Breast cancer | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Malignant melanoma | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |
| Myelodysplastic syndrome | 0 | 0 | 1 ( 2.4) | 1 ( 2.4) | 1 ( 2.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
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Table 7.7.2c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Enrolled Population (N=42) | | | | |
|---|---|---|---|---|---|
| AE Category<br>Preferred Term [a] | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Bone neoplasm | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Subjects with at least one grade 1 or 2 [b] AESI or selected AE [c] | 16 ( 42.1) | 24 ( 63.2) | 38 (100.0) | 38 (100.0) | 38 (100.0) |
| Cytopenia-Overall | 11 ( 28.9) | 19 ( 50.0) | 33 ( 86.8) | 33 ( 86.8) | 34 ( 89.5) |
| Neutropenia | 4 ( 10.5) | 6 ( 15.8) | 31 ( 81.6) | 31 ( 81.6) | 31 ( 81.6) |
| Anaemia | 7 ( 18.4) | 11 ( 28.9) | 27 ( 71.1) | 27 ( 71.1) | 28 ( 73.7) |
| Thrombocytopenia | 6 ( 15.8) | 5 ( 13.2) | 25 ( 65.8) | 25 ( 65.8) | 26 ( 68.4) |
| Leukopenia | 3 ( 7.9) | 10 ( 26.3) | 21 ( 55.3) | 21 ( 55.3) | 21 ( 55.3) |
| Lymphopenia | 3 ( 7.9) | 5 ( 13.2) | 14 ( 36.8) | 14 ( 36.8) | 14 ( 36.8) |
| Febrile neutropenia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| AE Category<br>Preferred Term [a] | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Neutrophil count decreased | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Platelet count decreased | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Cytopenia-Neutropenia | 5 ( 13.2) | 13 ( 34.2) | 32 ( 84.2) | 32 ( 84.2) | 32 ( 84.2) |
| Neutropenia | 4 ( 10.5) | 6 ( 15.8) | 31 ( 81.6) | 31 ( 81.6) | 31 ( 81.6) |
| Leukopenia | 3 ( 7.9) | 10 ( 26.3) | 21 ( 55.3) | 21 ( 55.3) | 21 ( 55.3) |
| Febrile neutropenia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Neutrophil count decreased | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Cytopenia-Anaemia | 7 ( 18.4) | 11 ( 28.9) | 27 ( 71.1) | 27 ( 71.1) | 28 ( 73.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C–F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Anaemia | 7 ( 18.4) | 11 ( 28.9) | 27 ( 71.1) | 27 ( 71.1) | 28 ( 73.7) |
| Cytopenia-Thrombocytopenia | 6 ( 15.8) | 5 ( 13.2) | 25 ( 65.8) | 25 ( 65.8) | 26 ( 68.4) |
| Thrombocytopenia | 6 ( 15.8) | 5 ( 13.2) | 25 ( 65.8) | 25 ( 65.8) | 26 ( 68.4) |
| Platelet count decreased | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Cytopenia-Lymphopenia | 3 ( 7.9) | 5 ( 13.2) | 14 ( 36.8) | 14 ( 36.8) | 14 ( 36.8) |
| Lymphopenia | 3 ( 7.9) | 5 ( 13.2) | 14 ( 36.8) | 14 ( 36.8) | 14 ( 36.8) |
| Neurologic Toxicity-Broad | 6 ( 15.8) | 9 ( 23.7) | 31 ( 81.6) | 33 ( 86.8) | 34 ( 89.5) |
| Headache | 1 ( 2.6) | 6 ( 15.8) | 18 ( 47.4) | 20 ( 52.6) | 20 ( 52.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions

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or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Protocol: CRB-401


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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Dizziness | 0 | 0 | 8 ( 21.1) | 8 ( 21.1) | 8 ( 21.1) |
| Confusional state | 0 | 0 | 7 ( 18.4) | 7 ( 18.4) | 7 ( 18.4) |
| Insomnia | 0 | 1 ( 2.6) | 5 ( 13.2) | 6 ( 15.8) | 6 ( 15.8) |
| Neurotoxicity | 0 | 0 | 6 ( 15.8) | 6 ( 15.8) | 6 ( 15.8) |
| Tremor | 2 ( 5.3) | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Muscular weakness | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Somnolence | 0 | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Gait disturbance | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Anxiety | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Depression | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Disturbance in attention | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Dysgeusia | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Failure to thrive | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Hypoaesthesia | 0 | 1 ( 2.6) | 1 ( 2.6) | 2 ( 5.3) | 2 ( 5.3) |
| Paraesthesia | 2 ( 5.3) | 0 | 2 ( 5.3) | 2 ( 5.3) | 3 ( 7.9) |
| Syncope | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Tinnitus | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Vision blurred | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Anal incontinence | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Aphasia | 0 | 0 | 0 | 0 | 0 |
| Bradyphrenia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Brain oedema | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Cognitive disorder | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Delirium | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Depressed level of consciousness | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Diplopia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Dysarthria | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Dysgraphia | 0 | 0 | 0 | 0 | 0 |
| Facial paralysis | 0 | 0 | 0 | 0 | 0 |
| Haemorrhage intracranial | 0 | 0 | 0 | 0 | 0 |
| Hallucination | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Incontinence | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Language disorder | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Lethargy | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Memory impairment | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Mental impairment | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Muscle atrophy | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Neuropathy peripheral | 0 | 0 | 0 | 0 | 0 |
| Nystagmus | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Orthostatic hypotension | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Photophobia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Postural tremor | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Sleep disorder | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Throat tightness | 0 | 0 | 0 | 0 | 0 |
| Carpal tunnel syndrome | 0 | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) |
| Neuralgia | 1 ( 2.6) | 0 | 0 | 0 | 1 ( 2.6) |
| Paraesthesia oral | 0 | 0 | 0 | 0 | 0 |
| Peripheral sensory neuropathy | 0 | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Presyncope | 1 ( 2.6) | 0 | 0 | 0 | 1 ( 2.6) |
| Neurologic Toxicity-Focused | 2 ( 5.3) | 1 ( 2.6) | 20 ( 52.6) | 20 ( 52.6) | 20 ( 52.6) |
| Confusional state | 0 | 0 | 7 ( 18.4) | 7 ( 18.4) | 7 ( 18.4) |
| Insomnia | 0 | 1 ( 2.6) | 5 ( 13.2) | 6 ( 15.8) | 6 ( 15.8) |
| Neurotoxicity | 0 | 0 | 6 ( 15.8) | 6 ( 15.8) | 6 ( 15.8) |
| Tremor | 2 ( 5.3) | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Somnolence | 0 | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Gait disturbance | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Disturbance in attention | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Aphasia | 0 | 0 | 0 | 0 | 0 |
| Bradyphrenia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Brain oedema | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Cognitive disorder | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Delirium | 0 | 0 | 0 | 0 | 0 |
| Depressed level of consciousness | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Dysarthria | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Dysgraphia | 0 | 0 | 0 | 0 | 0 |
| Hallucination | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Lethargy | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Memory impairment | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Nystagmus | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Postural tremor | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Sleep disorder | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Cytokine Release Syndrome | 0 | 0 | 34 ( 89.5) | 34 ( 89.5) | 34 ( 89.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions

or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.

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Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Cytokine release syndrome | 0 | 0 | 34 ( 89.5) | 34 ( 89.5) | 34 ( 89.5) |
| Infections-Overall | 2 ( 5.3) | 3 ( 7.9) | 28 ( 73.7) | 28 ( 73.7) | 29 ( 76.3) |
| Upper respiratory tract infection | 1 ( 2.6) | 0 | 12 ( 31.6) | 12 ( 31.6) | 13 ( 34.2) |
| Urinary tract infection | 0 | 0 | 7 ( 18.4) | 7 ( 18.4) | 7 ( 18.4) |
| Respiratory syncytial virus infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Sinusitis | 0 | 0 | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |
| Influenza | 0 | 0 | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |
| Bronchitis | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions

or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.

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Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Clostridium difficile infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Ear infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Lung infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Nasopharyngitis | 0 | 1 ( 2.6) | 2 ( 5.3) | 3 ( 7.9) | 3 ( 7.9) |
| Parvovirus infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Pneumonia | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Rhinovirus infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Skin infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
Date/time of run: 23NOV2020 16:38
Analysis Plan: 30JUN2020 Confidential

Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Acarodermatitis | 0 | 0 | 0 | 0 | 0 |
| Anal abscess | 0 | 0 | 0 | 0 | 0 |
| Bronchiolitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Chronic sinusitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Conjunctivitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Corona virus infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Diverticulitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Enterovirus infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Analysis Plan: 30JUN2020 Confidential

Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Folliculitis | 0 | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) |
| Gastroenteritis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Gastroenteritis viral | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Hordeolum | 0 | 0 | 0 | 0 | 0 |
| Otitis externa | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Paronychia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Parotitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Rhinitis | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Staphylococcal bacteraemia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Staphylococcal infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Stitch abscess | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Tooth infection | 0 | 0 | 0 | 0 | 0 |
| Vaginal infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Vascular access site infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Vulvovaginal mycotic infection | 0 | 0 | 0 | 0 | 0 |
| Device related infection | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| AE Category<br>Preferred Term [a] | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Fungal infection | 0 | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) |
| Subcutaneous abscess | 1 ( 2.6) | 0 | 0 | 0 | 1 ( 2.6) |
| Viral infection | 0 | 0 | 0 | 0 | 0 |
| Viral upper respiratory tract infection | 0 | 0 | 0 | 0 | 0 |
| Infections-Pathogen Unspecified | 2 ( 5.3) | 2 ( 5.3) | 23 ( 60.5) | 23 ( 60.5) | 24 ( 63.2) |
| Upper respiratory tract infection | 1 ( 2.6) | 0 | 12 ( 31.6) | 12 ( 31.6) | 13 ( 34.2) |
| Urinary tract infection | 0 | 0 | 7 ( 18.4) | 7 ( 18.4) | 7 ( 18.4) |
| Sinusitis | 0 | 0 | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Analysis Plan: 30JUN2020 Confidential

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Cut-off date: 07APR2020

Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Bronchitis | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Ear infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Lung infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Nasopharyngitis | 0 | 1 ( 2.6) | 2 ( 5.3) | 3 ( 7.9) | 3 ( 7.9) |
| Pneumonia | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Skin infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Anal abscess | 0 | 0 | 0 | 0 | 0 |
| Chronic sinusitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Conjunctivitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Diverticulitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Folliculitis | 0 | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) |
| Gastroenteritis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Hordeolum | 0 | 0 | 0 | 0 | 0 |
| Otitis externa | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Paronychia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Parotitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Rhinitis | 0 | 0 | 0 | 0 | 0 |
| Stitch abscess | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Tooth infection | 0 | 0 | 0 | 0 | 0 |
| Vaginal infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Vascular access site infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Device related infection | 0 | 0 | 0 | 0 | 0 |
| Subcutaneous abscess | 1 ( 2.6) | 0 | 0 | 0 | 1 ( 2.6) |
| Infections-Viral | 0 | 0 | 9 ( 23.7) | 9 ( 23.7) | 9 ( 23.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38)<br>Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
|---|---|---|---|---|---|
| Respiratory syncytial virus infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Influenza | 0 | 0 | 3 ( 7.9) | 3 ( 7.9) | 3 ( 7.9) |
| Parvovirus infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Rhinovirus infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Bronchiolitis | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Corona virus infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Enterovirus infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Gastroenteritis viral | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
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Cut-off date: 07APR2020

Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| AE Category<br>Preferred Term [a] | Reporting Period A: LP to Before LD<br>n (%) | Reporting Period B: LD to Before bb2121 Infusion<br>n (%) | Reporting Period C to F: Post bb2121 Infusion<br>n (%) | Reporting Period B to F: LD to End of Follow-up<br>n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up<br>n (%) |
| Viral infection | 0 | 0 | 0 | 0 | 0 |
| Viral upper respiratory tract infection | 0 | 0 | 0 | 0 | 0 |
| Infections-Bacterial | 0 | 0 | 4 ( 10.5) | 4 ( 10.5) | 4 ( 10.5) |
| Clostridium difficile infection | 0 | 0 | 2 ( 5.3) | 2 ( 5.3) | 2 ( 5.3) |
| Staphylococcal bacteraemia | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Staphylococcal infection | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Infections-Fungal | 0 | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) |
| Vulvovaginal mycotic infection | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
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Table 7.7.1c
Grade 1 or 2 Adverse Events of Special Interest (AESIs) and Selected AEs by AE Category and Preferred Term
bb2121-Treated Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| AE Category<br>Preferred Term [a] | bb2121-Treated Population (N=38) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Fungal infection | 0 | 1 ( 2.6) | 0 | 1 ( 2.6) | 1 ( 2.6) |
| New Malignancy | 0 | 0 | 5 ( 13.2) | 5 ( 13.2) | 5 ( 13.2) |
| Bowen's disease | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Basal cell carcinoma | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Breast cancer | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Malignant melanoma | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Myelodysplastic syndrome | 0 | 0 | 1 ( 2.6) | 1 ( 2.6) | 1 ( 2.6) |
| Bone neoplasm | 0 | 0 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/AE category.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
[c] The preferred terms under AE categories are selected using the protocol specified AESIs, Standardized MedDRA Query (SMQ) definitions
or MedDRA SOC and PT definitions, and medical judgement. All grades of AEs in the corresponding category are considered.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\TAB_7_1_1.SAS
Date/time of run: 23NOV2020 16:38
Analysis Plan: 30JUN2020 Confidential

# 13.Subgruppenanalysen (Datenschnitt vom 07.04.2020)

## 13.1 Gesamtüberleben

Celgene Corporation

Protocol: CRB-401
Cut-off date: 07APR2020

Table 1.2c
Summary of Overall Survival by Age
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

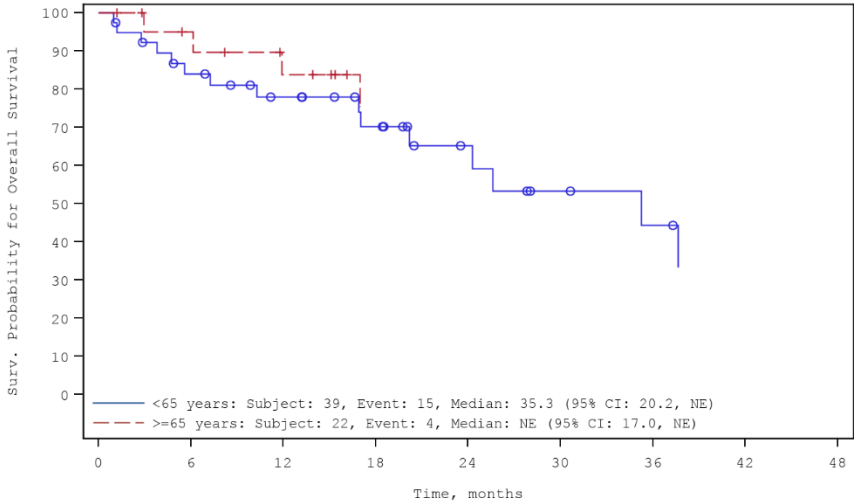
| | Statistics | <65 years (N=28) | >=65 years (N=14) | Overall (N=42) |
|---|---|---|---|---|
| Overall Survival | N | 28 | 14 | 42 |
| Censored | n (%) | 18 ( 64.3) | 12 ( 85.7) | 30 ( 71.4) |
| Died | n (%) | 10 ( 35.7) | 2 ( 14.3) | 12 ( 28.6) |
| Overall Survival | 25th Pcnt. (95% CI) | 24.3 ( 1.2, 35.3) | NE ( 6.1, NE ) | 24.3 ( 6.1, 35.3) |
| Time (months) [a] | Median (95% CI) | 35.3 (24.3, NE ) | NE (17.0, NE ) | 35.3 (24.3, NE ) |
| | 75th Pcnt. (95% CI) | 37.7 (35.3, NE ) | NE | 37.7 (35.3, NE ) |
| 6 Months Event-Free | % (SE) | 85.3 ( 6.8) | 100.0 ( 0.0) | 89.9 ( 4.8) |
| 12 Months Event-Free | % (SE) | 81.0 ( 7.7) | 90.9 ( 8.7) | 84.3 ( 5.9) |
| 18 Months Event-Free | % (SE) | 75.2 ( 9.1) | 79.5 (13.1) | 76.6 ( 7.5) |
| 24 Months Event-Free | % (SE) | 75.2 ( 9.1) | 79.5 (13.1) | 76.6 ( 7.5) |
| 30 Months Event-Free | % (SE) | 56.4 (13.4) | 79.5 (13.1) | 59.6 (12.1) |
| 36 Months Event-Free | % (SE) | 42.3 (15.8) | NE | 44.7 (15.8) |
| 42 Months Event-Free | % (SE) | 21.2 (16.9) | NE | 22.3 (17.7) |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable.
Pcnt.=Percentile. *Did not meet IQWIG criteria for subgroup analysis.
Subjects who did not die in CRB-401 study and the long-term follow-up studies are censored on last known alive date or current data cut-off date, whichever is earlier.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_1_1.SAS
Date/time of run: 05NOV2020 09:48
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Figure 1.2c
Kaplan-Meier Curve of Overall Survival by Age
Enrolled Population
For Subjects Treated with (150-450)x10^6 Cells (Combined RP2D) [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| <65 years: | 39 | 30 | 24 | 18 | 11 | 7 | 5 | 3 | 0 |
| >=65 years: | 22 | 18 | 14 | 9 | 3 | 1 | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. RP2D=Recommended phase 2 dose. Missing categories are not presented. Source Table: Table 1.2c.

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Fig_1_1.SAS
Date/time of run: 05NOV2020 10:00
Analysis Plan: 30JUN2020 Confidential

Table 1.2c
Summary of Overall Survival by Double Refractory
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Statistics | Yes (N=36) | No (N=6) | Overall (N=42) |
|---|---|---|---|---|
| Overall Survival | N | 36 | 6 | 42 |
| Censored | n (%) | 25 ( 69.4) | 5 ( 83.3) | 30 ( 71.4) |
| Died | n (%) | 11 ( 30.6) | 1 ( 16.7) | 12 ( 28.6) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | 24.3 ( 5.6, 35.3) | NE ( 6.1, NE ) | 24.3 ( 6.1, 35.3) |
| | Median (95% CI) | 35.3 (24.3, NE ) | NE ( 6.1, NE ) | 35.3 (24.3, NE ) |
| | 75th Pcnt. (95% CI) | 37.7 (35.3, NE ) | NE ( 6.1, NE ) | 37.7 (35.3, NE ) |
| 6 Months Event-Free | % (SE) | 88.2 ( 5.6) | 100.0 ( 0.0) | 89.9 ( 4.8) |
| 12 Months Event-Free | % (SE) | 84.8 ( 6.3) | 80.0 (17.9) | 84.3 ( 5.9) |
| 18 Months Event-Free | % (SE) | 75.4 ( 8.4) | 80.0 (17.9) | 76.6 ( 7.5) |
| 24 Months Event-Free | % (SE) | 75.4 ( 8.4) | 80.0 (17.9) | 76.6 ( 7.5) |
| 30 Months Event-Free | % (SE) | 56.5 (13.2) | 80.0 (17.9) | 59.6 (12.1) |
| 36 Months Event-Free | % (SE) | 42.4 (15.7) | NE | 44.7 (15.8) |
| 42 Months Event-Free | % (SE) | 21.2 (16.9) | NE | 22.3 (17.7) |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable.
Pcnt.=Percentile. *Did not meet IQWIG criteria for subgroup analysis.
Subjects who did not die in CRB-401 study and the long-term follow-up studies are censored on last known alive date or current data cut-off date, whichever is earlier.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_1_1.SAS
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Celgene Corporation
Protocol: CRB-401

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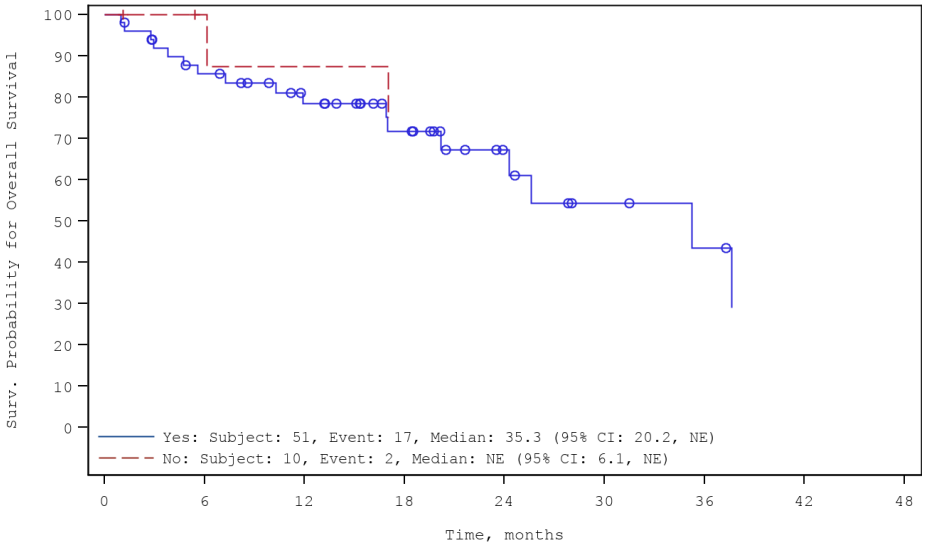
Cut-off date: 07APR2020

Figure 1.2c
Kaplan-Meier Curve of Overall Survival by Double Refractory
Enrolled Population
For Subjects Treated with (150-450)x10^6 Cells (Combined RP2D) [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Yes: | 51 | 40 | 31 | 21 | 11 | 6 | 4 | 2 | 0 |
| No: | 10 | 8 | 7 | 6 | 3 | 2 | 1 | 1 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. RP2D=Recommended phase 2 dose. Missing categories are not presented. Source Table: Table 1.2c.

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Fig_1_1.SAS
Date/time of run: 05NOV2020 10:00
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 1.2c
Summary of Overall Survival by Presence of Extramedullary Plasmacytoma
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Statistics | Yes (N=17) | No (N=25) | Overall (N=42) |
|---|---|---|---|---|
| Overall Survival | N | 17 | 25 | 42 |
| Censored | n (%) | 15 ( 88.2) | 15 ( 60.0) | 30 ( 71.4) |
| Died | n (%) | 2 ( 11.8) | 10 ( 40.0) | 12 ( 28.6) |
| Overall Survival Time (months) [a] | 25th Pcnt. (95% CI) | 37.7 (17.0, NE ) | 10.3 ( 1.0, 25.6) | 24.3 ( 6.1, 35.3) |
| | Median (95% CI) | 37.7 (17.0, NE ) | 25.6 (10.3, NE ) | 35.3 (24.3, NE ) |
| | 75th Pcnt. (95% CI) | 37.7 ( NE , NE ) | NE (25.6, NE ) | 37.7 (35.3, NE ) |
| 6 Months Event-Free | % (SE) | 100.0 ( 0.0) | 82.9 ( 7.8) | 89.9 ( 4.8) |
| 12 Months Event-Free | % (SE) | 100.0 ( 0.0) | 73.4 ( 9.4) | 84.3 ( 5.9) |
| 18 Months Event-Free | % (SE) | 87.5 (11.7) | 68.1 (10.1) | 76.6 ( 7.5) |
| 24 Months Event-Free | % (SE) | 87.5 (11.7) | 68.1 (10.1) | 76.6 ( 7.5) |
| 30 Months Event-Free | % (SE) | 87.5 (11.7) | 48.7 (13.7) | 59.6 (12.1) |
| 36 Months Event-Free | % (SE) | 87.5 (11.7) | 32.4 (16.1) | 44.7 (15.8) |
| 42 Months Event-Free | % (SE) | 0.0 | 32.4 (16.1) | 22.3 (17.7) |
| 48 Months Event-Free | % (SE) | 0.0 | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable.
Pcnt.=Percentile. *Did not meet IQWIG criteria for subgroup analysis.
Subjects who did not die in CRB-401 study and the long-term follow-up studies are censored on last known alive date or current data cut-off date, whichever is earlier.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_1_1.SAS
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Analysis Plan: 30JUN2020 Confidential

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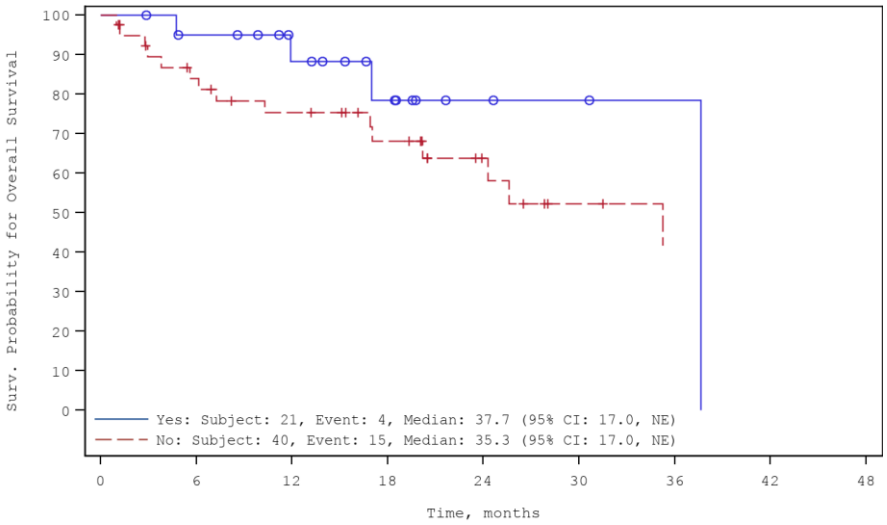
Protocol: CRB-401 Cut-off date: 07APR2020

Figure 1.2c
Kaplan-Meier Curve of Overall Survival by Presence of Extramedullary Plasmacytoma
Enrolled Population
For Subjects Treated with (150-450)x10^6 Cells (Combined RP2D) [Escalation and Expansion (Part A + B)]




No. of Subjects at Risk

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Yes: | 21 | 18 | 13 | 8 | 3 | 2 | 1 | 0 | 0 |
| No: | 40 | 30 | 25 | 19 | 11 | 6 | 4 | 3 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells.
NE=Not Estimable. RP2D=Recommended phase 2 dose. Missing categories are not presented. Source Table: Table 1.2c.
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Date/time of run: 05NOV2020 10:00
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## 13.2 Ansprechen

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 4.2c
Summary of Response Rate by IRC Assessment - Age <65 years
Enrolled Population

| | 150x10^6 (N=11) | 450x10^6 (N=28) | Combined RP2D (150-450)x10^6 (N=39) |
|---|---|---|---|
| Best Overall Response - n (%) | | | |
| Stringent Complete Response (sCR) | 4 ( 36.4) | 9 ( 32.1) | 13 ( 33.3) |
| Very Good Partial Response (VGPR) | 1 ( 9.1) | 8 ( 28.6) | 9 ( 23.1) |
| Partial Response (PR) | 0 | 4 ( 14.3) | 4 ( 10.3) |
| Minimal Response (MR) | 1 ( 9.1) | 0 | 1 ( 2.6) |
| Stable Disease (SD) | 3 ( 27.3) | 3 ( 10.7) | 6 ( 15.4) |
| Progressive Disease (PD) | 1 ( 9.1) | 1 ( 3.6) | 2 ( 5.1) |
| Inevaluable for Response (IE) [a] | 1 ( 9.1) | 3 ( 10.7) | 4 ( 10.3) |
| Overall Response Rate - n (%) [b] | 5 ( 45.5) | 21 ( 75.0) | 26 ( 66.7) |
| 95% CI [c] | 16.7, 76.6 | 55.1, 89.3 | 49.8, 80.9 |
| 90% CI [c] | 20.0, 72.9 | 58.1, 87.6 | 52.3, 79.0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.2c
Summary of Response Rate by IRC Assessment - Age <65 years
Enrolled Population

| | 150x10^6 (N=11) | 450x10^6 (N=28) | Combined RP2D (150-450)x10^6 (N=39) |
|---|---|---|---|
| Response Rate of VGPR or better - n (%) [b] | 5 ( 45.5) | 17 ( 60.7) | 22 ( 56.4) |
| 95% CI [c] | 16.7, 76.6 | 40.6, 78.5 | 39.6, 72.2 |
| 90% CI [c] | 20.0, 72.9 | 43.5, 76.2 | 42.1, 70.0 |
| Complete Response Rate - n (%) [b] | 4 ( 36.4) | 9 ( 32.1) | 13 ( 33.3) |
| 95% CI [c] | 10.9, 69.2 | 15.9, 52.4 | 19.1, 50.2 |
| 90% CI [c] | 13.5, 65.0 | 17.9, 49.4 | 21.0, 47.7 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.2c
Summary of Response Rate by IRC Assessment - Age >=65 years
Enrolled Population

| | 150x10^6 (N=8) | 450x10^6 (N=14) | Combined RP2D (150-450)x10^6 (N=22) |
|---|---|---|---|
| Best Overall Response - n (%) | | | |
| Stringent Complete Response (sCR) | 2 ( 25.0) | 6 ( 42.9) | 8 ( 36.4) |
| Very Good Partial Response (VGPR) | 0 | 3 ( 21.4) | 3 ( 13.6) |
| Partial Response (PR) | 3 ( 37.5) | 2 ( 14.3) | 5 ( 22.7) |
| Minimal Response (MR) | 0 | 1 ( 7.1) | 1 ( 4.5) |
| Stable Disease (SD) | 1 ( 12.5) | 0 | 1 ( 4.5) |
| Progressive Disease (PD) | 2 ( 25.0) | 1 ( 7.1) | 3 ( 13.6) |
| Inevaluable for Response (IE) [a] | 0 | 1 ( 7.1) | 1 ( 4.5) |
| Overall Response Rate - n (%) [b] | 5 ( 62.5) | 11 ( 78.6) | 16 ( 72.7) |
| 95% CI [c] | 24.5, 91.5 | 49.2, 95.3 | 49.8, 89.3 |
| 90% CI [c] | 28.9, 88.9 | 53.4, 93.9 | 53.2, 87.4 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.2c
Summary of Response Rate by IRC Assessment - Age >=65 years
Enrolled Population

| | 150x10^6 (N=8) | 450x10^6 (N=14) | Combined RP2D (150-450)x10^6 (N=22) |
|---|---|---|---|
| Response Rate of VGPR or better - n (%) [b] | 2 ( 25.0) | 9 ( 64.3) | 11 ( 50.0) |
| 95% CI [c] | 3.2, 65.1 | 35.1, 87.2 | 28.2, 71.8 |
| 90% CI [c] | 4.6, 60.0 | 39.0, 84.7 | 31.1, 68.9 |
| Complete Response Rate - n (%) [b] | 2 ( 25.0) | 6 ( 42.9) | 8 ( 36.4) |
| 95% CI [c] | 3.2, 65.1 | 17.7, 71.1 | 17.2, 59.3 |
| 90% CI [c] | 4.6, 60.0 | 20.6, 67.5 | 19.6, 56.1 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.2c
Summary of Response Rate by IRC Assessment - Double Refractory = Yes
Enrolled Population

| | 150x10^6 (N=15) | 450x10^6 (N=36) | Combined RP2D (150-450)x10^6 (N=51) |
|---|---|---|---|
| Best Overall Response - n (%) | | | |
| Stringent Complete Response (sCR) | 4 ( 26.7) | 11 ( 30.6) | 15 ( 29.4) |
| Very Good Partial Response (VGPR) | 1 ( 6.7) | 11 ( 30.6) | 12 ( 23.5) |
| Partial Response (PR) | 2 ( 13.3) | 5 ( 13.9) | 7 ( 13.7) |
| Minimal Response (MR) | 1 ( 6.7) | 0 | 1 ( 2.0) |
| Stable Disease (SD) | 4 ( 26.7) | 3 ( 8.3) | 7 ( 13.7) |
| Progressive Disease (PD) | 3 ( 20.0) | 2 ( 5.6) | 5 ( 9.8) |
| Inevaluable for Response (IE) [a] | 0 | 4 ( 11.1) | 4 ( 7.8) |
| Overall Response Rate - n (%) [b] | 7 ( 46.7) | 27 ( 75.0) | 34 ( 66.7) |
| 95% CI [c] | 21.3, 73.4 | 57.8, 87.9 | 52.1, 79.2 |
| 90% CI [c] | 24.4, 70.0 | 60.4, 86.3 | 54.3, 77.5 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.2c
Summary of Response Rate by IRC Assessment - Double Refractory = Yes
Enrolled Population

| | 150x10^6 (N=15) | 450x10^6 (N=36) | Combined RP2D (150-450)x10^6 (N=51) |
|---|---|---|---|
| Response Rate of VGPR or better - n (%) [b] | 5 ( 33.3) | 22 ( 61.1) | 27 ( 52.9) |
| 95% CI [c] | 11.8, 61.6 | 43.5, 76.9 | 38.5, 67.1 |
| 90% CI [c] | 14.2, 57.7 | 46.0, 74.7 | 40.6, 65.0 |
| Complete Response Rate - n (%) [b] | 4 ( 26.7) | 11 ( 30.6) | 15 ( 29.4) |
| 95% CI [c] | 7.8, 55.1 | 16.3, 48.1 | 17.5, 43.8 |
| 90% CI [c] | 9.7, 51.1 | 18.2, 45.5 | 19.1, 41.6 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.2c
Summary of Response Rate by IRC Assessment - Double Refractory = No
Enrolled Population

| | 150x10^6 (N=4) | 450x10^6 (N=6) | Combined RP2D (150-450)x10^6 (N=10) |
|---|---|---|---|
| Best Overall Response - n (%) | | | |
| Stringent Complete Response (sCR) | 2 ( 50.0) | 4 ( 66.7) | 6 ( 60.0) |
| Very Good Partial Response (VGPR) | 0 | 0 | 0 |
| Partial Response (PR) | 1 ( 25.0) | 1 ( 16.7) | 2 ( 20.0) |
| Minimal Response (MR) | 0 | 1 ( 16.7) | 1 ( 10.0) |
| Stable Disease (SD) | 0 | 0 | 0 |
| Progressive Disease (PD) | 0 | 0 | 0 |
| Inevaluable for Response (IE) [a] | 1 ( 25.0) | 0 | 1 ( 10.0) |
| Overall Response Rate - n (%) [b] | 3 ( 75.0) | 5 ( 83.3) | 8 ( 80.0) |
| 95% CI [c] | 19.4, 99.4 | 35.9, 99.6 | 44.4, 97.5 |
| 90% CI [c] | 24.9, 98.7 | 41.8, 99.1 | 49.3, 96.3 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.2c
Summary of Response Rate by IRC Assessment - Double Refractory = No
Enrolled Population

| | 150x10^6 (N=4) | 450x10^6 (N=6) | Combined RP2D (150-450)x10^6 (N=10) |
|---|---|---|---|
| Response Rate of VGPR or better - n (%) [b] | 2 ( 50.0) | 4 ( 66.7) | 6 ( 60.0) |
| 95% CI [c] | 6.8, 93.2 | 22.3, 95.7 | 26.2, 87.8 |
| 90% CI [c] | 9.8, 90.2 | 27.1, 93.7 | 30.4, 85.0 |
| Complete Response Rate - n (%) [b] | 2 ( 50.0) | 4 ( 66.7) | 6 ( 60.0) |
| 95% CI [c] | 6.8, 93.2 | 22.3, 95.7 | 26.2, 87.8 |
| 90% CI [c] | 9.8, 90.2 | 27.1, 93.7 | 30.4, 85.0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.2c
Summary of Response Rate by IRC Assessment - Presence of Extramedullary Plasmacytoma = Yes
Enrolled Population

| | 150x10^6 (N=4) | 450x10^6 (N=17) | Combined RP2D (150-450)x10^6 (N=21) |
|---|---|---|---|
| Best Overall Response - n (%) | | | |
| Stringent Complete Response (sCR) | 0 | 7 ( 41.2) | 7 ( 33.3) |
| Very Good Partial Response (VGPR) | 0 | 3 ( 17.6) | 3 ( 14.3) |
| Partial Response (PR) | 2 ( 50.0) | 4 ( 23.5) | 6 ( 28.6) |
| Minimal Response (MR) | 0 | 0 | 0 |
| Stable Disease (SD) | 1 ( 25.0) | 1 ( 5.9) | 2 ( 9.5) |
| Progressive Disease (PD) | 1 ( 25.0) | 1 ( 5.9) | 2 ( 9.5) |
| Inevaluable for Response (IE) [a] | 0 | 1 ( 5.9) | 1 ( 4.8) |
| Overall Response Rate - n (%) [b] | 2 ( 50.0) | 14 ( 82.4) | 16 ( 76.2) |
| 95% CI [c] | 6.8, 93.2 | 56.6, 96.2 | 52.8, 91.8 |
| 90% CI [c] | 9.8, 90.2 | 60.4, 95.0 | 56.3, 90.1 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.2c
Summary of Response Rate by IRC Assessment - Presence of Extramedullary Plasmacytoma = Yes
Enrolled Population

| | 150x10^6 (N=4) | 450x10^6 (N=17) | Combined RP2D (150-450)x10^6 (N=21) |
|---|---|---|---|
| Response Rate of VGPR or better - n (%) [b] | 0 | 10 ( 58.8) | 10 ( 47.6) |
| 95% CI [c] | 0.0, 60.2 | 32.9, 81.6 | 25.7, 70.2 |
| 90% CI [c] | 0.0, 52.7 | 36.4, 78.8 | 28.6, 67.2 |
| Complete Response Rate - n (%) [b] | 0 | 7 ( 41.2) | 7 ( 33.3) |
| 95% CI [c] | 0.0, 60.2 | 18.4, 67.1 | 14.6, 57.0 |
| 90% CI [c] | 0.0, 52.7 | 21.2, 63.6 | 16.8, 53.6 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
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Protocol: CRB-401


Cut-off date: 07APR2020

Table 4.2c
Summary of Response Rate by IRC Assessment - Presence of Extramedullary Plasmacytoma = No
Enrolled Population

| | 150x10^6 (N=15) | 450x10^6 (N=25) | Combined RP2D (150-450)x10^6 (N=40) |
|---|---|---|---|
| Best Overall Response - n (%) | | | |
| Stringent Complete Response (sCR) | 6 ( 40.0) | 8 ( 32.0) | 14 ( 35.0) |
| Very Good Partial Response (VGPR) | 1 ( 6.7) | 8 ( 32.0) | 9 ( 22.5) |
| Partial Response (PR) | 1 ( 6.7) | 2 ( 8.0) | 3 ( 7.5) |
| Minimal Response (MR) | 1 ( 6.7) | 1 ( 4.0) | 2 ( 5.0) |
| Stable Disease (SD) | 3 ( 20.0) | 2 ( 8.0) | 5 ( 12.5) |
| Progressive Disease (PD) | 2 ( 13.3) | 1 ( 4.0) | 3 ( 7.5) |
| Inevaluable for Response (IE) [a] | 1 ( 6.7) | 3 ( 12.0) | 4 ( 10.0) |
| Overall Response Rate - n (%) [b] | 8 ( 53.3) | 18 ( 72.0) | 26 ( 65.0) |
| 95% CI [c] | 26.6, 78.7 | 50.6, 87.9 | 48.3, 79.4 |
| 90% CI [c] | 30.0, 75.6 | 53.8, 86.1 | 50.8, 77.4 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_4_1.SAS
Date/time of run: 23OCT2020 14:46
Analysis Plan: 30JUN2020 Confidential

Table 4.2c
Summary of Response Rate by IRC Assessment - Presence of Extramedullary Plasmacytoma = No
Enrolled Population

| | 150x10^6 (N=15) | 450x10^6 (N=25) | Combined RP2D (150-450)x10^6 (N=40) |
|---|---|---|---|
| Response Rate of VGPR or better - n (%) [b] | 7 ( 46.7) | 16 ( 64.0) | 23 ( 57.5) |
| 95% CI [c] | 21.3, 73.4 | 42.5, 82.0 | 40.9, 73.0 |
| 90% CI [c] | 24.4, 70.0 | 45.6, 79.8 | 43.3, 70.8 |
| Complete Response Rate - n (%) [b] | 6 ( 40.0) | 8 ( 32.0) | 14 ( 35.0) |
| 95% CI [c] | 16.3, 67.7 | 14.9, 53.5 | 20.6, 51.7 |
| 90% CI [c] | 19.1, 64.0 | 17.0, 50.4 | 22.6, 49.2 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. RP2D = Recommended phase 2 dose; IRC = Independent response committee.
[a] Including subjects whose response assessment was not done or missing, or recorded as "Not-evaluable".
[b] Overall response rate is defined as the rate of subjects whose response is PR or better (i.e. sCR or CR or VGPR or PR); Response rate of VGPR or better includes sCR or CR or VGPR; Complete response rate is defined as the rate of subjects whose response is CR or better (i.e. sCR or CR). The denominator used for rate calculation is the number of subjects in the designated study population.
[c] Clopper-Pearson exact confidence interval (CI).

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Date/time of run: 23OCT2020 14:46
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## 13.3 Progressionsfreies Überleben

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Table 3.2c
Summary of Progression-free Survival by IRC Assessment (EMA Censoring Rules) by Age
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Statistics | <65 years (N=28) | >=65 years (N=14) | Overall (N=42) |
|---|---|---|---|---|
| Progression-free Survival | N | 28 | 14 | 42 |
| Censored | n (%) | 4 ( 14.3) | 4 ( 28.6) | 8 ( 19.0) |
| Progressed/Died | n (%) | 24 ( 85.7) | 10 ( 71.4) | 34 ( 81.0) |
| Progressed | n (%) | 22 ( 78.6) | 9 ( 64.3) | 31 ( 73.8) |
| Died | n (%) | 2 ( 7.1) | 1 ( 7.1) | 3 ( 7.1) |
| Progression-free Survival Time (months) [a] | 25th Pcnt. (95% CI) | 4.2 ( 1.2, 7.0) | 8.8 ( 2.3, 9.4) | 5.3 ( 2.7, 8.8) |
| | Median (95% CI) | 9.9 ( 4.4, 12.4) | 12.9 ( 6.1, 22.7) | 9.9 ( 7.3, 12.9) |
| | 75th Pcnt. (95% CI) | 14.8 (10.5, 19.4) | 22.7 ( 9.4, NE ) | 18.8 (12.1, 23.5) |
| 6 Months Event-Free | % (SE) | 66.7 ( 9.1) | 92.3 ( 7.4) | 75.0 ( 6.8) |
| 12 Months Event-Free | % (SE) | 37.0 ( 9.3) | 50.3 (14.4) | 41.4 ( 7.9) |
| 18 Months Event-Free | % (SE) | 18.5 ( 7.5) | 42.0 (14.3) | 25.9 ( 7.0) |
| 24 Months Event-Free | % (SE) | 9.3 ( 6.0) | 0.0 | 8.2 ( 5.2) |
| 30 Months Event-Free | % (SE) | 9.3 ( 6.0) | 0.0 | 8.2 ( 5.2) |
| 36 Months Event-Free | % (SE) | 9.3 ( 6.0) | 0.0 | 8.2 ( 5.2) |
| 42 Months Event-Free | % (SE) | NE | 0.0 | NE |
| 48 Months Event-Free | % (SE) | NE | 0.0 | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable.
Pcnt.=Percentile. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_1_1.SAS
Date/time of run: 05NOV2020 09:48
Analysis Plan: 30JUN2020 Confidential

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Protocol: CRB-401


Cut-off date: 07APR2020

Table 3.2c
Summary of Progression-free Survival by IRC Assessment (EMA Censoring Rules) by Double Refractory
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Statistics | Yes (N=36) | No (N=6) | Overall (N=42) |
|---|---|---|---|---|
| Progression-free Survival | N | 36 | 6 | 42 |
| Censored | n (%) | 5 ( 13.9) | 3 ( 50.0) | 8 ( 19.0) |
| Progressed/Died | n (%) | 31 ( 86.1) | 3 ( 50.0) | 34 ( 81.0) |
| Progressed | n (%) | 29 ( 80.6) | 2 ( 33.3) | 31 ( 73.8) |
| Died | n (%) | 2 ( 5.6) | 1 ( 16.7) | 3 ( 7.1) |
| Progression-free Survival Time (months) [a] | 25th Pcnt. (95% CI) | 4.4 ( 2.4, 8.6) | 8.8 ( 6.1, 19.4) | 5.3 ( 2.7, 8.8) |
| | Median (95% CI) | 9.7 ( 6.7, 12.4) | 19.4 ( 6.1, NE ) | 9.9 ( 7.3, 12.9) |
| | 75th Pcnt. (95% CI) | 14.8 (10.5, 22.7) | NE ( 6.1, NE ) | 18.8 (12.1, 23.5) |
| 6 Months Event-Free | % (SE) | 70.6 ( 7.8) | 100.0 ( 0.0) | 75.0 ( 6.8) |
| 12 Months Event-Free | % (SE) | 38.2 ( 8.3) | 60.0 (21.9) | 41.4 ( 7.9) |
| 18 Months Event-Free | % (SE) | 20.6 ( 6.9) | 60.0 (21.9) | 25.9 ( 7.0) |
| 24 Months Event-Free | % (SE) | 4.6 ( 4.3) | 30.0 (23.9) | 8.2 ( 5.2) |
| 30 Months Event-Free | % (SE) | 4.6 ( 4.3) | 30.0 (23.9) | 8.2 ( 5.2) |
| 36 Months Event-Free | % (SE) | 4.6 ( 4.3) | NE | 8.2 ( 5.2) |
| 42 Months Event-Free | % (SE) | NE | NE | NE |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable.
Pcnt.=Percentile. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_1_1.SAS
Date/time of run: 05NOV2020 09:48
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Table 3.2c
Summary of Progression-free Survival by IRC Assessment (EMA Censoring Rules) by Presence of Extramedullary Plasmacytoma
Enrolled Population
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | Statistics | Yes (N=17) | No (N=25) | Overall (N=42) |
|---|---|---|---|---|
| Progression-free Survival | N | 17 | 25 | 42 |
| Censored | n (%) | 4 ( 23.5) | 4 ( 16.0) | 8 ( 19.0) |
| Progressed/Died | n (%) | 13 ( 76.5) | 21 ( 84.0) | 34 ( 81.0) |
| Progressed | n (%) | 13 ( 76.5) | 18 ( 72.0) | 31 ( 73.8) |
| Died | n (%) | 0 | 3 ( 12.0) | 3 ( 7.1) |
| Progression-free Survival Time (months) [a] | 25th Pcnt. (95% CI) | 8.9 ( 2.4, 10.5) | 4.1 ( 1.0, 6.7) | 5.3 ( 2.7, 8.8) |
| | Median (95% CI) | 11.3 ( 8.6, 14.8) | 8.8 ( 4.2, 18.8) | 9.9 ( 7.3, 12.9) |
| | 75th Pcnt. (95% CI) | 15.3 (10.5, NE ) | 19.4 ( 9.9, 23.5) | 18.8 (12.1, 23.5) |
| 6 Months Event-Free | % (SE) | 87.5 ( 8.3) | 66.7 ( 9.6) | 75.0 ( 6.8) |
| 12 Months Event-Free | % (SE) | 50.0 (12.5) | 35.6 (10.0) | 41.4 ( 7.9) |
| 18 Months Event-Free | % (SE) | 18.8 ( 9.8) | 31.1 ( 9.7) | 25.9 ( 7.0) |
| 24 Months Event-Free | % (SE) | 18.8 ( 9.8) | 5.3 ( 5.1) | 8.2 ( 5.2) |
| 30 Months Event-Free | % (SE) | 18.8 ( 9.8) | 5.3 ( 5.1) | 8.2 ( 5.2) |
| 36 Months Event-Free | % (SE) | NE | 5.3 ( 5.1) | 8.2 ( 5.2) |
| 42 Months Event-Free | % (SE) | NE | NE | NE |
| 48 Months Event-Free | % (SE) | NE | NE | NE |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. RP2D=Recommended phase 2 dose. CI=Confidence interval. SE=Standard error. NE=Not Estimable.
Pcnt.=Percentile. *Did not meet IQWIG criteria for subgroup analysis.
[a] The 25th and 75th percentile, median and corresponding 95% confidence interval are based on Kaplan-Meier approach
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_1_1.SAS
Date/time of run: 05NOV2020 09:48
Analysis Plan: 30JUN2020 Confidential

## 13.4 Verträglichkeit

### 13.4.1 UE Gesamtraten

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Protocol: CRB-401


Cut-off date: 07APR2020

Table 5.1.3c
Overview of Adverse Events (AEs), Overall and by Subgroup
bb2121-Treated Population, Age <65 years
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=25) | | | |
|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) |
| Subjects with at least one AE | 17 ( 68.0) | 24 ( 96.0) | 25 (100.0) | 25 (100.0) |
| Subjects with at least one AE attributed to LP | 1 ( 4.0) | 0 | 0 | 0 |
| Subjects with at least one AE attributed to LD | 0 | 18 ( 72.0) | 17 ( 68.0) | 21 ( 84.0) |
| Subjects with at least one AE related [a] to bb2121 | 0 | 1 ( 4.0) | 25 (100.0) | 25 (100.0) |
| Subjects with at least one serious AE | 1 ( 4.0) | 1 ( 4.0) | 17 ( 68.0) | 17 ( 68.0) |
| Subjects with at least one serious AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE attributed to LD | 0 | 1 ( 4.0) | 0 | 1 ( 4.0) |
| Subjects with at least one serious AE related [a] to bb2121 | 0 | 0 | 7 ( 28.0) | 7 ( 28.0) |
| Subjects with at least one grade 1 or 2 [b] AE | 16 ( 64.0) | 22 ( 88.0) | 25 (100.0) | 25 (100.0) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LP | 1 ( 4.0) | 0 | 0 | 0 |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LD | 0 | 15 ( 60.0) | 13 ( 52.0) | 18 ( 72.0) |
| Subjects with at least one grade 1 or 2 [b] AE related [a] to bb2121 | 0 | 1 ( 4.0) | 25 (100.0) | 25 (100.0) |
| Subjects with at least one grade 3, 4 or 5 [b] AE | 6 ( 24.0) | 14 ( 56.0) | 24 ( 96.0) | 24 ( 96.0) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LD | 0 | 13 ( 52.0) | 15 ( 60.0) | 18 ( 72.0) |
| Subjects with at least one grade 3, 4 or 5 [b] AE related [a] to bb2121 | 0 | 0 | 18 ( 72.0) | 18 ( 72.0) |

Note: Footnotes are displayed on the last page only.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_5_1_3.SAS
Date/time of run: 02OCT2020 14:54
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 5.1.3c
Overview of Adverse Events (AEs), Overall and by Subgroup
bb2121-Treated Population, Age >=65 years
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=13) | | | |
|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) |
| Subjects with at least one AE | 10 ( 76.9) | 13 (100.0) | 13 (100.0) | 13 (100.0) |
| Subjects with at least one AE attributed to LP | 2 ( 15.4) | 2 ( 15.4) | 1 ( 7.7) | 2 ( 15.4) |
| Subjects with at least one AE attributed to LD | 1 ( 7.7) | 12 ( 92.3) | 11 ( 84.6) | 12 ( 92.3) |
| Subjects with at least one AE related [a] to bb2121 | 0 | 2 ( 15.4) | 12 ( 92.3) | 12 ( 92.3) |
| Subjects with at least one serious AE | 2 ( 15.4) | 0 | 12 ( 92.3) | 12 ( 92.3) |
| Subjects with at least one serious AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE attributed to LD | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE related [a] to bb2121 | 0 | 0 | 5 ( 38.5) | 5 ( 38.5) |
| Subjects with at least one grade 1 or 2 [b] AE | 10 ( 76.9) | 12 ( 92.3) | 13 (100.0) | 13 (100.0) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LP | 1 ( 7.7) | 1 ( 7.7) | 1 ( 7.7) | 2 ( 15.4) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LD | 1 ( 7.7) | 11 ( 84.6) | 10 ( 76.9) | 12 ( 92.3) |
| Subjects with at least one grade 1 or 2 [b] AE related [a] to bb2121 | 0 | 0 | 12 ( 92.3) | 12 ( 92.3) |
| Subjects with at least one grade 3, 4 or 5 [b] AE | 4 ( 30.8) | 11 ( 84.6) | 13 (100.0) | 13 (100.0) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LP | 1 ( 7.7) | 1 ( 7.7) | 1 ( 7.7) | 1 ( 7.7) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LD | 0 | 9 ( 69.2) | 11 ( 84.6) | 12 ( 92.3) |
| Subjects with at least one grade 3, 4 or 5 [b] AE related [a] to bb2121 | 0 | 2 ( 15.4) | 8 ( 61.5) | 8 ( 61.5) |

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Protocol: CRB-401


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Table 5.1.3c
Overview of Adverse Events (AEs), Overall and by Subgroup
bb2121-Treated Population, Double Refractory = Yes
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=32) | | | |
|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) |
| Subjects with at least one AE | 25 ( 78.1) | 31 ( 96.9) | 32 (100.0) | 32 (100.0) |
| Subjects with at least one AE attributed to LP | 3 ( 9.4) | 1 ( 3.1) | 1 ( 3.1) | 1 ( 3.1) |
| Subjects with at least one AE attributed to LD | 1 ( 3.1) | 24 ( 75.0) | 24 ( 75.0) | 27 ( 84.4) |
| Subjects with at least one AE related [a] to bb2121 | 0 | 3 ( 9.4) | 31 ( 96.9) | 31 ( 96.9) |
| Subjects with at least one serious AE | 3 ( 9.4) | 1 ( 3.1) | 25 ( 78.1) | 25 ( 78.1) |
| Subjects with at least one serious AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE attributed to LD | 0 | 1 ( 3.1) | 0 | 1 ( 3.1) |
| Subjects with at least one serious AE related [a] to bb2121 | 0 | 0 | 10 ( 31.3) | 10 ( 31.3) |
| Subjects with at least one grade 1 or 2 [b] AE | 24 ( 75.0) | 28 ( 87.5) | 32 (100.0) | 32 (100.0) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LP | 2 ( 6.3) | 0 | 1 ( 3.1) | 1 ( 3.1) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LD | 1 ( 3.1) | 20 ( 62.5) | 19 ( 59.4) | 24 ( 75.0) |
| Subjects with at least one grade 1 or 2 [b] AE related [a] to bb2121 | 0 | 1 ( 3.1) | 31 ( 96.9) | 31 ( 96.9) |
| Subjects with at least one grade 3, 4 or 5 [b] AE | 10 ( 31.3) | 22 ( 68.8) | 32 (100.0) | 32 (100.0) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LP | 1 ( 3.1) | 1 ( 3.1) | 1 ( 3.1) | 1 ( 3.1) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LD | 0 | 19 ( 59.4) | 23 ( 71.9) | 26 ( 81.3) |
| Subjects with at least one grade 3, 4 or 5 [b] AE related [a] to bb2121 | 0 | 2 ( 6.3) | 22 ( 68.8) | 22 ( 68.8) |

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Table 5.1.3c
Overview of Adverse Events (AEs), Overall and by Subgroup
bb2121-Treated Population, Double Refractory = No
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=6) | | | |
|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) |
| Subjects with at least one AE | 2 ( 33.3) | 6 (100.0) | 6 (100.0) | 6 (100.0) |
| Subjects with at least one AE attributed to LP | 0 | 1 ( 16.7) | 0 | 1 ( 16.7) |
| Subjects with at least one AE attributed to LD | 0 | 6 (100.0) | 4 ( 66.7) | 6 (100.0) |
| Subjects with at least one AE related [a] to bb2121 | 0 | 0 | 6 (100.0) | 6 (100.0) |
| Subjects with at least one serious AE | 0 | 0 | 4 ( 66.7) | 4 ( 66.7) |
| Subjects with at least one serious AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE attributed to LD | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE related [a] to bb2121 | 0 | 0 | 2 ( 33.3) | 2 ( 33.3) |
| Subjects with at least one grade 1 or 2 [b] AE | 2 ( 33.3) | 6 (100.0) | 6 (100.0) | 6 (100.0) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LP | 0 | 1 ( 16.7) | 0 | 1 ( 16.7) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LD | 0 | 6 (100.0) | 4 ( 66.7) | 6 (100.0) |
| Subjects with at least one grade 1 or 2 [b] AE related [a] to bb2121 | 0 | 0 | 6 (100.0) | 6 (100.0) |
| Subjects with at least one grade 3, 4 or 5 [b] AE | 0 | 3 ( 50.0) | 5 ( 83.3) | 5 ( 83.3) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LD | 0 | 3 ( 50.0) | 3 ( 50.0) | 4 ( 66.7) |
| Subjects with at least one grade 3, 4 or 5 [b] AE related [a] to bb2121 | 0 | 0 | 4 ( 66.7) | 4 ( 66.7) |

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Table 5.1.3c
Overview of Adverse Events (AEs), Overall and by Subgroup
bb2121-Treated Population, Presence of Extramedullary Plasmacytoma = Yes
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=16) | | | |
|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) |
| Subjects with at least one AE | 14 ( 87.5) | 15 ( 93.8) | 16 (100.0) | 16 (100.0) |
| Subjects with at least one AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one AE attributed to LD | 0 | 12 ( 75.0) | 10 ( 62.5) | 13 ( 81.3) |
| Subjects with at least one AE related [a] to bb2121 | 0 | 1 ( 6.3) | 16 (100.0) | 16 (100.0) |
| Subjects with at least one serious AE | 1 ( 6.3) | 1 ( 6.3) | 13 ( 81.3) | 13 ( 81.3) |
| Subjects with at least one serious AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE attributed to LD | 0 | 1 ( 6.3) | 0 | 1 ( 6.3) |
| Subjects with at least one serious AE related [a] to bb2121 | 0 | 0 | 6 ( 37.5) | 6 ( 37.5) |
| Subjects with at least one grade 1 or 2 [b] AE | 14 ( 87.5) | 15 ( 93.8) | 16 (100.0) | 16 (100.0) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LD | 0 | 11 ( 68.8) | 8 ( 50.0) | 11 ( 68.8) |
| Subjects with at least one grade 1 or 2 [b] AE related [a] to bb2121 | 0 | 0 | 16 (100.0) | 16 (100.0) |
| Subjects with at least one grade 3, 4 or 5 [b] AE | 3 ( 18.8) | 10 ( 62.5) | 15 ( 93.8) | 15 ( 93.8) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LD | 0 | 8 ( 50.0) | 9 ( 56.3) | 12 ( 75.0) |
| Subjects with at least one grade 3, 4 or 5 [b] AE related [a] to bb2121 | 0 | 1 ( 6.3) | 9 ( 56.3) | 9 ( 56.3) |

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Table 5.1.3c
Overview of Adverse Events (AEs), Overall and by Subgroup
bb2121-Treated Population, Presence of Extramedullary Plasmacytoma = No
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=22) | | | |
|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) |
| Subjects with at least one AE | 13 ( 59.1) | 22 (100.0) | 22 (100.0) | 22 (100.0) |
| Subjects with at least one AE attributed to LP | 3 ( 13.6) | 2 ( 9.1) | 1 ( 4.5) | 2 ( 9.1) |
| Subjects with at least one AE attributed to LD | 1 ( 4.5) | 18 ( 81.8) | 18 ( 81.8) | 20 ( 90.9) |
| Subjects with at least one AE related [a] to bb2121 | 0 | 2 ( 9.1) | 21 ( 95.5) | 21 ( 95.5) |
| Subjects with at least one serious AE | 2 ( 9.1) | 0 | 16 ( 72.7) | 16 ( 72.7) |
| Subjects with at least one serious AE attributed to LP | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE attributed to LD | 0 | 0 | 0 | 0 |
| Subjects with at least one serious AE related [a] to bb2121 | 0 | 0 | 6 ( 27.3) | 6 ( 27.3) |
| Subjects with at least one grade 1 or 2 [b] AE | 12 ( 54.5) | 19 ( 86.4) | 22 (100.0) | 22 (100.0) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LP | 2 ( 9.1) | 1 ( 4.5) | 1 ( 4.5) | 2 ( 9.1) |
| Subjects with at least one grade 1 or 2 [b] AE attributed to LD | 1 ( 4.5) | 15 ( 68.2) | 15 ( 68.2) | 19 ( 86.4) |
| Subjects with at least one grade 1 or 2 [b] AE related [a] to bb2121 | 0 | 1 ( 4.5) | 21 ( 95.5) | 21 ( 95.5) |
| Subjects with at least one grade 3, 4 or 5 [b] AE | 7 ( 31.8) | 15 ( 68.2) | 22 (100.0) | 22 (100.0) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LP | 1 ( 4.5) | 1 ( 4.5) | 1 ( 4.5) | 1 ( 4.5) |
| Subjects with at least one grade 3, 4 or 5 [b] AE attributed to LD | 0 | 14 ( 63.6) | 17 ( 77.3) | 18 ( 81.8) |
| Subjects with at least one grade 3, 4 or 5 [b] AE related [a] to bb2121 | 0 | 1 ( 4.5) | 17 ( 77.3) | 17 ( 77.3) |

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### 13.4.2 UESI

Table 7.5c
Adverse Events of Special Interest (AESIs) and Selected AEs Summary, Overall and by Subgroup
bb2121-Treated Population, Age <65 years
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=25) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI or Selected AE | 12 ( 48.0) | 18 ( 72.0) | 25 (100.0) | 25 (100.0) | 25 (100.0) |
| Subjects with at least one serious AESI or Selected AE | 1 ( 4.0) | 1 ( 4.0) | 13 ( 52.0) | 13 ( 52.0) | 13 ( 52.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI or Selected AE | 9 ( 36.0) | 14 ( 56.0) | 25 (100.0) | 25 (100.0) | 25 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI or Selected AE | 6 ( 24.0) | 14 ( 56.0) | 24 ( 96.0) | 24 ( 96.0) | 24 ( 96.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria
for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
Missing subgroup categories are not presented.
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Analysis Plan: 30JUN2020 Confidential

Table 7.5c
Adverse Events of Special Interest (AESIs) and Selected AEs Summary, Overall and by Subgroup
bb2121-Treated Population, Age >=65 years
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=13) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI or Selected AE | 8 ( 61.5) | 12 ( 92.3) | 13 (100.0) | 13 (100.0) | 13 (100.0) |
| Subjects with at least one serious AESI or Selected AE | 2 ( 15.4) | 0 | 9 ( 69.2) | 9 ( 69.2) | 10 ( 76.9) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI or Selected AE | 7 ( 53.8) | 10 ( 76.9) | 13 (100.0) | 13 (100.0) | 13 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI or Selected AE | 3 ( 23.1) | 10 ( 76.9) | 12 ( 92.3) | 12 ( 92.3) | 13 (100.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria
for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
Missing subgroup categories are not presented.
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Analysis Plan: 30JUN2020 Confidential

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Protocol: CRB-401


Cut-off date: 07APR2020

Table 7.5c
Adverse Events of Special Interest (AESIs) and Selected AEs Summary, Overall and by Subgroup
bb2121-Treated Population, Double Refractory = Yes
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=32) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI or Selected AE | 19 ( 59.4) | 25 ( 78.1) | 32 (100.0) | 32 (100.0) | 32 (100.0) |
| Subjects with at least one serious AESI or Selected AE | 3 ( 9.4) | 1 ( 3.1) | 19 ( 59.4) | 19 ( 59.4) | 20 ( 62.5) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI or Selected AE | 15 ( 46.9) | 20 ( 62.5) | 32 (100.0) | 32 (100.0) | 32 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI or Selected AE | 9 ( 28.1) | 21 ( 65.6) | 31 ( 96.9) | 31 ( 96.9) | 32 (100.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria
for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
Missing subgroup categories are not presented.
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Table 7.5c
Adverse Events of Special Interest (AESIs) and Selected AEs Summary, Overall and by Subgroup
bb2121-Treated Population, Double Refractory = No
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=6) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI or Selected AE | 1 ( 16.7) | 5 ( 83.3) | 6 (100.0) | 6 (100.0) | 6 (100.0) |
| Subjects with at least one serious AESI or Selected AE | 0 | 0 | 3 ( 50.0) | 3 ( 50.0) | 3 ( 50.0) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI or Selected AE | 1 ( 16.7) | 4 ( 66.7) | 6 (100.0) | 6 (100.0) | 6 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI or Selected AE | 0 | 3 ( 50.0) | 5 ( 83.3) | 5 ( 83.3) | 5 ( 83.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria
for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
Missing subgroup categories are not presented.
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Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 7.5c
Adverse Events of Special Interest (AESIs) and Selected AEs Summary, Overall and by Subgroup
bb2121-Treated Population, Presence of Extramedullary Plasmacytoma = Yes
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=16) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI or Selected AE | 9 ( 56.3) | 14 ( 87.5) | 16 (100.0) | 16 (100.0) | 16 (100.0) |
| Subjects with at least one serious AESI or Selected AE | 1 ( 6.3) | 1 ( 6.3) | 11 ( 68.8) | 11 ( 68.8) | 11 ( 68.8) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI or Selected AE | 8 ( 50.0) | 11 ( 68.8) | 16 (100.0) | 16 (100.0) | 16 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI or Selected AE | 2 ( 12.5) | 10 ( 62.5) | 15 ( 93.8) | 15 ( 93.8) | 15 ( 93.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included.
Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria
for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
Missing subgroup categories are not presented.
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Table 7.5c
Adverse Events of Special Interest (AESIs) and Selected AEs Summary, Overall and by Subgroup
bb2121-Treated Population, Presence of Extramedullary Plasmacytoma = No
For Subjects Treated with 450x10^6 Cells [Escalation and Expansion (Part A + B)]

| | bb2121-Treated Population (N=22) | | | | |
|---|---|---|---|---|---|
| | Reporting Period A: LP to Before LD n (%) | Reporting Period B: LD to Before bb2121 Infusion n (%) | Reporting Period C to F: Post bb2121 Infusion n (%) | Reporting Period B to F: LD to End of Follow-up n (%) | Reporting Period A to F: Leukapheresis to End of Follow-up n (%) |
| Subjects with at least one AESI or Selected AE | 11 ( 50.0) | 16 ( 72.7) | 22 (100.0) | 22 (100.0) | 22 (100.0) |
| Subjects with at least one serious AESI or Selected AE | 2 ( 9.1) | 0 | 11 ( 50.0) | 11 ( 50.0) | 12 ( 54.5) |
| Subjects with at least one CTCAE Grade 1 or 2 [a] AESI or Selected AE | 8 ( 36.4) | 13 ( 59.1) | 22 (100.0) | 22 (100.0) | 22 (100.0) |
| Subjects with at least one CTCAE Grade 3, 4 or 5 [a] AESI or Selected AE | 7 ( 31.8) | 14 ( 63.6) | 21 ( 95.5) | 21 ( 95.5) | 22 (100.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. LP = Leukapheresis; LD = Lymphodepletion; RP2D = Recommended phase 2 dose.
Reporting Periods A, B: For subjects who received retreatment, only the AEs started before initial bb2121 infusion are included. Reporting
Periods C-F: For subjects who received retreatment, only the AEs started before retreatment lymphodepletion are included.
[a] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteria
for Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximum grade.
Missing subgroup categories are not presented.
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Analysis Plan: 30JUN2020 Confidential

### 13.4.3 UE nach SOC und PT

Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one AE | 10 (100.0) | 25 (100.0) | 35 (100.0) |
| Blood and lymphatic system disorders | 10 (100.0) | 24 ( 96.0) | 34 ( 97.1) |
| Neutropenia | 10 (100.0) | 23 ( 92.0) | 33 ( 94.3) |
| Anaemia | 7 ( 70.0) | 19 ( 76.0) | 26 ( 74.3) |
| Thrombocytopenia | 7 ( 70.0) | 17 ( 68.0) | 24 ( 68.6) |
| Leukopenia | 8 ( 80.0) | 13 ( 52.0) | 21 ( 60.0) |
| Lymphopenia | 4 ( 40.0) | 11 ( 44.0) | 15 ( 42.9) |
| Febrile neutropenia | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Gastrointestinal disorders | 8 ( 80.0) | 23 ( 92.0) | 31 ( 88.6) |
| Nausea | 5 ( 50.0) | 17 ( 68.0) | 22 ( 62.9) |
| Diarrhoea | 3 ( 30.0) | 10 ( 40.0) | 13 ( 37.1) |
| Vomiting | 2 ( 20.0) | 8 ( 32.0) | 10 ( 28.6) |
| Constipation | 1 ( 10.0) | 9 ( 36.0) | 10 ( 28.6) |
| Abdominal pain | 0 | 6 ( 24.0) | 6 ( 17.1) |
| Abdominal discomfort | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Dry mouth | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Dyspepsia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Stomatitis | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| General disorders and administration site conditions | 8 ( 80.0) | 22 ( 88.0) | 30 ( 85.7) |
| Fatigue | 6 ( 60.0) | 13 ( 52.0) | 19 ( 54.3) |
| Pyrexia | 4 ( 40.0) | 11 ( 44.0) | 15 ( 42.9) |
| Oedema peripheral | 2 ( 20.0) | 7 ( 28.0) | 9 ( 25.7) |
| Chills | 2 ( 20.0) | 6 ( 24.0) | 8 ( 22.9) |
| Asthenia | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Pain | 0 | 1 ( 4.0) | 1 ( 2.9) |
| General physical health deterioration | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Gait disturbance | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Metabolism and nutrition disorders | 7 ( 70.0) | 21 ( 84.0) | 28 ( 80.0) |
| Hypophosphataemia | 5 ( 50.0) | 10 ( 40.0) | 15 ( 42.9) |
| Hypokalaemia | 2 ( 20.0) | 11 ( 44.0) | 13 ( 37.1) |
| Hypocalcaemia | 3 ( 30.0) | 6 ( 24.0) | 9 ( 25.7) |
| Hypoalbuminaemia | 3 ( 30.0) | 4 ( 16.0) | 7 ( 20.0) |
| Decreased appetite | 3 ( 30.0) | 4 ( 16.0) | 7 ( 20.0) |
| Hypomagnesaemia | 2 ( 20.0) | 5 ( 20.0) | 7 ( 20.0) |
| Hyperglycaemia | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Hyponatraemia | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |
| Hyperuricaemia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Hyperkalaemia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Hypermagnesaemia | 2 ( 20.0) | 0 | 2 ( 5.7) |
| Musculoskeletal and connective tissue disorders | 6 ( 60.0) | 20 ( 80.0) | 26 ( 74.3) |
| Arthralgia | 3 ( 30.0) | 13 ( 52.0) | 16 ( 45.7) |
| Back pain | 4 ( 40.0) | 4 ( 16.0) | 8 ( 22.9) |
| Musculoskeletal pain | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |
| Musculoskeletal chest pain | 3 ( 30.0) | 3 ( 12.0) | 6 ( 17.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Bone pain | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Myalgia | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Pain in extremity | 0 | 4 ( 16.0) | 4 ( 11.4) |
| Muscular weakness | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Musculoskeletal discomfort | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Neck pain | 2 ( 20.0) | 0 | 2 ( 5.7) |
| Immune system disorders | 4 ( 40.0) | 24 ( 96.0) | 28 ( 80.0) |
| Cytokine release syndrome | 4 ( 40.0) | 24 ( 96.0) | 28 ( 80.0) |
| Hypogammaglobulinaemia | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Infections and infestations | 8 ( 80.0) | 18 ( 72.0) | 26 ( 74.3) |
| Upper respiratory tract infection | 5 ( 50.0) | 9 ( 36.0) | 14 ( 40.0) |
| Urinary tract infection | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |
| Respiratory syncytial virus infection | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Lung infection | 2 ( 20.0) | 1 ( 4.0) | 3 ( 8.6) |
| Nervous system disorders | 8 ( 80.0) | 18 ( 72.0) | 26 ( 74.3) |
| Headache | 2 ( 20.0) | 10 ( 40.0) | 12 ( 34.3) |
| Dizziness | 4 ( 40.0) | 5 ( 20.0) | 9 ( 25.7) |
| Neurotoxicity | 1 ( 10.0) | 5 ( 20.0) | 6 ( 17.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Syncope | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Tremor | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Respiratory, thoracic and mediastinal disorders | 7 ( 70.0) | 19 ( 76.0) | 26 ( 74.3) |
| Cough | 4 ( 40.0) | 10 ( 40.0) | 14 ( 40.0) |
| Nasal congestion | 2 ( 20.0) | 10 ( 40.0) | 12 ( 34.3) |
| Dyspnoea | 3 ( 30.0) | 5 ( 20.0) | 8 ( 22.9) |
| Productive cough | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Hypoxia | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |
| Epistaxis | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Dyspnoea exertional | 2 ( 20.0) | 1 ( 4.0) | 3 ( 8.6) |
| Oropharyngeal pain | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Investigations | 4 ( 40.0) | 15 ( 60.0) | 19 ( 54.3) |
| Blood alkaline phosphatase increased | 0 | 4 ( 16.0) | 4 ( 11.4) |
| Transaminases increased | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |
| Blood creatinine increased | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Weight decreased | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Weight increased | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |
| Skin and subcutaneous tissue disorders | 5 ( 50.0) | 13 ( 52.0) | 18 ( 51.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
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Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Pruritus | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Rash | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |
| Rash maculo-papular | 0 | 0 | 0 |
| Skin disorder | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Vascular disorders | 5 ( 50.0) | 11 ( 44.0) | 16 ( 45.7) |
| Hypertension | 1 ( 10.0) | 5 ( 20.0) | 6 ( 17.1) |
| Hypotension | 4 ( 40.0) | 2 ( 8.0) | 6 ( 17.1) |
| Cardiac disorders | 4 ( 40.0) | 10 ( 40.0) | 14 ( 40.0) |
| Tachycardia | 2 ( 20.0) | 5 ( 20.0) | 7 ( 20.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Sinus tachycardia | 3 ( 30.0) | 1 ( 4.0) | 4 ( 11.4) |
| Atrial fibrillation | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Psychiatric disorders | 4 ( 40.0) | 9 ( 36.0) | 13 ( 37.1) |
| Insomnia | 2 ( 20.0) | 5 ( 20.0) | 7 ( 20.0) |
| Injury, poisoning and procedural complications | 2 ( 20.0) | 8 ( 32.0) | 10 ( 28.6) |
| Arthropod bite | 0 | 0 | 0 |
| Procedural pain | 2 ( 20.0) | 0 | 2 ( 5.7) |
| Eye disorders | 3 ( 30.0) | 6 ( 24.0) | 9 ( 25.7) |
| Lacrimation increased | 2 ( 20.0) | 1 ( 4.0) | 3 ( 8.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Renal and urinary disorders | 2 ( 20.0) | 5 ( 20.0) | 7 ( 20.0) |
| Ear and labyrinth disorders | 2 ( 20.0) | 4 ( 16.0) | 6 ( 17.1) |
| Ear pain | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one AE | 8 (100.0) | 13 (100.0) | 21 (100.0) |
| Blood and lymphatic system disorders | 7 ( 87.5) | 12 ( 92.3) | 19 ( 90.5) |
| Neutropenia | 6 ( 75.0) | 12 ( 92.3) | 18 ( 85.7) |
| Anaemia | 5 ( 62.5) | 12 ( 92.3) | 17 ( 81.0) |
| Thrombocytopenia | 6 ( 75.0) | 12 ( 92.3) | 18 ( 85.7) |
| Leukopenia | 4 ( 50.0) | 11 ( 84.6) | 15 ( 71.4) |
| Lymphopenia | 4 ( 50.0) | 8 ( 61.5) | 12 ( 57.1) |
| Febrile neutropenia | 2 ( 25.0) | 3 ( 23.1) | 5 ( 23.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Gastrointestinal disorders | 8 (100.0) | 13 (100.0) | 21 (100.0) |
| Nausea | 4 ( 50.0) | 10 ( 76.9) | 14 ( 66.7) |
| Diarrhoea | 1 ( 12.5) | 8 ( 61.5) | 9 ( 42.9) |
| Vomiting | 1 ( 12.5) | 6 ( 46.2) | 7 ( 33.3) |
| Constipation | 2 ( 25.0) | 4 ( 30.8) | 6 ( 28.6) |
| Abdominal pain | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Abdominal discomfort | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Dry mouth | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Dyspepsia | 2 ( 25.0) | 0 | 2 ( 9.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Stomatitis | 1 ( 12.5) | 0 | 1 ( 4.8) |
| General disorders and administration site conditions | 7 ( 87.5) | 12 ( 92.3) | 19 ( 90.5) |
| Fatigue | 3 ( 37.5) | 9 ( 69.2) | 12 ( 57.1) |
| Pyrexia | 3 ( 37.5) | 4 ( 30.8) | 7 ( 33.3) |
| Oedema peripheral | 3 ( 37.5) | 8 ( 61.5) | 11 ( 52.4) |
| Chills | 3 ( 37.5) | 4 ( 30.8) | 7 ( 33.3) |
| Asthenia | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Pain | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| General physical health deterioration | 1 ( 12.5) | 0 | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Gait disturbance | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Metabolism and nutrition disorders | 7 ( 87.5) | 11 ( 84.6) | 18 ( 85.7) |
| Hypophosphataemia | 2 ( 25.0) | 6 ( 46.2) | 8 ( 38.1) |
| Hypokalaemia | 1 ( 12.5) | 8 ( 61.5) | 9 ( 42.9) |
| Hypocalcaemia | 1 ( 12.5) | 7 ( 53.8) | 8 ( 38.1) |
| Hypoalbuminaemia | 0 | 8 ( 61.5) | 8 ( 38.1) |
| Decreased appetite | 3 ( 37.5) | 4 ( 30.8) | 7 ( 33.3) |
| Hypomagnesaemia | 3 ( 37.5) | 3 ( 23.1) | 6 ( 28.6) |
| Hyperglycaemia | 0 | 6 ( 46.2) | 6 ( 28.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Hyponatraemia | 0 | 5 ( 38.5) | 5 ( 23.8) |
| Hyperuricaemia | 2 ( 25.0) | 0 | 2 ( 9.5) |
| Hyperkalaemia | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Hypermagnesaemia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Musculoskeletal and connective tissue disorders | 8 (100.0) | 11 ( 84.6) | 19 ( 90.5) |
| Arthralgia | 3 ( 37.5) | 2 ( 15.4) | 5 ( 23.8) |
| Back pain | 2 ( 25.0) | 3 ( 23.1) | 5 ( 23.8) |
| Musculoskeletal pain | 2 ( 25.0) | 1 ( 7.7) | 3 ( 14.3) |
| Musculoskeletal chest pain | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Bone pain | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Myalgia | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Pain in extremity | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Muscular weakness | 2 ( 25.0) | 1 ( 7.7) | 3 ( 14.3) |
| Musculoskeletal discomfort | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Neck pain | 0 | 0 | 0 |
| Immune system disorders | 4 ( 50.0) | 11 ( 84.6) | 15 ( 71.4) |
| Cytokine release syndrome | 3 ( 37.5) | 11 ( 84.6) | 14 ( 66.7) |
| Hypogammaglobulinaemia | 3 ( 37.5) | 1 ( 7.7) | 4 ( 19.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Infections and infestations | 5 ( 62.5) | 11 ( 84.6) | 16 ( 76.2) |
| Upper respiratory tract infection | 3 ( 37.5) | 4 ( 30.8) | 7 ( 33.3) |
| Urinary tract infection | 0 | 4 ( 30.8) | 4 ( 19.0) |
| Respiratory syncytial virus infection | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Lung infection | 0 | 0 | 0 |
| Nervous system disorders | 4 ( 50.0) | 10 ( 76.9) | 14 ( 66.7) |
| Headache | 3 ( 37.5) | 4 ( 30.8) | 7 ( 33.3) |
| Dizziness | 0 | 3 ( 23.1) | 3 ( 14.3) |
| Neurotoxicity | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Syncope | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Tremor | 0 | 3 ( 23.1) | 3 ( 14.3) |
| Respiratory, thoracic and mediastinal disorders | 3 ( 37.5) | 11 ( 84.6) | 14 ( 66.7) |
| Cough | 3 ( 37.5) | 7 ( 53.8) | 10 ( 47.6) |
| Nasal congestion | 2 ( 25.0) | 1 ( 7.7) | 3 ( 14.3) |
| Dyspnoea | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Productive cough | 1 ( 12.5) | 4 ( 30.8) | 5 ( 23.8) |
| Hypoxia | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Epistaxis | 0 | 4 ( 30.8) | 4 ( 19.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Dyspnoea exertional | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Oropharyngeal pain | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Investigations | 4 ( 50.0) | 10 ( 76.9) | 14 ( 66.7) |
| Blood alkaline phosphatase increased | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Transaminases increased | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Blood creatinine increased | 2 ( 25.0) | 3 ( 23.1) | 5 ( 23.8) |
| Weight decreased | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Weight increased | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 3 ( 37.5) | 5 ( 38.5) | 8 ( 38.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Pruritus | 2 ( 25.0) | 1 ( 7.7) | 3 ( 14.3) |
| Rash | 0 | 0 | 0 |
| Rash maculo-papular | 2 ( 25.0) | 0 | 2 ( 9.5) |
| Skin disorder | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Vascular disorders | 2 ( 25.0) | 8 ( 61.5) | 10 ( 47.6) |
| Hypertension | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Hypotension | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Cardiac disorders | 2 ( 25.0) | 4 ( 30.8) | 6 ( 28.6) |
| Tachycardia | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Sinus tachycardia | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Atrial fibrillation | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Psychiatric disorders | 1 ( 12.5) | 4 ( 30.8) | 5 ( 23.8) |
| Insomnia | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Injury, poisoning and procedural complications | 4 ( 50.0) | 3 ( 23.1) | 7 ( 33.3) |
| Arthropod bite | 2 ( 25.0) | 0 | 2 ( 9.5) |
| Procedural pain | 0 | 0 | 0 |
| Eye disorders | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Lacrimation increased | 1 ( 12.5) | 0 | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Renal and urinary disorders | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Ear and labyrinth disorders | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Ear pain | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 12.5) | 4 ( 30.8) | 5 ( 23.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one AE | 15 (100.0) | 32 (100.0) | 47 (100.0) |
| Blood and lymphatic system disorders | 15 (100.0) | 31 ( 96.9) | 46 ( 97.9) |
| Neutropenia | 14 ( 93.3) | 30 ( 93.8) | 44 ( 93.6) |
| Anaemia | 11 ( 73.3) | 26 ( 81.3) | 37 ( 78.7) |
| Thrombocytopenia | 12 ( 80.0) | 24 ( 75.0) | 36 ( 76.6) |
| Leukopenia | 10 ( 66.7) | 20 ( 62.5) | 30 ( 63.8) |
| Lymphopenia | 8 ( 53.3) | 16 ( 50.0) | 24 ( 51.1) |
| Febrile neutropenia | 3 ( 20.0) | 4 ( 12.5) | 7 ( 14.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Gastrointestinal disorders | 13 ( 86.7) | 30 ( 93.8) | 43 ( 91.5) |
| Nausea | 8 ( 53.3) | 21 ( 65.6) | 29 ( 61.7) |
| Diarrhoea | 2 ( 13.3) | 13 ( 40.6) | 15 ( 31.9) |
| Vomiting | 2 ( 13.3) | 11 ( 34.4) | 13 ( 27.7) |
| Constipation | 2 ( 13.3) | 11 ( 34.4) | 13 ( 27.7) |
| Abdominal pain | 0 | 6 ( 18.8) | 6 ( 12.8) |
| Abdominal discomfort | 0 | 4 ( 12.5) | 4 ( 8.5) |
| Dry mouth | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Dyspepsia | 3 ( 20.0) | 1 ( 3.1) | 4 ( 8.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Stomatitis | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| General disorders and administration site conditions | 12 ( 80.0) | 28 ( 87.5) | 40 ( 85.1) |
| Fatigue | 7 ( 46.7) | 17 ( 53.1) | 24 ( 51.1) |
| Pyrexia | 5 ( 33.3) | 12 ( 37.5) | 17 ( 36.2) |
| Oedema peripheral | 3 ( 20.0) | 12 ( 37.5) | 15 ( 31.9) |
| Chills | 3 ( 20.0) | 7 ( 21.9) | 10 ( 21.3) |
| Asthenia | 1 ( 6.7) | 4 ( 12.5) | 5 ( 10.6) |
| Pain | 0 | 4 ( 12.5) | 4 ( 8.5) |
| General physical health deterioration | 2 ( 13.3) | 2 ( 6.3) | 4 ( 8.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Protocol: CRB-401


Cut-off date: 07APR2020

Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Gait disturbance | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Metabolism and nutrition disorders | 11 ( 73.3) | 26 ( 81.3) | 37 ( 78.7) |
| Hypophosphataemia | 5 ( 33.3) | 14 ( 43.8) | 19 ( 40.4) |
| Hypokalaemia | 2 ( 13.3) | 15 ( 46.9) | 17 ( 36.2) |
| Hypocalcaemia | 4 ( 26.7) | 9 ( 28.1) | 13 ( 27.7) |
| Hypoalbuminaemia | 1 ( 6.7) | 9 ( 28.1) | 10 ( 21.3) |
| Decreased appetite | 4 ( 26.7) | 6 ( 18.8) | 10 ( 21.3) |
| Hypomagnesaemia | 5 ( 33.3) | 7 ( 21.9) | 12 ( 25.5) |
| Hyperglycaemia | 1 ( 6.7) | 7 ( 21.9) | 8 ( 17.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Hyponatraemia | 1 ( 6.7) | 7 ( 21.9) | 8 ( 17.0) |
| Hyperuricaemia | 3 ( 20.0) | 1 ( 3.1) | 4 ( 8.5) |
| Hyperkalaemia | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Hypermagnesaemia | 2 ( 13.3) | 0 | 2 ( 4.3) |
| Musculoskeletal and connective tissue disorders | 11 ( 73.3) | 26 ( 81.3) | 37 ( 78.7) |
| Arthralgia | 4 ( 26.7) | 12 ( 37.5) | 16 ( 34.0) |
| Back pain | 4 ( 26.7) | 5 ( 15.6) | 9 ( 19.1) |
| Musculoskeletal pain | 3 ( 20.0) | 4 ( 12.5) | 7 ( 14.9) |
| Musculoskeletal chest pain | 2 ( 13.3) | 3 ( 9.4) | 5 ( 10.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Date/time of run: 02OCT2020 15:23
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Bone pain | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Myalgia | 2 ( 13.3) | 3 ( 9.4) | 5 ( 10.6) |
| Pain in extremity | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Muscular weakness | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Musculoskeletal discomfort | 0 | 4 ( 12.5) | 4 ( 8.5) |
| Neck pain | 2 ( 13.3) | 0 | 2 ( 4.3) |
| Immune system disorders | 7 ( 46.7) | 30 ( 93.8) | 37 ( 78.7) |
| Cytokine release syndrome | 6 ( 40.0) | 30 ( 93.8) | 36 ( 76.6) |
| Hypogammaglobulinaemia | 4 ( 26.7) | 3 ( 9.4) | 7 ( 14.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Infections and infestations | 10 ( 66.7) | 24 ( 75.0) | 34 ( 72.3) |
| Upper respiratory tract infection | 5 ( 33.3) | 10 ( 31.3) | 15 ( 31.9) |
| Urinary tract infection | 2 ( 13.3) | 7 ( 21.9) | 9 ( 19.1) |
| Respiratory syncytial virus infection | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Lung infection | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Nervous system disorders | 9 ( 60.0) | 22 ( 68.8) | 31 ( 66.0) |
| Headache | 4 ( 26.7) | 12 ( 37.5) | 16 ( 34.0) |
| Dizziness | 3 ( 20.0) | 7 ( 21.9) | 10 ( 21.3) |
| Neurotoxicity | 1 ( 6.7) | 6 ( 18.8) | 7 ( 14.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Syncope | 0 | 4 ( 12.5) | 4 ( 8.5) |
| Tremor | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Respiratory, thoracic and mediastinal disorders | 7 ( 46.7) | 25 ( 78.1) | 32 ( 68.1) |
| Cough | 4 ( 26.7) | 13 ( 40.6) | 17 ( 36.2) |
| Nasal congestion | 2 ( 13.3) | 10 ( 31.3) | 12 ( 25.5) |
| Dyspnoea | 2 ( 13.3) | 6 ( 18.8) | 8 ( 17.0) |
| Productive cough | 1 ( 6.7) | 5 ( 15.6) | 6 ( 12.8) |
| Hypoxia | 0 | 4 ( 12.5) | 4 ( 8.5) |
| Epistaxis | 0 | 5 ( 15.6) | 5 ( 10.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Dyspnoea exertional | 2 ( 13.3) | 3 ( 9.4) | 5 ( 10.6) |
| Oropharyngeal pain | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Investigations | 7 ( 46.7) | 22 ( 68.8) | 29 ( 61.7) |
| Blood alkaline phosphatase increased | 1 ( 6.7) | 6 ( 18.8) | 7 ( 14.9) |
| Transaminases increased | 3 ( 20.0) | 5 ( 15.6) | 8 ( 17.0) |
| Blood creatinine increased | 2 ( 13.3) | 4 ( 12.5) | 6 ( 12.8) |
| Weight decreased | 0 | 5 ( 15.6) | 5 ( 10.6) |
| Weight increased | 1 ( 6.7) | 4 ( 12.5) | 5 ( 10.6) |
| Skin and subcutaneous tissue disorders | 6 ( 40.0) | 15 ( 46.9) | 21 ( 44.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Pruritus | 2 ( 13.3) | 2 ( 6.3) | 4 ( 8.5) |
| Rash | 1 ( 6.7) | 4 ( 12.5) | 5 ( 10.6) |
| Rash maculo-papular | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Skin disorder | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Vascular disorders | 5 ( 33.3) | 15 ( 46.9) | 20 ( 42.6) |
| Hypertension | 1 ( 6.7) | 7 ( 21.9) | 8 ( 17.0) |
| Hypotension | 3 ( 20.0) | 2 ( 6.3) | 5 ( 10.6) |
| Cardiac disorders | 4 ( 26.7) | 11 ( 34.4) | 15 ( 31.9) |
| Tachycardia | 1 ( 6.7) | 4 ( 12.5) | 5 ( 10.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=15)<br>n (%) | 450x10^6<br>(N=32)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
| Sinus tachycardia | 2 ( 13.3) | 2 ( 6.3) | 4 ( 8.5) |
| Atrial fibrillation | 0 | 4 ( 12.5) | 4 ( 8.5) |
| Psychiatric disorders | 4 ( 26.7) | 11 ( 34.4) | 15 ( 31.9) |
| Insomnia | 3 ( 20.0) | 5 ( 15.6) | 8 ( 17.0) |
| Injury, poisoning and procedural complications | 4 ( 26.7) | 9 ( 28.1) | 13 ( 27.7) |
| Arthropod bite | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Procedural pain | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Eye disorders | 3 ( 20.0) | 8 ( 25.0) | 11 ( 23.4) |
| Lacrimation increased | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Renal and urinary disorders | 2 ( 13.3) | 7 ( 21.9) | 9 ( 19.1) |
| Ear and labyrinth disorders | 3 ( 20.0) | 5 ( 15.6) | 8 ( 17.0) |
| Ear pain | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 6.7) | 6 ( 18.8) | 7 ( 14.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one AE | 3 (100.0) | 6 (100.0) | 9 (100.0) |
| Blood and lymphatic system disorders | 2 ( 66.7) | 5 ( 83.3) | 7 ( 77.8) |
| Neutropenia | 2 ( 66.7) | 5 ( 83.3) | 7 ( 77.8) |
| Anaemia | 1 ( 33.3) | 5 ( 83.3) | 6 ( 66.7) |
| Thrombocytopenia | 1 ( 33.3) | 5 ( 83.3) | 6 ( 66.7) |
| Leukopenia | 2 ( 66.7) | 4 ( 66.7) | 6 ( 66.7) |
| Lymphopenia | 0 | 3 ( 50.0) | 3 ( 33.3) |
| Febrile neutropenia | 0 | 2 ( 33.3) | 2 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Gastrointestinal disorders | 3 (100.0) | 6 (100.0) | 9 (100.0) |
| Nausea | 1 ( 33.3) | 6 (100.0) | 7 ( 77.8) |
| Diarrhoea | 2 ( 66.7) | 5 ( 83.3) | 7 ( 77.8) |
| Vomiting | 1 ( 33.3) | 3 ( 50.0) | 4 ( 44.4) |
| Constipation | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Abdominal pain | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Abdominal discomfort | 0 | 0 | 0 |
| Dry mouth | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Dyspepsia | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Stomatitis | 0 | 0 | 0 |
| General disorders and administration site conditions | 3 (100.0) | 6 (100.0) | 9 (100.0) |
| Fatigue | 2 ( 66.7) | 5 ( 83.3) | 7 ( 77.8) |
| Pyrexia | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |
| Oedema peripheral | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |
| Chills | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |
| Asthenia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Pain | 1 ( 33.3) | 0 | 1 ( 11.1) |
| General physical health deterioration | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Gait disturbance | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 3 (100.0) | 6 (100.0) | 9 (100.0) |
| Hypophosphataemia | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Hypokalaemia | 1 ( 33.3) | 4 ( 66.7) | 5 ( 55.6) |
| Hypocalcaemia | 0 | 4 ( 66.7) | 4 ( 44.4) |
| Hypoalbuminaemia | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |
| Decreased appetite | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Hypomagnesaemia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Hyperglycaemia | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Hyponatraemia | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Hyperuricaemia | 0 | 0 | 0 |
| Hyperkalaemia | 0 | 0 | 0 |
| Hypermagnesaemia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Musculoskeletal and connective tissue disorders | 3 (100.0) | 5 ( 83.3) | 8 ( 88.9) |
| Arthralgia | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |
| Back pain | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Musculoskeletal pain | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Musculoskeletal chest pain | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Bone pain | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Myalgia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Pain in extremity | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Muscular weakness | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Musculoskeletal discomfort | 0 | 0 | 0 |
| Neck pain | 0 | 0 | 0 |
| Immune system disorders | 1 ( 33.3) | 5 ( 83.3) | 6 ( 66.7) |
| Cytokine release syndrome | 1 ( 33.3) | 5 ( 83.3) | 6 ( 66.7) |
| Hypogammaglobulinaemia | 0 | 2 ( 33.3) | 2 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Infections and infestations | 3 (100.0) | 5 ( 83.3) | 8 ( 88.9) |
| Upper respiratory tract infection | 3 (100.0) | 3 ( 50.0) | 6 ( 66.7) |
| Urinary tract infection | 0 | 0 | 0 |
| Respiratory syncytial virus infection | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Lung infection | 2 ( 66.7) | 0 | 2 ( 22.2) |
| Nervous system disorders | 3 (100.0) | 6 (100.0) | 9 (100.0) |
| Headache | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Dizziness | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Neurotoxicity | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Syncope | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Tremor | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Respiratory, thoracic and mediastinal disorders | 3 (100.0) | 5 ( 83.3) | 8 ( 88.9) |
| Cough | 3 (100.0) | 4 ( 66.7) | 7 ( 77.8) |
| Nasal congestion | 2 ( 66.7) | 1 ( 16.7) | 3 ( 33.3) |
| Dyspnoea | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Productive cough | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Hypoxia | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Epistaxis | 1 ( 33.3) | 0 | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Dyspnoea exertional | 0 | 0 | 0 |
| Oropharyngeal pain | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Investigations | 1 ( 33.3) | 3 ( 50.0) | 4 ( 44.4) |
| Blood alkaline phosphatase increased | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Transaminases increased | 0 | 0 | 0 |
| Blood creatinine increased | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Weight decreased | 0 | 0 | 0 |
| Weight increased | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Pruritus | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Rash | 0 | 0 | 0 |
| Rash maculo-papular | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Skin disorder | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Vascular disorders | 2 ( 66.7) | 4 ( 66.7) | 6 ( 66.7) |
| Hypertension | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Hypotension | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Cardiac disorders | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |
| Tachycardia | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Sinus tachycardia | 2 ( 66.7) | 1 ( 16.7) | 3 ( 33.3) |
| Atrial fibrillation | 0 | 0 | 0 |
| Psychiatric disorders | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Insomnia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Injury, poisoning and procedural complications | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Arthropod bite | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Procedural pain | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Eye disorders | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Lacrimation increased | 1 ( 33.3) | 0 | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Renal and urinary disorders | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Ear and labyrinth disorders | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Ear pain | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 ( 66.7) | 1 ( 16.7) | 3 ( 33.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one AE | 4 (100.0) | 16 (100.0) | 20 (100.0) |
| Blood and lymphatic system disorders | 4 (100.0) | 15 ( 93.8) | 19 ( 95.0) |
| Neutropenia | 4 (100.0) | 14 ( 87.5) | 18 ( 90.0) |
| Anaemia | 4 (100.0) | 14 ( 87.5) | 18 ( 90.0) |
| Thrombocytopenia | 3 ( 75.0) | 11 ( 68.8) | 14 ( 70.0) |
| Leukopenia | 4 (100.0) | 10 ( 62.5) | 14 ( 70.0) |
| Lymphopenia | 2 ( 50.0) | 6 ( 37.5) | 8 ( 40.0) |
| Febrile neutropenia | 1 ( 25.0) | 3 ( 18.8) | 4 ( 20.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Gastrointestinal disorders | 4 (100.0) | 14 ( 87.5) | 18 ( 90.0) |
| Nausea | 3 ( 75.0) | 11 ( 68.8) | 14 ( 70.0) |
| Diarrhoea | 1 ( 25.0) | 10 ( 62.5) | 11 ( 55.0) |
| Vomiting | 1 ( 25.0) | 8 ( 50.0) | 9 ( 45.0) |
| Constipation | 1 ( 25.0) | 3 ( 18.8) | 4 ( 20.0) |
| Abdominal pain | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Abdominal discomfort | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Dry mouth | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Dyspepsia | 2 ( 50.0) | 0 | 2 ( 10.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Stomatitis | 0 | 0 | 0 |
| General disorders and administration site conditions | 3 ( 75.0) | 15 ( 93.8) | 18 ( 90.0) |
| Fatigue | 1 ( 25.0) | 8 ( 50.0) | 9 ( 45.0) |
| Pyrexia | 2 ( 50.0) | 9 ( 56.3) | 11 ( 55.0) |
| Oedema peripheral | 0 | 5 ( 31.3) | 5 ( 25.0) |
| Chills | 2 ( 50.0) | 4 ( 25.0) | 6 ( 30.0) |
| Asthenia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Pain | 0 | 3 ( 18.8) | 3 ( 15.0) |
| General physical health deterioration | 1 ( 25.0) | 0 | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Gait disturbance | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Metabolism and nutrition disorders | 3 ( 75.0) | 12 ( 75.0) | 15 ( 75.0) |
| Hypophosphataemia | 2 ( 50.0) | 7 ( 43.8) | 9 ( 45.0) |
| Hypokalaemia | 0 | 7 ( 43.8) | 7 ( 35.0) |
| Hypocalcaemia | 1 ( 25.0) | 4 ( 25.0) | 5 ( 25.0) |
| Hypoalbuminaemia | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Decreased appetite | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Hypomagnesaemia | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |
| Hyperglycaemia | 0 | 2 ( 12.5) | 2 ( 10.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Hyponatraemia | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Hyperuricaemia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Hyperkalaemia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Hypermagnesaemia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Musculoskeletal and connective tissue disorders | 3 ( 75.0) | 15 ( 93.8) | 18 ( 90.0) |
| Arthralgia | 1 ( 25.0) | 8 ( 50.0) | 9 ( 45.0) |
| Back pain | 1 ( 25.0) | 4 ( 25.0) | 5 ( 25.0) |
| Musculoskeletal pain | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Musculoskeletal chest pain | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Bone pain | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Myalgia | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Pain in extremity | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Muscular weakness | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Musculoskeletal discomfort | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Neck pain | 0 | 0 | 0 |
| Immune system disorders | 1 ( 25.0) | 15 ( 93.8) | 16 ( 80.0) |
| Cytokine release syndrome | 1 ( 25.0) | 15 ( 93.8) | 16 ( 80.0) |
| Hypogammaglobulinaemia | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Infections and infestations | 3 ( 75.0) | 13 ( 81.3) | 16 ( 80.0) |
| Upper respiratory tract infection | 2 ( 50.0) | 9 ( 56.3) | 11 ( 55.0) |
| Urinary tract infection | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Respiratory syncytial virus infection | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Lung infection | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Nervous system disorders | 2 ( 50.0) | 12 ( 75.0) | 14 ( 70.0) |
| Headache | 2 ( 50.0) | 8 ( 50.0) | 10 ( 50.0) |
| Dizziness | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Neurotoxicity | 0 | 3 ( 18.8) | 3 ( 15.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Syncope | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Tremor | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 1 ( 25.0) | 13 ( 81.3) | 14 ( 70.0) |
| Cough | 1 ( 25.0) | 8 ( 50.0) | 9 ( 45.0) |
| Nasal congestion | 0 | 6 ( 37.5) | 6 ( 30.0) |
| Dyspnoea | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Productive cough | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Hypoxia | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Epistaxis | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Dyspnoea exertional | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Oropharyngeal pain | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Investigations | 2 ( 50.0) | 9 ( 56.3) | 11 ( 55.0) |
| Blood alkaline phosphatase increased | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Transaminases increased | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Blood creatinine increased | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Weight decreased | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Weight increased | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Skin and subcutaneous tissue disorders | 2 ( 50.0) | 6 ( 37.5) | 8 ( 40.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Pruritus | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Rash | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Rash maculo-papular | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Skin disorder | 0 | 0 | 0 |
| Vascular disorders | 1 ( 25.0) | 9 ( 56.3) | 10 ( 50.0) |
| Hypertension | 1 ( 25.0) | 6 ( 37.5) | 7 ( 35.0) |
| Hypotension | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Cardiac disorders | 1 ( 25.0) | 5 ( 31.3) | 6 ( 30.0) |
| Tachycardia | 0 | 2 ( 12.5) | 2 ( 10.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Sinus tachycardia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Atrial fibrillation | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Psychiatric disorders | 1 ( 25.0) | 4 ( 25.0) | 5 ( 25.0) |
| Insomnia | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Injury, poisoning and procedural complications | 1 ( 25.0) | 6 ( 37.5) | 7 ( 35.0) |
| Arthropod bite | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Procedural pain | 0 | 0 | 0 |
| Eye disorders | 1 ( 25.0) | 3 ( 18.8) | 4 ( 20.0) |
| Lacrimation increased | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Renal and urinary disorders | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Ear and labyrinth disorders | 1 ( 25.0) | 4 ( 25.0) | 5 ( 25.0) |
| Ear pain | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 25.0) | 4 ( 25.0) | 5 ( 25.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one AE | 14 (100.0) | 22 (100.0) | 36 (100.0) |
| Blood and lymphatic system disorders | 13 ( 92.9) | 21 ( 95.5) | 34 ( 94.4) |
| Neutropenia | 12 ( 85.7) | 21 ( 95.5) | 33 ( 91.7) |
| Anaemia | 8 ( 57.1) | 17 ( 77.3) | 25 ( 69.4) |
| Thrombocytopenia | 10 ( 71.4) | 18 ( 81.8) | 28 ( 77.8) |
| Leukopenia | 8 ( 57.1) | 14 ( 63.6) | 22 ( 61.1) |
| Lymphopenia | 6 ( 42.9) | 13 ( 59.1) | 19 ( 52.8) |
| Febrile neutropenia | 2 ( 14.3) | 3 ( 13.6) | 5 ( 13.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Gastrointestinal disorders | 12 ( 85.7) | 22 (100.0) | 34 ( 94.4) |
| Nausea | 6 ( 42.9) | 16 ( 72.7) | 22 ( 61.1) |
| Diarrhoea | 3 ( 21.4) | 8 ( 36.4) | 11 ( 30.6) |
| Vomiting | 2 ( 14.3) | 6 ( 27.3) | 8 ( 22.2) |
| Constipation | 2 ( 14.3) | 10 ( 45.5) | 12 ( 33.3) |
| Abdominal pain | 0 | 7 ( 31.8) | 7 ( 19.4) |
| Abdominal discomfort | 0 | 3 ( 13.6) | 3 ( 8.3) |
| Dry mouth | 2 ( 14.3) | 1 ( 4.5) | 3 ( 8.3) |
| Dyspepsia | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Stomatitis | 2 ( 14.3) | 1 ( 4.5) | 3 ( 8.3) |
| General disorders and administration site conditions | 12 ( 85.7) | 19 ( 86.4) | 31 ( 86.1) |
| Fatigue | 8 ( 57.1) | 14 ( 63.6) | 22 ( 61.1) |
| Pyrexia | 5 ( 35.7) | 6 ( 27.3) | 11 ( 30.6) |
| Oedema peripheral | 5 ( 35.7) | 10 ( 45.5) | 15 ( 41.7) |
| Chills | 3 ( 21.4) | 6 ( 27.3) | 9 ( 25.0) |
| Asthenia | 1 ( 7.1) | 4 ( 18.2) | 5 ( 13.9) |
| Pain | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| General physical health deterioration | 1 ( 7.1) | 2 ( 9.1) | 3 ( 8.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Gait disturbance | 2 ( 14.3) | 0 | 2 ( 5.6) |
| Metabolism and nutrition disorders | 11 ( 78.6) | 20 ( 90.9) | 31 ( 86.1) |
| Hypophosphataemia | 5 ( 35.7) | 9 ( 40.9) | 14 ( 38.9) |
| Hypokalaemia | 3 ( 21.4) | 12 ( 54.5) | 15 ( 41.7) |
| Hypocalcaemia | 3 ( 21.4) | 9 ( 40.9) | 12 ( 33.3) |
| Hypoalbuminaemia | 3 ( 21.4) | 8 ( 36.4) | 11 ( 30.6) |
| Decreased appetite | 6 ( 42.9) | 4 ( 18.2) | 10 ( 27.8) |
| Hypomagnesaemia | 4 ( 28.6) | 7 ( 31.8) | 11 ( 30.6) |
| Hyperglycaemia | 2 ( 14.3) | 7 ( 31.8) | 9 ( 25.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Hyponatraemia | 2 ( 14.3) | 4 ( 18.2) | 6 ( 16.7) |
| Hyperuricaemia | 2 ( 14.3) | 1 ( 4.5) | 3 ( 8.3) |
| Hyperkalaemia | 2 ( 14.3) | 0 | 2 ( 5.6) |
| Hypermagnesaemia | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| Musculoskeletal and connective tissue disorders | 11 ( 78.6) | 16 ( 72.7) | 27 ( 75.0) |
| Arthralgia | 5 ( 35.7) | 7 ( 31.8) | 12 ( 33.3) |
| Back pain | 5 ( 35.7) | 3 ( 13.6) | 8 ( 22.2) |
| Musculoskeletal pain | 3 ( 21.4) | 3 ( 13.6) | 6 ( 16.7) |
| Musculoskeletal chest pain | 2 ( 14.3) | 3 ( 13.6) | 5 ( 13.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Bone pain | 2 ( 14.3) | 3 ( 13.6) | 5 ( 13.9) |
| Myalgia | 1 ( 7.1) | 2 ( 9.1) | 3 ( 8.3) |
| Pain in extremity | 0 | 3 ( 13.6) | 3 ( 8.3) |
| Muscular weakness | 2 ( 14.3) | 1 ( 4.5) | 3 ( 8.3) |
| Musculoskeletal discomfort | 0 | 1 ( 4.5) | 1 ( 2.8) |
| Neck pain | 2 ( 14.3) | 0 | 2 ( 5.6) |
| Immune system disorders | 7 ( 50.0) | 20 ( 90.9) | 27 ( 75.0) |
| Cytokine release syndrome | 6 ( 42.9) | 20 ( 90.9) | 26 ( 72.2) |
| Hypogammaglobulinaemia | 4 ( 28.6) | 4 ( 18.2) | 8 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Infections and infestations | 10 ( 71.4) | 16 ( 72.7) | 26 ( 72.2) |
| Upper respiratory tract infection | 6 ( 42.9) | 4 ( 18.2) | 10 ( 27.8) |
| Urinary tract infection | 2 ( 14.3) | 3 ( 13.6) | 5 ( 13.9) |
| Respiratory syncytial virus infection | 2 ( 14.3) | 1 ( 4.5) | 3 ( 8.3) |
| Lung infection | 2 ( 14.3) | 0 | 2 ( 5.6) |
| Nervous system disorders | 10 ( 71.4) | 16 ( 72.7) | 26 ( 72.2) |
| Headache | 3 ( 21.4) | 6 ( 27.3) | 9 ( 25.0) |
| Dizziness | 4 ( 28.6) | 5 ( 22.7) | 9 ( 25.0) |
| Neurotoxicity | 1 ( 7.1) | 3 ( 13.6) | 4 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Syncope | 1 ( 7.1) | 2 ( 9.1) | 3 ( 8.3) |
| Tremor | 1 ( 7.1) | 4 ( 18.2) | 5 ( 13.9) |
| Respiratory, thoracic and mediastinal disorders | 9 ( 64.3) | 17 ( 77.3) | 26 ( 72.2) |
| Cough | 6 ( 42.9) | 9 ( 40.9) | 15 ( 41.7) |
| Nasal congestion | 4 ( 28.6) | 5 ( 22.7) | 9 ( 25.0) |
| Dyspnoea | 3 ( 21.4) | 3 ( 13.6) | 6 ( 16.7) |
| Productive cough | 2 ( 14.3) | 4 ( 18.2) | 6 ( 16.7) |
| Hypoxia | 1 ( 7.1) | 4 ( 18.2) | 5 ( 13.9) |
| Epistaxis | 1 ( 7.1) | 4 ( 18.2) | 5 ( 13.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Dyspnoea exertional | 2 ( 14.3) | 2 ( 9.1) | 4 ( 11.1) |
| Oropharyngeal pain | 0 | 1 ( 4.5) | 1 ( 2.8) |
| Investigations | 6 ( 42.9) | 16 ( 72.7) | 22 ( 61.1) |
| Blood alkaline phosphatase increased | 1 ( 7.1) | 5 ( 22.7) | 6 ( 16.7) |
| Transaminases increased | 2 ( 14.3) | 3 ( 13.6) | 5 ( 13.9) |
| Blood creatinine increased | 1 ( 7.1) | 3 ( 13.6) | 4 ( 11.1) |
| Weight decreased | 0 | 2 ( 9.1) | 2 ( 5.6) |
| Weight increased | 1 ( 7.1) | 2 ( 9.1) | 3 ( 8.3) |
| Skin and subcutaneous tissue disorders | 6 ( 42.9) | 12 ( 54.5) | 18 ( 50.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Pruritus | 3 ( 21.4) | 3 ( 13.6) | 6 ( 16.7) |
| Rash | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| Rash maculo-papular | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Skin disorder | 2 ( 14.3) | 0 | 2 ( 5.6) |
| Vascular disorders | 6 ( 42.9) | 10 ( 45.5) | 16 ( 44.4) |
| Hypertension | 1 ( 7.1) | 2 ( 9.1) | 3 ( 8.3) |
| Hypotension | 5 ( 35.7) | 3 ( 13.6) | 8 ( 22.2) |
| Cardiac disorders | 5 ( 35.7) | 9 ( 40.9) | 14 ( 38.9) |
| Tachycardia | 2 ( 14.3) | 4 ( 18.2) | 6 ( 16.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=14)<br>n (%) | 450x10^6<br>(N=22)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
| Sinus tachycardia | 4 ( 28.6) | 2 ( 9.1) | 6 ( 16.7) |
| Atrial fibrillation | 0 | 3 ( 13.6) | 3 ( 8.3) |
| Psychiatric disorders | 4 ( 28.6) | 9 ( 40.9) | 13 ( 36.1) |
| Insomnia | 2 ( 14.3) | 4 ( 18.2) | 6 ( 16.7) |
| Injury, poisoning and procedural complications | 5 ( 35.7) | 5 ( 22.7) | 10 ( 27.8) |
| Arthropod bite | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Procedural pain | 2 ( 14.3) | 0 | 2 ( 5.6) |
| Eye disorders | 3 ( 21.4) | 6 ( 27.3) | 9 ( 25.0) |
| Lacrimation increased | 2 ( 14.3) | 0 | 2 ( 5.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.1.3c
Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 10% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Renal and urinary disorders | 2 ( 14.3) | 6 ( 27.3) | 8 ( 22.2) |
| Ear and labyrinth disorders | 2 ( 14.3) | 3 ( 13.6) | 5 ( 13.9) |
| Ear pain | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 ( 14.3) | 3 ( 13.6) | 5 ( 13.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 10% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
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### 13.4.3.1 UE Grad 1 und 2 nach SOC und PT

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE [b] | 10 (100.0) | 25 (100.0) | 35 (100.0) |
| Gastrointestinal disorders | 8 ( 80.0) | 23 ( 92.0) | 31 ( 88.6) |
| Nausea | 5 ( 50.0) | 17 ( 68.0) | 22 ( 62.9) |
| Diarrhoea | 3 ( 30.0) | 10 ( 40.0) | 13 ( 37.1) |
| Constipation | 1 ( 10.0) | 9 ( 36.0) | 10 ( 28.6) |
| Vomiting | 2 ( 20.0) | 7 ( 28.0) | 9 ( 25.7) |
| Abdominal pain | 0 | 6 ( 24.0) | 6 ( 17.1) |
| Abdominal discomfort | 0 | 3 ( 12.0) | 3 ( 8.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Abdominal distension | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Dry mouth | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Dyspepsia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Stomatitis | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Dysphagia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Flatulence | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Gastrooesophageal reflux disease | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Pancreatitis | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Abdominal pain lower | 1 ( 10.0) | 0 | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Abdominal tenderness | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Gingival swelling | 0 | 0 | 0 |
| Haemorrhoids | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Inguinal hernia | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Retching | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Toothache | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Blood and lymphatic system disorders | 10 (100.0) | 21 ( 84.0) | 31 ( 88.6) |
| Neutropenia | 9 ( 90.0) | 19 ( 76.0) | 28 ( 80.0) |
| Anaemia | 6 ( 60.0) | 15 ( 60.0) | 21 ( 60.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Thrombocytopenia | 5 ( 50.0) | 14 ( 56.0) | 19 ( 54.3) |
| Leukopenia | 7 ( 70.0) | 10 ( 40.0) | 17 ( 48.6) |
| Lymphopenia | 3 ( 30.0) | 7 ( 28.0) | 10 ( 28.6) |
| Febrile neutropenia | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Erythropenia | 1 ( 10.0) | 0 | 1 ( 2.9) |
| General disorders and administration site conditions | 7 ( 70.0) | 22 ( 88.0) | 29 ( 82.9) |
| Fatigue | 5 ( 50.0) | 13 ( 52.0) | 18 ( 51.4) |
| Pyrexia | 4 ( 40.0) | 11 ( 44.0) | 15 ( 42.9) |
| Oedema peripheral | 2 ( 20.0) | 7 ( 28.0) | 9 ( 25.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Chills | 2 ( 20.0) | 6 ( 24.0) | 8 ( 22.9) |
| Pain | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Asthenia | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Chest discomfort | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Gait disturbance | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Malaise | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Influenza like illness | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Mass | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Oedema | 0 | 2 ( 8.0) | 2 ( 5.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Chest pain | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Musculoskeletal and connective tissue disorders | 6 ( 60.0) | 20 ( 80.0) | 26 ( 74.3) |
| Arthralgia | 3 ( 30.0) | 13 ( 52.0) | 16 ( 45.7) |
| Back pain | 4 ( 40.0) | 3 ( 12.0) | 7 ( 20.0) |
| Musculoskeletal pain | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |
| Bone pain | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Musculoskeletal chest pain | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |
| Myalgia | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Pain in extremity | 0 | 4 ( 16.0) | 4 ( 11.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Muscular weakness | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Musculoskeletal discomfort | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Muscle spasms | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Neck pain | 2 ( 20.0) | 0 | 2 ( 5.7) |
| Tendonitis | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Metabolism and nutrition disorders | 7 ( 70.0) | 21 ( 84.0) | 28 ( 80.0) |
| Hypokalaemia | 2 ( 20.0) | 11 ( 44.0) | 13 ( 37.1) |
| Hypophosphataemia | 5 ( 50.0) | 8 ( 32.0) | 13 ( 37.1) |
| Hypocalcaemia | 3 ( 30.0) | 6 ( 24.0) | 9 ( 25.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Hypoalbuminaemia | 3 ( 30.0) | 4 ( 16.0) | 7 ( 20.0) |
| Decreased appetite | 3 ( 30.0) | 4 ( 16.0) | 7 ( 20.0) |
| Hypomagnesaemia | 2 ( 20.0) | 5 ( 20.0) | 7 ( 20.0) |
| Hyperglycaemia | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |
| Hyponatraemia | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Hypernatraemia | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Hyperuricaemia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Fluid overload | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Hyperkalaemia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=10)<br>n (%) | 450x10^6<br>(N=25)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
| Dehydration | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Failure to thrive | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Hypermagnesaemia | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Hypoglycaemia | 0 | 0 | 0 |
| Immune system disorders | 4 ( 40.0) | 23 ( 92.0) | 27 ( 77.1) |
| Cytokine release syndrome | 4 ( 40.0) | 23 ( 92.0) | 27 ( 77.1) |
| Hypogammaglobulinaemia | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |
| Infections and infestations | 8 ( 80.0) | 18 ( 72.0) | 26 ( 74.3) |
| Upper respiratory tract infection | 5 ( 50.0) | 9 ( 36.0) | 14 ( 40.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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Missing subgroup categories are not presented.
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| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Urinary tract infection | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |
| Respiratory syncytial virus infection | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Sinusitis | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Influenza | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Nasopharyngitis | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Bronchitis | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Clostridium difficile infection | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Ear infection | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Folliculitis | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Lung infection | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Parvovirus infection | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Pneumonia | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Rhinovirus infection | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Skin infection | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Acarodermatitis | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Anal abscess | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Hordeolum | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Rhinitis | 1 ( 10.0) | 0 | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Tooth infection | 0 | 0 | 0 |
| Vulvovaginal mycotic infection | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Nervous system disorders | 8 ( 80.0) | 18 ( 72.0) | 26 ( 74.3) |
| Headache | 2 ( 20.0) | 10 ( 40.0) | 12 ( 34.3) |
| Dizziness | 4 ( 40.0) | 5 ( 20.0) | 9 ( 25.7) |
| Neurotoxicity | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |
| Tremor | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Hypoaesthesia | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Disturbance in attention | 0 | 1 ( 4.0) | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Dysgeusia | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Paraesthesia | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Somnolence | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Syncope | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Aphasia | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Dysgraphia | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Facial paralysis | 0 | 0 | 0 |
| Haemorrhage intracranial | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Neuropathy peripheral | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 7 ( 70.0) | 18 ( 72.0) | 25 ( 71.4) |
| Cough | 4 ( 40.0) | 10 ( 40.0) | 14 ( 40.0) |
| Nasal congestion | 2 ( 20.0) | 10 ( 40.0) | 12 ( 34.3) |
| Dyspnoea | 3 ( 30.0) | 5 ( 20.0) | 8 ( 22.9) |
| Productive cough | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Epistaxis | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Oropharyngeal pain | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Dyspnoea exertional | 2 ( 20.0) | 1 ( 4.0) | 3 ( 8.6) |
| Hypoxia | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Rhinorrhoea | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Upper-airway cough syndrome | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Wheezing | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Pleural effusion | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Pneumonitis | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Pulmonary oedema | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Rales | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Rhinitis allergic | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Sinus congestion | 0 | 1 ( 4.0) | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=10)<br>n (%) | 450x10^6<br>(N=25)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
| Throat tightness | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Investigations | 3 ( 30.0) | 14 ( 56.0) | 17 ( 48.6) |
| Blood alkaline phosphatase increased | 0 | 4 ( 16.0) | 4 ( 11.4) |
| Transaminases increased | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |
| Blood creatinine increased | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Weight decreased | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Weight increased | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |
| Blood bilirubin increased | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Activated partial thromboplastin time prolonged | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Aspartate aminotransferase increased | 0 | 0 | 0 |
| International normalised ratio increased | 0 | 0 | 0 |
| Heart rate irregular | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 4 ( 40.0) | 13 ( 52.0) | 17 ( 48.6) |
| Pruritus | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Rash | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |
| Erythema | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Alopecia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Dry skin | 0 | 1 ( 4.0) | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Ecchymosis | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Rash maculo-papular | 0 | 0 | 0 |
| Skin disorder | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Skin lesion | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Blister | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Vascular disorders | 5 ( 50.0) | 8 ( 32.0) | 13 ( 37.1) |
| Hypotension | 4 ( 40.0) | 2 ( 8.0) | 6 ( 17.1) |
| Hypertension | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Hot flush | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=10)<br>n (%) | 450x10^6<br>(N=25)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
| Deep vein thrombosis | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Cardiac disorders | 4 ( 40.0) | 10 ( 40.0) | 14 ( 40.0) |
| Tachycardia | 2 ( 20.0) | 5 ( 20.0) | 7 ( 20.0) |
| Sinus tachycardia | 3 ( 30.0) | 1 ( 4.0) | 4 ( 11.4) |
| Atrial fibrillation | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Bradycardia | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Ventricular arrhythmia | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Sinus bradycardia | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Ventricular extrasystoles | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Ventricular tachycardia | 0 | 0 | 0 |
| Psychiatric disorders | 4 ( 40.0) | 8 ( 32.0) | 12 ( 34.3) |
| Insomnia | 2 ( 20.0) | 5 ( 20.0) | 7 ( 20.0) |
| Confusional state | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Anxiety | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Depression | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Delirium | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Injury, poisoning and procedural complications | 2 ( 20.0) | 7 ( 28.0) | 9 ( 25.7) |
| Arthropod bite | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=10)<br>n (%) | 450x10^6<br>(N=25)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
| Contusion | 0 | 0 | 0 |
| Fall | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Procedural pain | 2 ( 20.0) | 0 | 2 ( 5.7) |
| Skin laceration | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Infusion related reaction | 0 | 0 | 0 |
| Spinal fracture | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Eye disorders | 3 ( 30.0) | 6 ( 24.0) | 9 ( 25.7) |
| Lacrimation increased | 2 ( 20.0) | 1 ( 4.0) | 3 ( 8.6) |
| Visual impairment | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Dry eye | 0 | 0 | 0 |
| Vision blurred | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Ear and labyrinth disorders | 2 ( 20.0) | 4 ( 16.0) | 6 ( 17.1) |
| Ear pain | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Ear congestion | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Tinnitus | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Deafness | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Renal and urinary disorders | 2 ( 20.0) | 4 ( 16.0) | 6 ( 17.1) |
| Dysuria | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Pollakiuria | 0 | 0 | 0 |
| Haematuria | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Urinary retention | 0 | 0 | 0 |
| Nephrolithiasis | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Proteinuria | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Bowen's disease | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Plasmacytoma | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Endocrine disorders | 0 | 1 ( 4.0) | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Reproductive system and breast disorders | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Vaginal discharge | 1 ( 10.0) | 0 | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE [b] | 8 (100.0) | 13 (100.0) | 21 (100.0) |
| Gastrointestinal disorders | 8 (100.0) | 13 (100.0) | 21 (100.0) |
| Nausea | 4 ( 50.0) | 10 ( 76.9) | 14 ( 66.7) |
| Diarrhoea | 1 ( 12.5) | 8 ( 61.5) | 9 ( 42.9) |
| Constipation | 2 ( 25.0) | 4 ( 30.8) | 6 ( 28.6) |
| Vomiting | 1 ( 12.5) | 6 ( 46.2) | 7 ( 33.3) |
| Abdominal pain | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Abdominal discomfort | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Abdominal distension | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Dry mouth | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Dyspepsia | 2 ( 25.0) | 0 | 2 ( 9.5) |
| Stomatitis | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Dysphagia | 0 | 0 | 0 |
| Flatulence | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Pancreatitis | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Abdominal pain lower | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Abdominal tenderness | 0 | 0 | 0 |
| Gingival swelling | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Haemorrhoids | 0 | 0 | 0 |
| Inguinal hernia | 0 | 0 | 0 |
| Retching | 0 | 0 | 0 |
| Toothache | 0 | 0 | 0 |
| Blood and lymphatic system disorders | 6 ( 75.0) | 12 ( 92.3) | 18 ( 85.7) |
| Neutropenia | 5 ( 62.5) | 12 ( 92.3) | 17 ( 81.0) |
| Anaemia | 4 ( 50.0) | 12 ( 92.3) | 16 ( 76.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Analysis Plan: 30JUN2020 Confidential

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Thrombocytopenia | 5 ( 62.5) | 11 ( 84.6) | 16 ( 76.2) |
| Leukopenia | 2 ( 25.0) | 11 ( 84.6) | 13 ( 61.9) |
| Lymphopenia | 2 ( 25.0) | 7 ( 53.8) | 9 ( 42.9) |
| Febrile neutropenia | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Erythropenia | 0 | 0 | 0 |
| General disorders and administration site conditions | 7 ( 87.5) | 12 ( 92.3) | 19 ( 90.5) |
| Fatigue | 3 ( 37.5) | 8 ( 61.5) | 11 ( 52.4) |
| Pyrexia | 3 ( 37.5) | 3 ( 23.1) | 6 ( 28.6) |
| Oedema peripheral | 3 ( 37.5) | 8 ( 61.5) | 11 ( 52.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Chills | 3 ( 37.5) | 4 ( 30.8) | 7 ( 33.3) |
| Pain | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Asthenia | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Chest discomfort | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Gait disturbance | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Malaise | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Influenza like illness | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Mass | 0 | 0 | 0 |
| Oedema | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Chest pain | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 8 (100.0) | 11 ( 84.6) | 19 ( 90.5) |
| Arthralgia | 3 ( 37.5) | 2 ( 15.4) | 5 ( 23.8) |
| Back pain | 2 ( 25.0) | 3 ( 23.1) | 5 ( 23.8) |
| Musculoskeletal pain | 2 ( 25.0) | 1 ( 7.7) | 3 ( 14.3) |
| Bone pain | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Musculoskeletal chest pain | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Myalgia | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Pain in extremity | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Muscular weakness | 2 ( 25.0) | 1 ( 7.7) | 3 ( 14.3) |
| Musculoskeletal discomfort | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Muscle spasms | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Neck pain | 0 | 0 | 0 |
| Tendonitis | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 6 ( 75.0) | 10 ( 76.9) | 16 ( 76.2) |
| Hypokalaemia | 1 ( 12.5) | 8 ( 61.5) | 9 ( 42.9) |
| Hypophosphataemia | 1 ( 12.5) | 6 ( 46.2) | 7 ( 33.3) |
| Hypocalcaemia | 1 ( 12.5) | 7 ( 53.8) | 8 ( 38.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Hypoalbuminaemia | 0 | 8 ( 61.5) | 8 ( 38.1) |
| Decreased appetite | 3 ( 37.5) | 4 ( 30.8) | 7 ( 33.3) |
| Hypomagnesaemia | 3 ( 37.5) | 3 ( 23.1) | 6 ( 28.6) |
| Hyperglycaemia | 0 | 4 ( 30.8) | 4 ( 19.0) |
| Hyponatraemia | 0 | 5 ( 38.5) | 5 ( 23.8) |
| Hypernatraemia | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Hyperuricaemia | 2 ( 25.0) | 0 | 2 ( 9.5) |
| Fluid overload | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Hyperkalaemia | 1 ( 12.5) | 0 | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Dehydration | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Failure to thrive | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Hypermagnesaemia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Hypoglycaemia | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Immune system disorders | 4 ( 50.0) | 11 ( 84.6) | 15 ( 71.4) |
| Cytokine release syndrome | 3 ( 37.5) | 11 ( 84.6) | 14 ( 66.7) |
| Hypogammaglobulinaemia | 3 ( 37.5) | 1 ( 7.7) | 4 ( 19.0) |
| Infections and infestations | 5 ( 62.5) | 10 ( 76.9) | 15 ( 71.4) |
| Upper respiratory tract infection | 3 ( 37.5) | 3 ( 23.1) | 6 ( 28.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Urinary tract infection | 0 | 4 ( 30.8) | 4 ( 19.0) |
| Respiratory syncytial virus infection | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Sinusitis | 0 | 0 | 0 |
| Influenza | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Nasopharyngitis | 0 | 0 | 0 |
| Bronchitis | 0 | 0 | 0 |
| Clostridium difficile infection | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Ear infection | 0 | 0 | 0 |
| Folliculitis | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Analysis Plan: 30JUN2020 Confidential

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Lung infection | 0 | 0 | 0 |
| Parvovirus infection | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Pneumonia | 0 | 0 | 0 |
| Rhinovirus infection | 0 | 0 | 0 |
| Skin infection | 0 | 0 | 0 |
| Acarodermatitis | 0 | 0 | 0 |
| Anal abscess | 0 | 0 | 0 |
| Hordeolum | 0 | 0 | 0 |
| Rhinitis | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are includedunder target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple eventswithin preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequencyof PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjectsreported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Tooth infection | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Vulvovaginal mycotic infection | 0 | 0 | 0 |
| Nervous system disorders | 4 ( 50.0) | 9 ( 69.2) | 13 ( 61.9) |
| Headache | 3 ( 37.5) | 4 ( 30.8) | 7 ( 33.3) |
| Dizziness | 0 | 3 ( 23.1) | 3 ( 14.3) |
| Neurotoxicity | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Tremor | 0 | 3 ( 23.1) | 3 ( 14.3) |
| Hypoaesthesia | 0 | 0 | 0 |
| Disturbance in attention | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Dysgeusia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Paraesthesia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Somnolence | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Syncope | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Aphasia | 0 | 0 | 0 |
| Dysgraphia | 0 | 0 | 0 |
| Facial paralysis | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Haemorrhage intracranial | 0 | 0 | 0 |
| Neuropathy peripheral | 1 ( 12.5) | 0 | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple eventswithin preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequencyof PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjectsreported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 3 ( 37.5) | 11 ( 84.6) | 14 ( 66.7) |
| Cough | 3 ( 37.5) | 7 ( 53.8) | 10 ( 47.6) |
| Nasal congestion | 2 ( 25.0) | 1 ( 7.7) | 3 ( 14.3) |
| Dyspnoea | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Productive cough | 1 ( 12.5) | 4 ( 30.8) | 5 ( 23.8) |
| Epistaxis | 0 | 3 ( 23.1) | 3 ( 14.3) |
| Oropharyngeal pain | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Dyspnoea exertional | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Hypoxia | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjectsreported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Rhinorrhoea | 0 | 0 | 0 |
| Upper-airway cough syndrome | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Wheezing | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Pleural effusion | 0 | 0 | 0 |
| Pneumonitis | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Pulmonary oedema | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Rales | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Rhinitis allergic | 0 | 0 | 0 |
| Sinus congestion | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Throat tightness | 0 | 0 | 0 |
| Investigations | 3 ( 37.5) | 10 ( 76.9) | 13 ( 61.9) |
| Blood alkaline phosphatase increased | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Transaminases increased | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Blood creatinine increased | 2 ( 25.0) | 3 ( 23.1) | 5 ( 23.8) |
| Weight decreased | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Weight increased | 0 | 0 | 0 |
| Blood bilirubin increased | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Activated partial thromboplastin time prolonged | 0 | 2 ( 15.4) | 2 ( 9.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Aspartate aminotransferase increased | 0 | 2 ( 15.4) | 2 ( 9.5) |
| International normalised ratio increased | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Heart rate irregular | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Skin and subcutaneous tissue disorders | 3 ( 37.5) | 5 ( 38.5) | 8 ( 38.1) |
| Pruritus | 2 ( 25.0) | 1 ( 7.7) | 3 ( 14.3) |
| Rash | 0 | 0 | 0 |
| Erythema | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Alopecia | 0 | 0 | 0 |
| Dry skin | 1 ( 12.5) | 0 | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
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Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Ecchymosis | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Rash maculo-papular | 2 ( 25.0) | 0 | 2 ( 9.5) |
| Skin disorder | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Skin lesion | 0 | 0 | 0 |
| Blister | 0 | 0 | 0 |
| Vascular disorders | 1 ( 12.5) | 7 ( 53.8) | 8 ( 38.1) |
| Hypotension | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Hypertension | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Hot flush | 0 | 2 ( 15.4) | 2 ( 9.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Deep vein thrombosis | 0 | 0 | 0 |
| Cardiac disorders | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Tachycardia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Sinus tachycardia | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Atrial fibrillation | 0 | 0 | 0 |
| Bradycardia | 0 | 0 | 0 |
| Ventricular arrhythmia | 0 | 0 | 0 |
| Sinus bradycardia | 0 | 0 | 0 |
| Ventricular extrasystoles | 1 ( 12.5) | 0 | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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|---|---|---|---|
| Ventricular tachycardia | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Psychiatric disorders | 1 ( 12.5) | 4 ( 30.8) | 5 ( 23.8) |
| Insomnia | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Confusional state | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Anxiety | 0 | 0 | 0 |
| Depression | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Delirium | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 4 ( 50.0) | 2 ( 15.4) | 6 ( 28.6) |
| Arthropod bite | 2 ( 25.0) | 0 | 2 ( 9.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
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|---|---|---|---|
| Contusion | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Fall | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Procedural pain | 0 | 0 | 0 |
| Skin laceration | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Infusion related reaction | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Spinal fracture | 0 | 0 | 0 |
| Eye disorders | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Lacrimation increased | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Visual impairment | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Dry eye | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Vision blurred | 0 | 0 | 0 |
| Ear and labyrinth disorders | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Ear pain | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Ear congestion | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Tinnitus | 0 | 0 | 0 |
| Deafness | 0 | 0 | 0 |
| Renal and urinary disorders | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Dysuria | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Pollakiuria | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Haematuria | 0 | 0 | 0 |
| Urinary retention | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Nephrolithiasis | 0 | 0 | 0 |
| Proteinuria | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 12.5) | 4 ( 30.8) | 5 ( 23.8) |
| Bowen's disease | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Plasmacytoma | 0 | 0 | 0 |
| Endocrine disorders | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Analysis Plan: 30JUN2020 Confidential

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Reproductive system and breast disorders | 0 | 0 | 0 |
| Vaginal discharge | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE [b] | 15 (100.0) | 32 (100.0) | 47 (100.0) |
| Gastrointestinal disorders | 13 ( 86.7) | 30 ( 93.8) | 43 ( 91.5) |
| Nausea | 8 ( 53.3) | 21 ( 65.6) | 29 ( 61.7) |
| Diarrhoea | 2 ( 13.3) | 13 ( 40.6) | 15 ( 31.9) |
| Constipation | 2 ( 13.3) | 11 ( 34.4) | 13 ( 27.7) |
| Vomiting | 2 ( 13.3) | 10 ( 31.3) | 12 ( 25.5) |
| Abdominal pain | 0 | 6 ( 18.8) | 6 ( 12.8) |
| Abdominal discomfort | 0 | 4 ( 12.5) | 4 ( 8.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Abdominal distension | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Dry mouth | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Dyspepsia | 3 ( 20.0) | 1 ( 3.1) | 4 ( 8.5) |
| Stomatitis | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Dysphagia | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Flatulence | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Gastrooesophageal reflux disease | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Pancreatitis | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Abdominal pain lower | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Date/time of run: 02OCT2020 15:23
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Abdominal tenderness | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Gingival swelling | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Haemorrhoids | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Inguinal hernia | 0 | 0 | 0 |
| Retching | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Toothache | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Blood and lymphatic system disorders | 14 ( 93.3) | 28 ( 87.5) | 42 ( 89.4) |
| Neutropenia | 12 ( 80.0) | 26 ( 81.3) | 38 ( 80.9) |
| Anaemia | 9 ( 60.0) | 22 ( 68.8) | 31 ( 66.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
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Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Thrombocytopenia | 9 ( 60.0) | 21 ( 65.6) | 30 ( 63.8) |
| Leukopenia | 7 ( 46.7) | 17 ( 53.1) | 24 ( 51.1) |
| Lymphopenia | 5 ( 33.3) | 12 ( 37.5) | 17 ( 36.2) |
| Febrile neutropenia | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Erythropenia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| General disorders and administration site conditions | 11 ( 73.3) | 28 ( 87.5) | 39 ( 83.0) |
| Fatigue | 6 ( 40.0) | 16 ( 50.0) | 22 ( 46.8) |
| Pyrexia | 5 ( 33.3) | 11 ( 34.4) | 16 ( 34.0) |
| Oedema peripheral | 3 ( 20.0) | 12 ( 37.5) | 15 ( 31.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Chills | 3 ( 20.0) | 7 ( 21.9) | 10 ( 21.3) |
| Pain | 0 | 4 ( 12.5) | 4 ( 8.5) |
| Asthenia | 1 ( 6.7) | 3 ( 9.4) | 4 ( 8.5) |
| Chest discomfort | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Gait disturbance | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Malaise | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Influenza like illness | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Mass | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Oedema | 0 | 2 ( 6.3) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Chest pain | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Musculoskeletal and connective tissue disorders | 11 ( 73.3) | 26 ( 81.3) | 37 ( 78.7) |
| Arthralgia | 4 ( 26.7) | 12 ( 37.5) | 16 ( 34.0) |
| Back pain | 4 ( 26.7) | 4 ( 12.5) | 8 ( 17.0) |
| Musculoskeletal pain | 3 ( 20.0) | 4 ( 12.5) | 7 ( 14.9) |
| Bone pain | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Musculoskeletal chest pain | 2 ( 13.3) | 3 ( 9.4) | 5 ( 10.6) |
| Myalgia | 2 ( 13.3) | 3 ( 9.4) | 5 ( 10.6) |
| Pain in extremity | 0 | 3 ( 9.4) | 3 ( 6.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Muscular weakness | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Musculoskeletal discomfort | 0 | 4 ( 12.5) | 4 ( 8.5) |
| Muscle spasms | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Neck pain | 2 ( 13.3) | 0 | 2 ( 4.3) |
| Tendonitis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Metabolism and nutrition disorders | 10 ( 66.7) | 25 ( 78.1) | 35 ( 74.5) |
| Hypokalaemia | 2 ( 13.3) | 15 ( 46.9) | 17 ( 36.2) |
| Hypophosphataemia | 4 ( 26.7) | 12 ( 37.5) | 16 ( 34.0) |
| Hypocalcaemia | 4 ( 26.7) | 9 ( 28.1) | 13 ( 27.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Hypoalbuminaemia | 1 ( 6.7) | 9 ( 28.1) | 10 ( 21.3) |
| Decreased appetite | 4 ( 26.7) | 6 ( 18.8) | 10 ( 21.3) |
| Hypomagnesaemia | 5 ( 33.3) | 7 ( 21.9) | 12 ( 25.5) |
| Hyperglycaemia | 1 ( 6.7) | 6 ( 18.8) | 7 ( 14.9) |
| Hyponatraemia | 1 ( 6.7) | 6 ( 18.8) | 7 ( 14.9) |
| Hypernatraemia | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Hyperuricaemia | 3 ( 20.0) | 1 ( 3.1) | 4 ( 8.5) |
| Fluid overload | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Hyperkalaemia | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
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bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Dehydration | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Failure to thrive | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Hypermagnesaemia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Hypoglycaemia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Immune system disorders | 7 ( 46.7) | 29 ( 90.6) | 36 ( 76.6) |
| Cytokine release syndrome | 6 ( 40.0) | 29 ( 90.6) | 35 ( 74.5) |
| Hypogammaglobulinaemia | 4 ( 26.7) | 3 ( 9.4) | 7 ( 14.9) |
| Infections and infestations | 10 ( 66.7) | 24 ( 75.0) | 34 ( 72.3) |
| Upper respiratory tract infection | 5 ( 33.3) | 9 ( 28.1) | 14 ( 29.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Urinary tract infection | 2 ( 13.3) | 7 ( 21.9) | 9 ( 19.1) |
| Respiratory syncytial virus infection | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Sinusitis | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Influenza | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Nasopharyngitis | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Bronchitis | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Clostridium difficile infection | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Ear infection | 0 | 0 | 0 |
| Folliculitis | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Lung infection | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Parvovirus infection | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Pneumonia | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Rhinovirus infection | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Skin infection | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Acarodermatitis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Anal abscess | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Hordeolum | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Rhinitis | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Tooth infection | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Vulvovaginal mycotic infection | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Nervous system disorders | 9 ( 60.0) | 21 ( 65.6) | 30 ( 63.8) |
| Headache | 4 ( 26.7) | 12 ( 37.5) | 16 ( 34.0) |
| Dizziness | 3 ( 20.0) | 7 ( 21.9) | 10 ( 21.3) |
| Neurotoxicity | 1 ( 6.7) | 5 ( 15.6) | 6 ( 12.8) |
| Tremor | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Hypoaesthesia | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Disturbance in attention | 0 | 1 ( 3.1) | 1 ( 2.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Dysgeusia | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Paraesthesia | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Somnolence | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Syncope | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Aphasia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Dysgraphia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Facial paralysis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Haemorrhage intracranial | 0 | 0 | 0 |
| Neuropathy peripheral | 1 ( 6.7) | 0 | 1 ( 2.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 7 ( 46.7) | 24 ( 75.0) | 31 ( 66.0) |
| Cough | 4 ( 26.7) | 13 ( 40.6) | 17 ( 36.2) |
| Nasal congestion | 2 ( 13.3) | 10 ( 31.3) | 12 ( 25.5) |
| Dyspnoea | 2 ( 13.3) | 6 ( 18.8) | 8 ( 17.0) |
| Productive cough | 1 ( 6.7) | 5 ( 15.6) | 6 ( 12.8) |
| Epistaxis | 0 | 4 ( 12.5) | 4 ( 8.5) |
| Oropharyngeal pain | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Dyspnoea exertional | 2 ( 13.3) | 2 ( 6.3) | 4 ( 8.5) |
| Hypoxia | 0 | 2 ( 6.3) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Rhinorrhoea | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Upper-airway cough syndrome | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Wheezing | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Pleural effusion | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Pneumonitis | 0 | 0 | 0 |
| Pulmonary oedema | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Rales | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Rhinitis allergic | 0 | 0 | 0 |
| Sinus congestion | 0 | 2 ( 6.3) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Throat tightness | 0 | 0 | 0 |
| Investigations | 6 ( 40.0) | 21 ( 65.6) | 27 ( 57.4) |
| Blood alkaline phosphatase increased | 1 ( 6.7) | 6 ( 18.8) | 7 ( 14.9) |
| Transaminases increased | 3 ( 20.0) | 5 ( 15.6) | 8 ( 17.0) |
| Blood creatinine increased | 2 ( 13.3) | 4 ( 12.5) | 6 ( 12.8) |
| Weight decreased | 0 | 5 ( 15.6) | 5 ( 10.6) |
| Weight increased | 1 ( 6.7) | 4 ( 12.5) | 5 ( 10.6) |
| Blood bilirubin increased | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Activated partial thromboplastin time prolonged | 0 | 2 ( 6.3) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Aspartate aminotransferase increased | 0 | 1 ( 3.1) | 1 ( 2.1) |
| International normalised ratio increased | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Heart rate irregular | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Skin and subcutaneous tissue disorders | 6 ( 40.0) | 15 ( 46.9) | 21 ( 44.7) |
| Pruritus | 2 ( 13.3) | 2 ( 6.3) | 4 ( 8.5) |
| Rash | 1 ( 6.7) | 4 ( 12.5) | 5 ( 10.6) |
| Erythema | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Alopecia | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Dry skin | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
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bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Ecchymosis | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Rash maculo-papular | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Skin disorder | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Skin lesion | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Blister | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Vascular disorders | 4 ( 26.7) | 11 ( 34.4) | 15 ( 31.9) |
| Hypotension | 3 ( 20.0) | 2 ( 6.3) | 5 ( 10.6) |
| Hypertension | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Hot flush | 0 | 2 ( 6.3) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=15)<br>n (%) | 450x10^6<br>(N=32)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
| Deep vein thrombosis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Cardiac disorders | 3 ( 20.0) | 10 ( 31.3) | 13 ( 27.7) |
| Tachycardia | 1 ( 6.7) | 4 ( 12.5) | 5 ( 10.6) |
| Sinus tachycardia | 2 ( 13.3) | 2 ( 6.3) | 4 ( 8.5) |
| Atrial fibrillation | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Bradycardia | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Ventricular arrhythmia | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Sinus bradycardia | 0 | 0 | 0 |
| Ventricular extrasystoles | 1 ( 6.7) | 0 | 1 ( 2.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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|---|---|---|---|
| Ventricular tachycardia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Psychiatric disorders | 4 ( 26.7) | 10 ( 31.3) | 14 ( 29.8) |
| Insomnia | 3 ( 20.0) | 5 ( 15.6) | 8 ( 17.0) |
| Confusional state | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Anxiety | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Depression | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Delirium | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 4 ( 26.7) | 7 ( 21.9) | 11 ( 23.4) |
| Arthropod bite | 1 ( 6.7) | 0 | 1 ( 2.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
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Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Contusion | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Fall | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Procedural pain | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Skin laceration | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Infusion related reaction | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Spinal fracture | 0 | 0 | 0 |
| Eye disorders | 3 ( 20.0) | 8 ( 25.0) | 11 ( 23.4) |
| Lacrimation increased | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Visual impairment | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Protocol: CRB-401


Cut-off date: 07APR2020

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Dry eye | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Vision blurred | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Ear and labyrinth disorders | 3 ( 20.0) | 5 ( 15.6) | 8 ( 17.0) |
| Ear pain | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Ear congestion | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Tinnitus | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Deafness | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Renal and urinary disorders | 2 ( 13.3) | 6 ( 18.8) | 8 ( 17.0) |
| Dysuria | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
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Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Pollakiuria | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Haematuria | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Urinary retention | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Nephrolithiasis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Proteinuria | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 6.7) | 6 ( 18.8) | 7 ( 14.9) |
| Bowen's disease | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Plasmacytoma | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Endocrine disorders | 0 | 2 ( 6.3) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=15)<br>n (%) | 450x10^6<br>(N=32)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
| Reproductive system and breast disorders | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Vaginal discharge | 1 ( 6.7) | 0 | 1 ( 2.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE [b] | 3 (100.0) | 6 (100.0) | 9 (100.0) |
| Gastrointestinal disorders | 3 (100.0) | 6 (100.0) | 9 (100.0) |
| Nausea | 1 ( 33.3) | 6 (100.0) | 7 ( 77.8) |
| Diarrhoea | 2 ( 66.7) | 5 ( 83.3) | 7 ( 77.8) |
| Constipation | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Vomiting | 1 ( 33.3) | 3 ( 50.0) | 4 ( 44.4) |
| Abdominal pain | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Abdominal discomfort | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Abdominal distension | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Dry mouth | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Dyspepsia | 0 | 0 | 0 |
| Stomatitis | 0 | 0 | 0 |
| Dysphagia | 0 | 0 | 0 |
| Flatulence | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Pancreatitis | 0 | 0 | 0 |
| Abdominal pain lower | 1 ( 33.3) | 0 | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Abdominal tenderness | 0 | 0 | 0 |
| Gingival swelling | 0 | 0 | 0 |
| Haemorrhoids | 0 | 0 | 0 |
| Inguinal hernia | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Retching | 0 | 0 | 0 |
| Toothache | 0 | 0 | 0 |
| Blood and lymphatic system disorders | 2 ( 66.7) | 5 ( 83.3) | 7 ( 77.8) |
| Neutropenia | 2 ( 66.7) | 5 ( 83.3) | 7 ( 77.8) |
| Anaemia | 1 ( 33.3) | 5 ( 83.3) | 6 ( 66.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
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reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Thrombocytopenia | 1 ( 33.3) | 4 ( 66.7) | 5 ( 55.6) |
| Leukopenia | 2 ( 66.7) | 4 ( 66.7) | 6 ( 66.7) |
| Lymphopenia | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Febrile neutropenia | 0 | 0 | 0 |
| Erythropenia | 0 | 0 | 0 |
| General disorders and administration site conditions | 3 (100.0) | 6 (100.0) | 9 (100.0) |
| Fatigue | 2 ( 66.7) | 5 ( 83.3) | 7 ( 77.8) |
| Pyrexia | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |
| Oedema peripheral | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
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Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Chills | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |
| Pain | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Asthenia | 0 | 0 | 0 |
| Chest discomfort | 0 | 0 | 0 |
| Gait disturbance | 0 | 0 | 0 |
| Malaise | 0 | 0 | 0 |
| Influenza like illness | 0 | 0 | 0 |
| Mass | 0 | 0 | 0 |
| Oedema | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
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bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Chest pain | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 3 (100.0) | 5 ( 83.3) | 8 ( 88.9) |
| Arthralgia | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |
| Back pain | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Musculoskeletal pain | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Bone pain | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Musculoskeletal chest pain | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Myalgia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Pain in extremity | 0 | 2 ( 33.3) | 2 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
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bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Muscular weakness | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Musculoskeletal discomfort | 0 | 0 | 0 |
| Muscle spasms | 0 | 0 | 0 |
| Neck pain | 0 | 0 | 0 |
| Tendonitis | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 3 (100.0) | 6 (100.0) | 9 (100.0) |
| Hypokalaemia | 1 ( 33.3) | 4 ( 66.7) | 5 ( 55.6) |
| Hypophosphataemia | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Hypocalcaemia | 0 | 4 ( 66.7) | 4 ( 44.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
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Missing subgroup categories are not presented.
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bb2121-Treated Population

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|---|---|---|---|
| Hypoalbuminaemia | 2 ( 66.7) | 3 ( 50.0) | 5 ( 55.6) |
| Decreased appetite | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Hypomagnesaemia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Hyperglycaemia | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Hyponatraemia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Hypernatraemia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Hyperuricaemia | 0 | 0 | 0 |
| Fluid overload | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Hyperkalaemia | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
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[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Dehydration | 0 | 0 | 0 |
| Failure to thrive | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Hypermagnesaemia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Hypoglycaemia | 0 | 0 | 0 |
| Immune system disorders | 1 ( 33.3) | 5 ( 83.3) | 6 ( 66.7) |
| Cytokine release syndrome | 1 ( 33.3) | 5 ( 83.3) | 6 ( 66.7) |
| Hypogammaglobulinaemia | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Infections and infestations | 3 (100.0) | 4 ( 66.7) | 7 ( 77.8) |
| Upper respiratory tract infection | 3 (100.0) | 3 ( 50.0) | 6 ( 66.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Analysis Plan: 30JUN2020 Confidential

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Urinary tract infection | 0 | 0 | 0 |
| Respiratory syncytial virus infection | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Sinusitis | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Influenza | 0 | 0 | 0 |
| Nasopharyngitis | 0 | 0 | 0 |
| Bronchitis | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Clostridium difficile infection | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Ear infection | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Folliculitis | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Lung infection | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Parvovirus infection | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Pneumonia | 0 | 0 | 0 |
| Rhinovirus infection | 0 | 0 | 0 |
| Skin infection | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Acarodermatitis | 0 | 0 | 0 |
| Anal abscess | 0 | 0 | 0 |
| Hordeolum | 0 | 0 | 0 |
| Rhinitis | 1 ( 33.3) | 0 | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Tooth infection | 0 | 0 | 0 |
| Vulvovaginal mycotic infection | 0 | 0 | 0 |
| Nervous system disorders | 3 (100.0) | 6 (100.0) | 9 (100.0) |
| Headache | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Dizziness | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Neurotoxicity | 0 | 0 | 0 |
| Tremor | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Hypoaesthesia | 0 | 0 | 0 |
| Disturbance in attention | 0 | 1 ( 16.7) | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Dysgeusia | 0 | 0 | 0 |
| Paraesthesia | 0 | 0 | 0 |
| Somnolence | 0 | 0 | 0 |
| Syncope | 0 | 0 | 0 |
| Aphasia | 0 | 0 | 0 |
| Dysgraphia | 0 | 0 | 0 |
| Facial paralysis | 0 | 0 | 0 |
| Haemorrhage intracranial | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Neuropathy peripheral | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 3 (100.0) | 5 ( 83.3) | 8 ( 88.9) |
| Cough | 3 (100.0) | 4 ( 66.7) | 7 ( 77.8) |
| Nasal congestion | 2 ( 66.7) | 1 ( 16.7) | 3 ( 33.3) |
| Dyspnoea | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Productive cough | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Epistaxis | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Oropharyngeal pain | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Dyspnoea exertional | 0 | 0 | 0 |
| Hypoxia | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Rhinorrhoea | 0 | 0 | 0 |
| Upper-airway cough syndrome | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Wheezing | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Pleural effusion | 0 | 0 | 0 |
| Pneumonitis | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Pulmonary oedema | 0 | 0 | 0 |
| Rales | 0 | 0 | 0 |
| Rhinitis allergic | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Sinus congestion | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Throat tightness | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Investigations | 0 | 3 ( 50.0) | 3 ( 33.3) |
| Blood alkaline phosphatase increased | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Transaminases increased | 0 | 0 | 0 |
| Blood creatinine increased | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Weight decreased | 0 | 0 | 0 |
| Weight increased | 0 | 0 | 0 |
| Blood bilirubin increased | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Activated partial thromboplastin time prolonged | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=3)<br>n (%) | 450x10^6<br>(N=6)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
| Aspartate aminotransferase increased | 0 | 1 ( 16.7) | 1 ( 11.1) |
| International normalised ratio increased | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Heart rate irregular | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 1 ( 33.3) | 3 ( 50.0) | 4 ( 44.4) |
| Pruritus | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Rash | 0 | 0 | 0 |
| Erythema | 0 | 0 | 0 |
| Alopecia | 0 | 0 | 0 |
| Dry skin | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=3)<br>n (%) | 450x10^6<br>(N=6)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
| Ecchymosis | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Rash maculo-papular | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Skin disorder | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Skin lesion | 0 | 0 | 0 |
| Blister | 0 | 0 | 0 |
| Vascular disorders | 2 ( 66.7) | 4 ( 66.7) | 6 ( 66.7) |
| Hypotension | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Hypertension | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Hot flush | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Deep vein thrombosis | 0 | 0 | 0 |
| Cardiac disorders | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Tachycardia | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Sinus tachycardia | 2 ( 66.7) | 0 | 2 ( 22.2) |
| Atrial fibrillation | 0 | 0 | 0 |
| Bradycardia | 0 | 0 | 0 |
| Ventricular arrhythmia | 0 | 0 | 0 |
| Sinus bradycardia | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Ventricular extrasystoles | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Ventricular tachycardia | 0 | 0 | 0 |
| Psychiatric disorders | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Insomnia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Confusional state | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Anxiety | 0 | 0 | 0 |
| Depression | 0 | 0 | 0 |
| Delirium | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Injury, poisoning and procedural complications | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Arthropod bite | 1 ( 33.3) | 0 | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Contusion | 0 | 0 | 0 |
| Fall | 0 | 0 | 0 |
| Procedural pain | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Skin laceration | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Infusion related reaction | 0 | 0 | 0 |
| Spinal fracture | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Eye disorders | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Lacrimation increased | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Visual impairment | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Dry eye | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Vision blurred | 0 | 0 | 0 |
| Ear and labyrinth disorders | 0 | 2 ( 33.3) | 2 ( 22.2) |
| Ear pain | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Ear congestion | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Tinnitus | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Deafness | 0 | 0 | 0 |
| Renal and urinary disorders | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Dysuria | 0 | 1 ( 16.7) | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Pollakiuria | 0 | 0 | 0 |
| Haematuria | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Urinary retention | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Nephrolithiasis | 0 | 0 | 0 |
| Proteinuria | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Bowen's disease | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Plasmacytoma | 0 | 0 | 0 |
| Endocrine disorders | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Reproductive system and breast disorders | 0 | 0 | 0 |
| Vaginal discharge | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 1 or 2 AE [b] | 4 (100.0) | 16 (100.0) | 20 (100.0) |
| Gastrointestinal disorders | 4 (100.0) | 14 ( 87.5) | 18 ( 90.0) |
| Nausea | 3 ( 75.0) | 11 ( 68.8) | 14 ( 70.0) |
| Diarrhoea | 1 ( 25.0) | 10 ( 62.5) | 11 ( 55.0) |
| Constipation | 1 ( 25.0) | 3 ( 18.8) | 4 ( 20.0) |
| Vomiting | 1 ( 25.0) | 7 ( 43.8) | 8 ( 40.0) |
| Abdominal pain | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Abdominal discomfort | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.

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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Abdominal distension | 0 | 0 | 0 |
| Dry mouth | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Dyspepsia | 2 ( 50.0) | 0 | 2 ( 10.0) |
| Stomatitis | 0 | 0 | 0 |
| Dysphagia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Flatulence | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Pancreatitis | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Abdominal pain lower | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.

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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Abdominal tenderness | 0 | 0 | 0 |
| Gingival swelling | 0 | 0 | 0 |
| Haemorrhoids | 0 | 0 | 0 |
| Inguinal hernia | 0 | 0 | 0 |
| Retching | 0 | 0 | 0 |
| Toothache | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Blood and lymphatic system disorders | 3 ( 75.0) | 13 ( 81.3) | 16 ( 80.0) |
| Neutropenia | 3 ( 75.0) | 11 ( 68.8) | 14 ( 70.0) |
| Anaemia | 3 ( 75.0) | 12 ( 75.0) | 15 ( 75.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Thrombocytopenia | 2 ( 50.0) | 11 ( 68.8) | 13 ( 65.0) |
| Leukopenia | 3 ( 75.0) | 10 ( 62.5) | 13 ( 65.0) |
| Lymphopenia | 2 ( 50.0) | 5 ( 31.3) | 7 ( 35.0) |
| Febrile neutropenia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Erythropenia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| General disorders and administration site conditions | 2 ( 50.0) | 15 ( 93.8) | 17 ( 85.0) |
| Fatigue | 1 ( 25.0) | 8 ( 50.0) | 9 ( 45.0) |
| Pyrexia | 2 ( 50.0) | 9 ( 56.3) | 11 ( 55.0) |
| Oedema peripheral | 0 | 5 ( 31.3) | 5 ( 25.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Chills | 2 ( 50.0) | 4 ( 25.0) | 6 ( 30.0) |
| Pain | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Asthenia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Chest discomfort | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Gait disturbance | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Malaise | 0 | 0 | 0 |
| Influenza like illness | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |
| Mass | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Oedema | 0 | 2 ( 12.5) | 2 ( 10.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Chest pain | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 3 ( 75.0) | 15 ( 93.8) | 18 ( 90.0) |
| Arthralgia | 1 ( 25.0) | 8 ( 50.0) | 9 ( 45.0) |
| Back pain | 1 ( 25.0) | 4 ( 25.0) | 5 ( 25.0) |
| Musculoskeletal pain | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Bone pain | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Musculoskeletal chest pain | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |
| Myalgia | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Pain in extremity | 0 | 2 ( 12.5) | 2 ( 10.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
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[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
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Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Muscular weakness | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Musculoskeletal discomfort | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Muscle spasms | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Neck pain | 0 | 0 | 0 |
| Tendonitis | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 2 ( 50.0) | 12 ( 75.0) | 14 ( 70.0) |
| Hypokalaemia | 0 | 7 ( 43.8) | 7 ( 35.0) |
| Hypophosphataemia | 1 ( 25.0) | 7 ( 43.8) | 8 ( 40.0) |
| Hypocalcaemia | 1 ( 25.0) | 4 ( 25.0) | 5 ( 25.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
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Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Hypoalbuminaemia | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Decreased appetite | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Hypomagnesaemia | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |
| Hyperglycaemia | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Hyponatraemia | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Hypernatraemia | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Hyperuricaemia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Fluid overload | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Hyperkalaemia | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Dehydration | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Failure to thrive | 0 | 0 | 0 |
| Hypermagnesaemia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Hypoglycaemia | 0 | 0 | 0 |
| Immune system disorders | 1 ( 25.0) | 15 ( 93.8) | 16 ( 80.0) |
| Cytokine release syndrome | 1 ( 25.0) | 15 ( 93.8) | 16 ( 80.0) |
| Hypogammaglobulinaemia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Infections and infestations | 3 ( 75.0) | 13 ( 81.3) | 16 ( 80.0) |
| Upper respiratory tract infection | 2 ( 50.0) | 8 ( 50.0) | 10 ( 50.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Urinary tract infection | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Respiratory syncytial virus infection | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Sinusitis | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Influenza | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Nasopharyngitis | 0 | 0 | 0 |
| Bronchitis | 0 | 0 | 0 |
| Clostridium difficile infection | 0 | 0 | 0 |
| Ear infection | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Folliculitis | 1 ( 25.0) | 0 | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Lung infection | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Parvovirus infection | 0 | 0 | 0 |
| Pneumonia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Rhinovirus infection | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Skin infection | 0 | 0 | 0 |
| Acarodermatitis | 0 | 0 | 0 |
| Anal abscess | 0 | 0 | 0 |
| Hordeolum | 0 | 0 | 0 |
| Rhinitis | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Tooth infection | 0 | 0 | 0 |
| Vulvovaginal mycotic infection | 0 | 0 | 0 |
| Nervous system disorders | 2 ( 50.0) | 12 ( 75.0) | 14 ( 70.0) |
| Headache | 2 ( 50.0) | 8 ( 50.0) | 10 ( 50.0) |
| Dizziness | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Neurotoxicity | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Tremor | 0 | 0 | 0 |
| Hypoaesthesia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Disturbance in attention | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Protocol: CRB-401 Cut-off date: 07APR2020

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Dysgeusia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Paraesthesia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Somnolence | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Syncope | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Aphasia | 0 | 0 | 0 |
| Dysgraphia | 0 | 0 | 0 |
| Facial paralysis | 0 | 0 | 0 |
| Haemorrhage intracranial | 0 | 0 | 0 |
| Neuropathy peripheral | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.

SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 1 ( 25.0) | 12 ( 75.0) | 13 ( 65.0) |
| Cough | 1 ( 25.0) | 8 ( 50.0) | 9 ( 45.0) |
| Nasal congestion | 0 | 6 ( 37.5) | 6 ( 30.0) |
| Dyspnoea | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Productive cough | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Epistaxis | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Oropharyngeal pain | 0 | 4 ( 25.0) | 4 ( 20.0) |
| Dyspnoea exertional | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Hypoxia | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Rhinorrhoea | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Upper-airway cough syndrome | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Wheezing | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Pleural effusion | 0 | 0 | 0 |
| Pneumonitis | 0 | 0 | 0 |
| Pulmonary oedema | 0 | 0 | 0 |
| Rales | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Rhinitis allergic | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Sinus congestion | 0 | 2 ( 12.5) | 2 ( 10.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.

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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Throat tightness | 0 | 0 | 0 |
| Investigations | 2 ( 50.0) | 9 ( 56.3) | 11 ( 55.0) |
| Blood alkaline phosphatase increased | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Transaminases increased | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Blood creatinine increased | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Weight decreased | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Weight increased | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Blood bilirubin increased | 0 | 0 | 0 |
| Activated partial thromboplastin time prolonged | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.

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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Aspartate aminotransferase increased | 0 | 1 ( 6.3) | 1 ( 5.0) |
| International normalised ratio increased | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Heart rate irregular | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 2 ( 50.0) | 6 ( 37.5) | 8 ( 40.0) |
| Pruritus | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Rash | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Erythema | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Alopecia | 0 | 0 | 0 |
| Dry skin | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Ecchymosis | 0 | 0 | 0 |
| Rash maculo-papular | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Skin disorder | 0 | 0 | 0 |
| Skin lesion | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Blister | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Vascular disorders | 0 | 6 ( 37.5) | 6 ( 30.0) |
| Hypotension | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Hypertension | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Hot flush | 0 | 2 ( 12.5) | 2 ( 10.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Deep vein thrombosis | 0 | 0 | 0 |
| Cardiac disorders | 0 | 5 ( 31.3) | 5 ( 25.0) |
| Tachycardia | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Sinus tachycardia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Atrial fibrillation | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Bradycardia | 0 | 0 | 0 |
| Ventricular arrhythmia | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Sinus bradycardia | 0 | 0 | 0 |
| Ventricular extrasystoles | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.

RP2D = Recommended phase 2 dose.

[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.

Missing subgroup categories are not presented.

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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Ventricular tachycardia | 0 | 0 | 0 |
| Psychiatric disorders | 1 ( 25.0) | 4 ( 25.0) | 5 ( 25.0) |
| Insomnia | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Confusional state | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Anxiety | 0 | 0 | 0 |
| Depression | 0 | 0 | 0 |
| Delirium | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 1 ( 25.0) | 5 ( 31.3) | 6 ( 30.0) |
| Arthropod bite | 1 ( 25.0) | 0 | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Contusion | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |
| Fall | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Procedural pain | 0 | 0 | 0 |
| Skin laceration | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Infusion related reaction | 0 | 0 | 0 |
| Spinal fracture | 0 | 0 | 0 |
| Eye disorders | 1 ( 25.0) | 3 ( 18.8) | 4 ( 20.0) |
| Lacrimation increased | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |
| Visual impairment | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.

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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Dry eye | 0 | 0 | 0 |
| Vision blurred | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Ear and labyrinth disorders | 1 ( 25.0) | 4 ( 25.0) | 5 ( 25.0) |
| Ear pain | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Ear congestion | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Tinnitus | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Deafness | 0 | 0 | 0 |
| Renal and urinary disorders | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Dysuria | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Pollakiuria | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Haematuria | 0 | 0 | 0 |
| Urinary retention | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Nephrolithiasis | 0 | 0 | 0 |
| Proteinuria | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 25.0) | 4 ( 25.0) | 5 ( 25.0) |
| Bowen's disease | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Plasmacytoma | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |
| Endocrine disorders | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.

RP2D = Recommended phase 2 dose.

[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.

Missing subgroup categories are not presented.

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Table 6.4.2c
Grade 1 or 2 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Reproductive system and breast disorders | 0 | 0 | 0 |
| Vaginal discharge | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.

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#### 13.4.3.2 UE Grad 3-5 nach SOC und PT

Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE [b] | 10 (100.0) | 24 ( 96.0) | 34 ( 97.1) |
| Blood and lymphatic system disorders | 10 (100.0) | 24 ( 96.0) | 34 ( 97.1) |
| Neutropenia | 9 ( 90.0) | 22 ( 88.0) | 31 ( 88.6) |
| Leukopenia | 8 ( 80.0) | 12 ( 48.0) | 20 ( 57.1) |
| Anaemia | 3 ( 30.0) | 14 ( 56.0) | 17 ( 48.6) |
| Thrombocytopenia | 5 ( 50.0) | 13 ( 52.0) | 18 ( 51.4) |
| Lymphopenia | 4 ( 40.0) | 10 ( 40.0) | 14 ( 40.0) |
| Febrile neutropenia | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Haemolysis | 0 | 0 | 0 |
| Leukocytosis | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Metabolism and nutrition disorders | 4 ( 40.0) | 7 ( 28.0) | 11 ( 31.4) |
| Hypophosphataemia | 2 ( 20.0) | 6 ( 24.0) | 8 ( 22.9) |
| Hypocalcaemia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Hypokalaemia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Hyponatraemia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Hyperglycaemia | 0 | 0 | 0 |
| Hypermagnesaemia | 1 ( 10.0) | 0 | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Hyperuricaemia | 0 | 0 | 0 |
| Infections and infestations | 3 ( 30.0) | 5 ( 20.0) | 8 ( 22.9) |
| Upper respiratory tract infection | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Lung infection | 2 ( 20.0) | 1 ( 4.0) | 3 ( 8.6) |
| Pneumonia | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Anal abscess | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Parvovirus infection | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Investigations | 1 ( 10.0) | 5 ( 20.0) | 6 ( 17.1) |
| Activated partial thromboplastin time prolonged | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Blood phosphorus decreased | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Platelet count decreased | 1 ( 10.0) | 0 | 1 ( 2.9) |
| CD4 lymphocytes decreased | 0 | 0 | 0 |
| General disorders and administration site conditions | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |
| Fatigue | 1 ( 10.0) | 0 | 1 ( 2.9) |
| General physical health deterioration | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Asthenia | 0 | 0 | 0 |
| Death | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Gastrointestinal disorders | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Diarrhoea | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Vomiting | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Intestinal obstruction | 0 | 0 | 0 |
| Vascular disorders | 1 ( 10.0) | 4 ( 16.0) | 5 ( 14.3) |
| Hypertension | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Hypotension | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Cardiac disorders | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Sinus tachycardia | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Pericardial effusion | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 1 ( 10.0) | 3 ( 12.0) | 4 ( 11.4) |
| Hypoxia | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Respiratory failure | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Musculoskeletal and connective tissue disorders | 2 ( 20.0) | 1 ( 4.0) | 3 ( 8.6) |
| Back pain | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Musculoskeletal chest pain | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Osteolysis | 0 | 0 | 0 |
| Nervous system disorders | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Syncope | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=10)<br>n (%) | 450x10^6<br>(N=25)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
| Renal and urinary disorders | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Nephrolithiasis | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Ureterolithiasis | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Immune system disorders | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Cytokine release syndrome | 0 | 3 ( 12.0) | 3 ( 8.6) |
| Injury, poisoning and procedural complications | 0 | 2 ( 8.0) | 2 ( 5.7) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 ( 20.0) | 0 | 2 ( 5.7) |
| Myelodysplastic syndrome | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Tumour pain | 1 ( 10.0) | 0 | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.

[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Surgical and medical procedures | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Internal fixation of fracture | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Skin ulcer | 1 ( 10.0) | 0 | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE [b] | 8 (100.0) | 13 (100.0) | 21 (100.0) |
| Blood and lymphatic system disorders | 7 ( 87.5) | 12 ( 92.3) | 19 ( 90.5) |
| Neutropenia | 6 ( 75.0) | 12 ( 92.3) | 18 ( 85.7) |
| Leukopenia | 3 ( 37.5) | 11 ( 84.6) | 14 ( 66.7) |
| Anaemia | 4 ( 50.0) | 11 ( 84.6) | 15 ( 71.4) |
| Thrombocytopenia | 5 ( 62.5) | 8 ( 61.5) | 13 ( 61.9) |
| Lymphopenia | 4 ( 50.0) | 8 ( 61.5) | 12 ( 57.1) |
| Febrile neutropenia | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Haemolysis | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Leukocytosis | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 2 ( 25.0) | 6 ( 46.2) | 8 ( 38.1) |
| Hypophosphataemia | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Hypocalcaemia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Hypokalaemia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Hyponatraemia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Hyperglycaemia | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Hypermagnesaemia | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Hyperuricaemia | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Infections and infestations | 0 | 5 ( 38.5) | 5 ( 23.8) |
| Upper respiratory tract infection | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Lung infection | 0 | 0 | 0 |
| Pneumonia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Anal abscess | 0 | 0 | 0 |
| Parvovirus infection | 0 | 0 | 0 |
| Investigations | 1 ( 12.5) | 5 ( 38.5) | 6 ( 28.6) |
| Activated partial thromboplastin time prolonged | 0 | 2 ( 15.4) | 2 ( 9.5) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Blood phosphorus decreased | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Platelet count decreased | 0 | 1 ( 7.7) | 1 ( 4.8) |
| CD4 lymphocytes decreased | 1 ( 12.5) | 0 | 1 ( 4.8) |
| General disorders and administration site conditions | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Fatigue | 0 | 3 ( 23.1) | 3 ( 14.3) |
| General physical health deterioration | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Asthenia | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Death | 0 | 0 | 0 |
| Gastrointestinal disorders | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Diarrhoea | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Vomiting | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Intestinal obstruction | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Vascular disorders | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Hypertension | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Hypotension | 0 | 0 | 0 |
| Cardiac disorders | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Sinus tachycardia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Pericardial effusion | 1 ( 12.5) | 0 | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Hypoxia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Respiratory failure | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Back pain | 0 | 0 | 0 |
| Musculoskeletal chest pain | 0 | 0 | 0 |
| Osteolysis | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Nervous system disorders | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Syncope | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Renal and urinary disorders | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Nephrolithiasis | 0 | 0 | 0 |
| Ureterolithiasis | 0 | 0 | 0 |
| Immune system disorders | 0 | 0 | 0 |
| Cytokine release syndrome | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Myelodysplastic syndrome | 0 | 0 | 0 |
| Tumour pain | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.

[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Surgical and medical procedures | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Internal fixation of fracture | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Skin and subcutaneous tissue disorders | 0 | 0 | 0 |
| Skin ulcer | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE [b] | 15 (100.0) | 32 (100.0) | 47 (100.0) |
| Blood and lymphatic system disorders | 15 (100.0) | 31 ( 96.9) | 46 ( 97.9) |
| Neutropenia | 13 ( 86.7) | 29 ( 90.6) | 42 ( 89.4) |
| Leukopenia | 9 ( 60.0) | 19 ( 59.4) | 28 ( 59.6) |
| Anaemia | 6 ( 40.0) | 22 ( 68.8) | 28 ( 59.6) |
| Thrombocytopenia | 9 ( 60.0) | 19 ( 59.4) | 28 ( 59.6) |
| Lymphopenia | 8 ( 53.3) | 15 ( 46.9) | 23 ( 48.9) |
| Febrile neutropenia | 2 ( 13.3) | 3 ( 9.4) | 5 ( 10.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Haemolysis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Leukocytosis | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 5 ( 33.3) | 11 ( 34.4) | 16 ( 34.0) |
| Hypophosphataemia | 2 ( 13.3) | 7 ( 21.9) | 9 ( 19.1) |
| Hypocalcaemia | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Hypokalaemia | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Hyponatraemia | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Hyperglycaemia | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Hypermagnesaemia | 1 ( 6.7) | 0 | 1 ( 2.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Hyperuricaemia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Infections and infestations | 1 ( 6.7) | 8 ( 25.0) | 9 ( 19.1) |
| Upper respiratory tract infection | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Lung infection | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Pneumonia | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Anal abscess | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Parvovirus infection | 0 | 0 | 0 |
| Investigations | 1 ( 6.7) | 9 ( 28.1) | 10 ( 21.3) |
| Activated partial thromboplastin time prolonged | 0 | 2 ( 6.3) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=15)<br>n (%) | 450x10^6<br>(N=32)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
| Blood phosphorus decreased | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Platelet count decreased | 0 | 1 ( 3.1) | 1 ( 2.1) |
| CD4 lymphocytes decreased | 1 ( 6.7) | 0 | 1 ( 2.1) |
| General disorders and administration site conditions | 3 ( 20.0) | 5 ( 15.6) | 8 ( 17.0) |
| Fatigue | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| General physical health deterioration | 2 ( 13.3) | 2 ( 6.3) | 4 ( 8.5) |
| Asthenia | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Death | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Gastrointestinal disorders | 1 ( 6.7) | 5 ( 15.6) | 6 ( 12.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Diarrhoea | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Vomiting | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Intestinal obstruction | 0 | 0 | 0 |
| Vascular disorders | 1 ( 6.7) | 6 ( 18.8) | 7 ( 14.9) |
| Hypertension | 1 ( 6.7) | 5 ( 15.6) | 6 ( 12.8) |
| Hypotension | 0 | 0 | 0 |
| Cardiac disorders | 1 ( 6.7) | 3 ( 9.4) | 4 ( 8.5) |
| Sinus tachycardia | 0 | 0 | 0 |
| Pericardial effusion | 1 ( 6.7) | 0 | 1 ( 2.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 0 | 4 ( 12.5) | 4 ( 8.5) |
| Hypoxia | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Respiratory failure | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Back pain | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Musculoskeletal chest pain | 0 | 0 | 0 |
| Osteolysis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Nervous system disorders | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Syncope | 0 | 2 ( 6.3) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=15)<br>n (%) | 450x10^6<br>(N=32)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
| Renal and urinary disorders | 1 ( 6.7) | 2 ( 6.3) | 3 ( 6.4) |
| Nephrolithiasis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Ureterolithiasis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Immune system disorders | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Cytokine release syndrome | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Injury, poisoning and procedural complications | 0 | 3 ( 9.4) | 3 ( 6.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Myelodysplastic syndrome | 0 | 0 | 0 |
| Tumour pain | 1 ( 6.7) | 0 | 1 ( 2.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.

[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Surgical and medical procedures | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Internal fixation of fracture | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Skin and subcutaneous tissue disorders | 0 | 0 | 0 |
| Skin ulcer | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology
Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
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Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE [b] | 3 (100.0) | 5 ( 83.3) | 8 ( 88.9) |
| Blood and lymphatic system disorders | 2 ( 66.7) | 5 ( 83.3) | 7 ( 77.8) |
| Neutropenia | 2 ( 66.7) | 5 ( 83.3) | 7 ( 77.8) |
| Leukopenia | 2 ( 66.7) | 4 ( 66.7) | 6 ( 66.7) |
| Anaemia | 1 ( 33.3) | 3 ( 50.0) | 4 ( 44.4) |
| Thrombocytopenia | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Lymphopenia | 0 | 3 ( 50.0) | 3 ( 33.3) |
| Febrile neutropenia | 0 | 2 ( 33.3) | 2 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Haemolysis | 0 | 0 | 0 |
| Leukocytosis | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Metabolism and nutrition disorders | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Hypophosphataemia | 1 ( 33.3) | 2 ( 33.3) | 3 ( 33.3) |
| Hypocalcaemia | 0 | 0 | 0 |
| Hypokalaemia | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Hyponatraemia | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Hyperglycaemia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Hypermagnesaemia | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Hyperuricaemia | 0 | 0 | 0 |
| Infections and infestations | 2 ( 66.7) | 2 ( 33.3) | 4 ( 44.4) |
| Upper respiratory tract infection | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Lung infection | 2 ( 66.7) | 0 | 2 ( 22.2) |
| Pneumonia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Anal abscess | 0 | 0 | 0 |
| Parvovirus infection | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Investigations | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Activated partial thromboplastin time prolonged | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=3)<br>n (%) | 450x10^6<br>(N=6)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
| Blood phosphorus decreased | 0 | 0 | 0 |
| Platelet count decreased | 1 ( 33.3) | 0 | 1 ( 11.1) |
| CD4 lymphocytes decreased | 0 | 0 | 0 |
| General disorders and administration site conditions | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Fatigue | 0 | 1 ( 16.7) | 1 ( 11.1) |
| General physical health deterioration | 0 | 0 | 0 |
| Asthenia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Death | 0 | 0 | 0 |
| Gastrointestinal disorders | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
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bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Diarrhoea | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Vomiting | 0 | 0 | 0 |
| Intestinal obstruction | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Vascular disorders | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Hypertension | 0 | 0 | 0 |
| Hypotension | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Cardiac disorders | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Sinus tachycardia | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Pericardial effusion | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
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Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Hypoxia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Respiratory failure | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Musculoskeletal and connective tissue disorders | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Back pain | 0 | 0 | 0 |
| Musculoskeletal chest pain | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Osteolysis | 0 | 0 | 0 |
| Nervous system disorders | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Syncope | 1 ( 33.3) | 0 | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Renal and urinary disorders | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Nephrolithiasis | 0 | 0 | 0 |
| Ureterolithiasis | 0 | 0 | 0 |
| Immune system disorders | 0 | 0 | 0 |
| Cytokine release syndrome | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Myelodysplastic syndrome | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Tumour pain | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Surgical and medical procedures | 0 | 0 | 0 |
| Internal fixation of fracture | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Skin ulcer | 1 ( 33.3) | 0 | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE [b] | 4 (100.0) | 15 ( 93.8) | 19 ( 95.0) |
| Blood and lymphatic system disorders | 4 (100.0) | 15 ( 93.8) | 19 ( 95.0) |
| Neutropenia | 3 ( 75.0) | 14 ( 87.5) | 17 ( 85.0) |
| Leukopenia | 4 (100.0) | 10 ( 62.5) | 14 ( 70.0) |
| Anaemia | 1 ( 25.0) | 13 ( 81.3) | 14 ( 70.0) |
| Thrombocytopenia | 1 ( 25.0) | 8 ( 50.0) | 9 ( 45.0) |
| Lymphopenia | 2 ( 50.0) | 6 ( 37.5) | 8 ( 40.0) |
| Febrile neutropenia | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Haemolysis | 0 | 0 | 0 |
| Leukocytosis | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 2 ( 50.0) | 4 ( 25.0) | 6 ( 30.0) |
| Hypophosphataemia | 1 ( 25.0) | 2 ( 12.5) | 3 ( 15.0) |
| Hypocalcaemia | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Hypokalaemia | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Hyponatraemia | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Hyperglycaemia | 0 | 0 | 0 |
| Hypermagnesaemia | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Hyperuricaemia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Infections and infestations | 0 | 6 ( 37.5) | 6 ( 30.0) |
| Upper respiratory tract infection | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Lung infection | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Pneumonia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Anal abscess | 0 | 0 | 0 |
| Parvovirus infection | 0 | 0 | 0 |
| Investigations | 0 | 3 ( 18.8) | 3 ( 15.0) |
| Activated partial thromboplastin time prolonged | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Blood phosphorus decreased | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Platelet count decreased | 0 | 1 ( 6.3) | 1 ( 5.0) |
| CD4 lymphocytes decreased | 0 | 0 | 0 |
| General disorders and administration site conditions | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Fatigue | 0 | 0 | 0 |
| General physical health deterioration | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Asthenia | 0 | 0 | 0 |
| Death | 0 | 0 | 0 |
| Gastrointestinal disorders | 0 | 2 ( 12.5) | 2 ( 10.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Diarrhoea | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Vomiting | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Intestinal obstruction | 0 | 0 | 0 |
| Vascular disorders | 1 ( 25.0) | 5 ( 31.3) | 6 ( 30.0) |
| Hypertension | 1 ( 25.0) | 5 ( 31.3) | 6 ( 30.0) |
| Hypotension | 0 | 0 | 0 |
| Cardiac disorders | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Sinus tachycardia | 0 | 0 | 0 |
| Pericardial effusion | 1 ( 25.0) | 0 | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Hypoxia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Respiratory failure | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 0 | 0 | 0 |
| Back pain | 0 | 0 | 0 |
| Musculoskeletal chest pain | 0 | 0 | 0 |
| Osteolysis | 0 | 0 | 0 |
| Nervous system disorders | 0 | 0 | 0 |
| Syncope | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Renal and urinary disorders | 0 | 0 | 0 |
| Nephrolithiasis | 0 | 0 | 0 |
| Ureterolithiasis | 0 | 0 | 0 |
| Immune system disorders | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Cytokine release syndrome | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Injury, poisoning and procedural complications | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Myelodysplastic syndrome | 0 | 0 | 0 |
| Tumour pain | 1 ( 25.0) | 0 | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.

[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Surgical and medical procedures | 0 | 0 | 0 |
| Internal fixation of fracture | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 0 | 0 | 0 |
| Skin ulcer | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one Grade 3-5 AE [b] | 14 (100.0) | 22 (100.0) | 36 (100.0) |
| Blood and lymphatic system disorders | 13 ( 92.9) | 21 ( 95.5) | 34 ( 94.4) |
| Neutropenia | 12 ( 85.7) | 20 ( 90.9) | 32 ( 88.9) |
| Leukopenia | 7 ( 50.0) | 13 ( 59.1) | 20 ( 55.6) |
| Anaemia | 6 ( 42.9) | 12 ( 54.5) | 18 ( 50.0) |
| Thrombocytopenia | 9 ( 64.3) | 13 ( 59.1) | 22 ( 61.1) |
| Lymphopenia | 6 ( 42.9) | 12 ( 54.5) | 18 ( 50.0) |
| Febrile neutropenia | 1 ( 7.1) | 3 ( 13.6) | 4 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Haemolysis | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Leukocytosis | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Metabolism and nutrition disorders | 4 ( 28.6) | 9 ( 40.9) | 13 ( 36.1) |
| Hypophosphataemia | 2 ( 14.3) | 7 ( 31.8) | 9 ( 25.0) |
| Hypocalcaemia | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Hypokalaemia | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Hyponatraemia | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Hyperglycaemia | 0 | 2 ( 9.1) | 2 ( 5.6) |
| Hypermagnesaemia | 1 ( 7.1) | 0 | 1 ( 2.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Hyperuricaemia | 0 | 0 | 0 |
| Infections and infestations | 3 ( 21.4) | 4 ( 18.2) | 7 ( 19.4) |
| Upper respiratory tract infection | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| Lung infection | 2 ( 14.3) | 0 | 2 ( 5.6) |
| Pneumonia | 0 | 1 ( 4.5) | 1 ( 2.8) |
| Anal abscess | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Parvovirus infection | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Investigations | 2 ( 14.3) | 7 ( 31.8) | 9 ( 25.0) |
| Activated partial thromboplastin time prolonged | 0 | 1 ( 4.5) | 1 ( 2.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=14)<br>n (%) | 450x10^6<br>(N=22)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
| Blood phosphorus decreased | 0 | 1 ( 4.5) | 1 ( 2.8) |
| Platelet count decreased | 1 ( 7.1) | 0 | 1 ( 2.8) |
| CD4 lymphocytes decreased | 1 ( 7.1) | 0 | 1 ( 2.8) |
| General disorders and administration site conditions | 2 ( 14.3) | 6 ( 27.3) | 8 ( 22.2) |
| Fatigue | 1 ( 7.1) | 3 ( 13.6) | 4 ( 11.1) |
| General physical health deterioration | 1 ( 7.1) | 2 ( 9.1) | 3 ( 8.3) |
| Asthenia | 0 | 2 ( 9.1) | 2 ( 5.6) |
| Death | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Gastrointestinal disorders | 2 ( 14.3) | 4 ( 18.2) | 6 ( 16.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Diarrhoea | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| Vomiting | 0 | 0 | 0 |
| Intestinal obstruction | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Vascular disorders | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| Hypertension | 0 | 0 | 0 |
| Hypotension | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Cardiac disorders | 1 ( 7.1) | 4 ( 18.2) | 5 ( 13.9) |
| Sinus tachycardia | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| Pericardial effusion | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=14)<br>n (%) | 450x10^6<br>(N=22)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
| Respiratory, thoracic and mediastinal disorders | 1 ( 7.1) | 4 ( 18.2) | 5 ( 13.9) |
| Hypoxia | 0 | 2 ( 9.1) | 2 ( 5.6) |
| Respiratory failure | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Musculoskeletal and connective tissue disorders | 3 ( 21.4) | 1 ( 4.5) | 4 ( 11.1) |
| Back pain | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| Musculoskeletal chest pain | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Osteolysis | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Nervous system disorders | 1 ( 7.1) | 3 ( 13.6) | 4 ( 11.1) |
| Syncope | 1 ( 7.1) | 2 ( 9.1) | 3 ( 8.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Analysis Plan: 30JUN2020 Confidential

Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Renal and urinary disorders | 1 ( 7.1) | 3 ( 13.6) | 4 ( 11.1) |
| Nephrolithiasis | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Ureterolithiasis | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Immune system disorders | 0 | 2 ( 9.1) | 2 ( 5.6) |
| Cytokine release syndrome | 0 | 2 ( 9.1) | 2 ( 5.6) |
| Injury, poisoning and procedural complications | 0 | 2 ( 9.1) | 2 ( 5.6) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| Myelodysplastic syndrome | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Tumour pain | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.

[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.3.2c
Grade 3-5 Adverse Events (AEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Surgical and medical procedures | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| Internal fixation of fracture | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Skin and subcutaneous tissue disorders | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Skin ulcer | 1 ( 7.1) | 0 | 1 ( 2.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events
within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
[b] CRS was graded using Lee's criteria, and all other AEs were graded using National Cancer Institute (NCI) Common Terminology Criteriafor Adverse Events (CTCAE) version 4.03. A subject is counted only once under the maximal grade.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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#### 13.4.3.3 SUE nach SOC und PT

Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Pyrexia | 0 | 3 ( 12.0) | 3 ( 8.6) |
| General physical health deterioration | 1 ( 10.0) | 2 ( 8.0) | 3 ( 8.6) |
| Death | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Oedema peripheral | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Immune system disorders | 2 ( 20.0) | 5 ( 20.0) | 7 ( 20.0) |
| Cytokine release syndrome | 2 ( 20.0) | 5 ( 20.0) | 7 ( 20.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 ( 20.0) | 3 ( 12.0) | 5 ( 14.3) |
| Bowen's disease | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Myelodysplastic syndrome | 1 ( 10.0) | 0 | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Tumour pain | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Blood and lymphatic system disorders | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Febrile neutropenia | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Neutropenia | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Haemolysis | 0 | 0 | 0 |
| Leukopenia | 0 | 0 | 0 |
| Thrombocytopenia | 0 | 0 | 0 |
| Renal and urinary disorders | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Nephrolithiasis | 1 ( 10.0) | 0 | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Ureterolithiasis | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Urinary retention | 0 | 0 | 0 |
| Cardiac disorders | 0 | 1 ( 4.0) | 1 ( 2.9) |
| Pericardial effusion | 0 | 0 | 0 |
| Nervous system disorders | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |
| Haemorrhage intracranial | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Syncope | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 20.0) | 1 ( 4.0) | 3 ( 8.6) |
| Hypoxia | 1 ( 10.0) | 1 ( 4.0) | 2 ( 5.7) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age <65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=10)<br>n (%) | <br>450x10^6<br>(N=25)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=35)<br>n (%) |
|---|---|---|---|
| Internal fixation of fracture | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 0 | 0 | 0 |
| Osteolysis | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Skin ulcer | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Vascular disorders | 1 ( 10.0) | 0 | 1 ( 2.9) |
| Hypotension | 1 ( 10.0) | 0 | 1 ( 2.9) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one serious AE | 7 ( 87.5) | 12 ( 92.3) | 19 ( 90.5) |
| Infections and infestations | 1 ( 12.5) | 4 ( 30.8) | 5 ( 23.8) |
| Lung infection | 0 | 0 | 0 |
| Upper respiratory tract infection | 0 | 2 ( 15.4) | 2 ( 9.5) |
| Anal abscess | 0 | 0 | 0 |
| Respiratory syncytial virus infection | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Skin infection | 0 | 0 | 0 |
| General disorders and administration site conditions | 3 ( 37.5) | 2 ( 15.4) | 5 ( 23.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=8)<br>n (%) | 450x10^6<br>(N=13)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
| Pyrexia | 2 ( 25.0) | 1 ( 7.7) | 3 ( 14.3) |
| General physical health deterioration | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Death | 0 | 0 | 0 |
| Oedema peripheral | 0 | 0 | 0 |
| Immune system disorders | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Cytokine release syndrome | 1 ( 12.5) | 2 ( 15.4) | 3 ( 14.3) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 12.5) | 3 ( 23.1) | 4 ( 19.0) |
| Bowen's disease | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Myelodysplastic syndrome | 0 | 1 ( 7.7) | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Protocol: CRB-401 Cut-off date: 07APR2020

Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Tumour pain | 0 | 0 | 0 |
| Blood and lymphatic system disorders | 2 ( 25.0) | 1 ( 7.7) | 3 ( 14.3) |
| Febrile neutropenia | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Neutropenia | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Haemolysis | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Leukopenia | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Thrombocytopenia | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Renal and urinary disorders | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Nephrolithiasis | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401 Cut-off date: 07APR2020

Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=8)<br>n (%) | 450x10^6<br>(N=13)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
| Ureterolithiasis | 0 | 0 | 0 |
| Urinary retention | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Cardiac disorders | 1 ( 12.5) | 1 ( 7.7) | 2 ( 9.5) |
| Pericardial effusion | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Nervous system disorders | 0 | 1 ( 7.7) | 1 ( 4.8) |
| Haemorrhage intracranial | 0 | 0 | 0 |
| Syncope | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 0 | 0 | 0 |
| Hypoxia | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Pneumonitis | 0 | 0 | 0 |
| Respiratory failure | 0 | 0 | 0 |
| Gastrointestinal disorders | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Diarrhoea | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Intestinal obstruction | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Injury, poisoning and procedural complications | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Hyperuricaemia | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Surgical and medical procedures | 1 ( 12.5) | 0 | 1 ( 4.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Age >=65 years
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=8)<br>n (%) | <br>450x10^6<br>(N=13)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=21)<br>n (%) |
|---|---|---|---|
| Internal fixation of fracture | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Musculoskeletal and connective tissue disorders | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Osteolysis | 1 ( 12.5) | 0 | 1 ( 4.8) |
| Skin and subcutaneous tissue disorders | 0 | 0 | 0 |
| Skin ulcer | 0 | 0 | 0 |
| Vascular disorders | 0 | 0 | 0 |
| Hypotension | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one serious AE | 10 ( 66.7) | 25 ( 78.1) | 35 ( 74.5) |
| Infections and infestations | 2 ( 13.3) | 9 ( 28.1) | 11 ( 23.4) |
| Lung infection | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Upper respiratory tract infection | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Anal abscess | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Respiratory syncytial virus infection | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Skin infection | 0 | 0 | 0 |
| General disorders and administration site conditions | 5 ( 33.3) | 6 ( 18.8) | 11 ( 23.4) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Pyrexia | 2 ( 13.3) | 3 ( 9.4) | 5 ( 10.6) |
| General physical health deterioration | 2 ( 13.3) | 2 ( 6.3) | 4 ( 8.5) |
| Death | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Oedema peripheral | 0 | 0 | 0 |
| Immune system disorders | 2 ( 13.3) | 7 ( 21.9) | 9 ( 19.1) |
| Cytokine release syndrome | 2 ( 13.3) | 7 ( 21.9) | 9 ( 19.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 6.7) | 5 ( 15.6) | 6 ( 12.8) |
| Bowen's disease | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Myelodysplastic syndrome | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Tumour pain | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Blood and lymphatic system disorders | 2 ( 13.3) | 1 ( 3.1) | 3 ( 6.4) |
| Febrile neutropenia | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Neutropenia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Haemolysis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Leukopenia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Thrombocytopenia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Renal and urinary disorders | 2 ( 13.3) | 2 ( 6.3) | 4 ( 8.5) |
| Nephrolithiasis | 1 ( 6.7) | 0 | 1 ( 2.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Ureterolithiasis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Urinary retention | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Cardiac disorders | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Pericardial effusion | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Nervous system disorders | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Haemorrhage intracranial | 0 | 0 | 0 |
| Syncope | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Hypoxia | 0 | 1 ( 3.1) | 1 ( 2.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=15)<br>n (%) | 450x10^6<br>(N=32)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
| Pneumonitis | 0 | 0 | 0 |
| Respiratory failure | 0 | 0 | 0 |
| Gastrointestinal disorders | 0 | 1 ( 3.1) | 1 ( 2.1) |
| Diarrhoea | 0 | 0 | 0 |
| Intestinal obstruction | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 0 | 2 ( 6.3) | 2 ( 4.3) |
| Metabolism and nutrition disorders | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |
| Hyperuricaemia | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Surgical and medical procedures | 1 ( 6.7) | 1 ( 3.1) | 2 ( 4.3) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=15)<br>n (%) | <br>450x10^6<br>(N=32)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=47)<br>n (%) |
|---|---|---|---|
| Internal fixation of fracture | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Musculoskeletal and connective tissue disorders | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Osteolysis | 1 ( 6.7) | 0 | 1 ( 2.1) |
| Skin and subcutaneous tissue disorders | 0 | 0 | 0 |
| Skin ulcer | 0 | 0 | 0 |
| Vascular disorders | 0 | 0 | 0 |
| Hypotension | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one serious AE | 3 (100.0) | 4 ( 66.7) | 7 ( 77.8) |
| Infections and infestations | 2 ( 66.7) | 1 ( 16.7) | 3 ( 33.3) |
| Lung infection | 2 ( 66.7) | 0 | 2 ( 22.2) |
| Upper respiratory tract infection | 0 | 0 | 0 |
| Anal abscess | 0 | 0 | 0 |
| Respiratory syncytial virus infection | 0 | 0 | 0 |
| Skin infection | 1 ( 33.3) | 0 | 1 ( 11.1) |
| General disorders and administration site conditions | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Pyrexia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| General physical health deterioration | 0 | 0 | 0 |
| Death | 0 | 0 | 0 |
| Oedema peripheral | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Immune system disorders | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Cytokine release syndrome | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 ( 66.7) | 1 ( 16.7) | 3 ( 33.3) |
| Bowen's disease | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Myelodysplastic syndrome | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Tumour pain | 0 | 0 | 0 |
| Blood and lymphatic system disorders | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Febrile neutropenia | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Neutropenia | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Haemolysis | 0 | 0 | 0 |
| Leukopenia | 0 | 0 | 0 |
| Thrombocytopenia | 0 | 0 | 0 |
| Renal and urinary disorders | 0 | 0 | 0 |
| Nephrolithiasis | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Ureterolithiasis | 0 | 0 | 0 |
| Urinary retention | 0 | 0 | 0 |
| Cardiac disorders | 0 | 1 ( 16.7) | 1 ( 11.1) |
| Pericardial effusion | 0 | 0 | 0 |
| Nervous system disorders | 1 ( 33.3) | 1 ( 16.7) | 2 ( 22.2) |
| Haemorrhage intracranial | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Syncope | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 66.7) | 0 | 2 ( 22.2) |
| Hypoxia | 1 ( 33.3) | 0 | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Pneumonitis | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Respiratory failure | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Gastrointestinal disorders | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Diarrhoea | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Intestinal obstruction | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Injury, poisoning and procedural complications | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 0 | 0 | 0 |
| Hyperuricaemia | 0 | 0 | 0 |
| Surgical and medical procedures | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Double Refractory = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=3)<br>n (%) | <br>450x10^6<br>(N=6)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=9)<br>n (%) |
|---|---|---|---|
| Internal fixation of fracture | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 0 | 0 | 0 |
| Osteolysis | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Skin ulcer | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Vascular disorders | 1 ( 33.3) | 0 | 1 ( 11.1) |
| Hypotension | 1 ( 33.3) | 0 | 1 ( 11.1) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects
reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Number of subjects with at least one serious AE | 2 ( 50.0) | 13 ( 81.3) | 15 ( 75.0) |
| Infections and infestations | 0 | 6 ( 37.5) | 6 ( 30.0) |
| Lung infection | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Upper respiratory tract infection | 0 | 2 ( 12.5) | 2 ( 10.0) |
| Anal abscess | 0 | 0 | 0 |
| Respiratory syncytial virus infection | 0 | 0 | 0 |
| Skin infection | 0 | 0 | 0 |
| General disorders and administration site conditions | 2 ( 50.0) | 1 ( 6.3) | 3 ( 15.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Pyrexia | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |
| General physical health deterioration | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Death | 0 | 0 | 0 |
| Oedema peripheral | 0 | 0 | 0 |
| Immune system disorders | 0 | 5 ( 31.3) | 5 ( 25.0) |
| Cytokine release syndrome | 0 | 5 ( 31.3) | 5 ( 25.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 ( 25.0) | 3 ( 18.8) | 4 ( 20.0) |
| Bowen's disease | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Myelodysplastic syndrome | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Tumour pain | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Blood and lymphatic system disorders | 1 ( 25.0) | 1 ( 6.3) | 2 ( 10.0) |
| Febrile neutropenia | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Neutropenia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Haemolysis | 0 | 0 | 0 |
| Leukopenia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Thrombocytopenia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Renal and urinary disorders | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Nephrolithiasis | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Ureterolithiasis | 0 | 0 | 0 |
| Urinary retention | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Cardiac disorders | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Pericardial effusion | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Nervous system disorders | 0 | 0 | 0 |
| Haemorrhage intracranial | 0 | 0 | 0 |
| Syncope | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 0 | 1 ( 6.3) | 1 ( 5.0) |
| Hypoxia | 0 | 1 ( 6.3) | 1 ( 5.0) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=4)<br>n (%) | 450x10^6<br>(N=16)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
| Pneumonitis | 0 | 0 | 0 |
| Respiratory failure | 0 | 0 | 0 |
| Gastrointestinal disorders | 0 | 0 | 0 |
| Diarrhoea | 0 | 0 | 0 |
| Intestinal obstruction | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Hyperuricaemia | 1 ( 25.0) | 0 | 1 ( 5.0) |
| Surgical and medical procedures | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = Yes
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=4)<br>n (%) | <br>450x10^6<br>(N=16)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=20)<br>n (%) |
|---|---|---|---|
| Internal fixation of fracture | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 0 | 0 | 0 |
| Osteolysis | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 0 | 0 | 0 |
| Skin ulcer | 0 | 0 | 0 |
| Vascular disorders | 0 | 0 | 0 |
| Hypotension | 0 | 0 | 0 |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency
of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=14)<br>n (%) | 450x10^6<br>(N=22)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
| Number of subjects with at least one serious AE | 11 ( 78.6) | 16 ( 72.7) | 27 ( 75.0) |
| Infections and infestations | 4 ( 28.6) | 4 ( 18.2) | 8 ( 22.2) |
| Lung infection | 2 ( 14.3) | 0 | 2 ( 5.6) |
| Upper respiratory tract infection | 0 | 0 | 0 |
| Anal abscess | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Respiratory syncytial virus infection | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Skin infection | 1 ( 7.1) | 0 | 1 ( 2.8) |
| General disorders and administration site conditions | 4 ( 28.6) | 6 ( 27.3) | 10 ( 27.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included
under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Pyrexia | 1 ( 7.1) | 3 ( 13.6) | 4 ( 11.1) |
| General physical health deterioration | 1 ( 7.1) | 2 ( 9.1) | 3 ( 8.3) |
| Death | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Oedema peripheral | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Immune system disorders | 3 ( 21.4) | 2 ( 9.1) | 5 ( 13.9) |
| Cytokine release syndrome | 3 ( 21.4) | 2 ( 9.1) | 5 ( 13.9) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 ( 14.3) | 3 ( 13.6) | 5 ( 13.9) |
| Bowen's disease | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Myelodysplastic syndrome | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| | Escalation and Expansion (Part A + B) | | |
|---|---|---|---|
| System Organ Class<br>Preferred Term [a] | 150x10^6<br>(N=14)<br>n (%) | 450x10^6<br>(N=22)<br>n (%) | Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
| Tumour pain | 0 | 0 | 0 |
| Blood and lymphatic system disorders | 2 ( 14.3) | 1 ( 4.5) | 3 ( 8.3) |
| Febrile neutropenia | 0 | 1 ( 4.5) | 1 ( 2.8) |
| Neutropenia | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Haemolysis | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Leukopenia | 0 | 0 | 0 |
| Thrombocytopenia | 0 | 0 | 0 |
| Renal and urinary disorders | 1 ( 7.1) | 2 ( 9.1) | 3 ( 8.3) |
| Nephrolithiasis | 1 ( 7.1) | 0 | 1 ( 2.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
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Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Ureterolithiasis | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Urinary retention | 0 | 0 | 0 |
| Cardiac disorders | 0 | 2 ( 9.1) | 2 ( 5.6) |
| Pericardial effusion | 0 | 0 | 0 |
| Nervous system disorders | 1 ( 7.1) | 2 ( 9.1) | 3 ( 8.3) |
| Haemorrhage intracranial | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Syncope | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Respiratory, thoracic and mediastinal disorders | 2 ( 14.3) | 0 | 2 ( 5.6) |
| Hypoxia | 1 ( 7.1) | 0 | 1 ( 2.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Celgene Corporation
Protocol: CRB-401


Cut-off date: 07APR2020

Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Pneumonitis | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Respiratory failure | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Gastrointestinal disorders | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |
| Diarrhoea | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Intestinal obstruction | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Injury, poisoning and procedural complications | 0 | 2 ( 9.1) | 2 ( 5.6) |
| Metabolism and nutrition disorders | 0 | 1 ( 4.5) | 1 ( 2.8) |
| Hyperuricaemia | 0 | 0 | 0 |
| Surgical and medical procedures | 1 ( 7.1) | 1 ( 4.5) | 2 ( 5.6) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

Table 6.2.1c
Serious Adverse Events (SAEs) by System Organ Class and Preferred Term Reported for At Least 5% of Subjects
Reporting Period B to F (LD-Chemo to end of follow-up), Presence of Extramedullary Plasmacytoma = No
bb2121-Treated Population

| System Organ Class<br>Preferred Term [a] | Escalation and Expansion (Part A + B)<br>150x10^6<br>(N=14)<br>n (%) | <br>450x10^6<br>(N=22)<br>n (%) | <br>Combined RP2D<br>(150-450)x10^6<br>(N=36)<br>n (%) |
|---|---|---|---|
| Internal fixation of fracture | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Musculoskeletal and connective tissue disorders | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Osteolysis | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Skin and subcutaneous tissue disorders | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Skin ulcer | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Vascular disorders | 1 ( 7.1) | 0 | 1 ( 2.8) |
| Hypotension | 1 ( 7.1) | 0 | 1 ( 2.8) |

Note: One subject dosed at 205x10^6 cells in Part B Cohort 1 and one subject dosed at 305x10^6 cells in Part B Cohort 3 are included under target dose of 450x10^6 cells. AEs designated as symptoms of cytokine release syndrome are excluded from analysis.
RP2D = Recommended phase 2 dose.
[a] Coded using Medical Dictionary for Regulatory Activities (MedDRA) version 22.0. A subject is counted only once for multiple events within preferred term (PT)/system organ class (SOC). AEs are sorted by descending frequency of SOCs and then by descending frequency of PTs within each SOC based on the combined RP2D of the 'Overall' analysis. SOCs/PTs are presented only if at least 5% of subjects reported an event in at least one treatment group, based on the 'Overall' analysis.
Missing subgroup categories are not presented.
SOURCE: X:\Numerus\Studies\CLG\CLG103\Analysis\Prod\Progs\Tab_6_1_3.SAS
Date/time of run: 02OCT2020 15:23
Analysis Plan: 30JUN2020 Confidential

# III. Indirekte Vergleiche ohne Brückenkomparator

## 14. Mediane Nachbeobachtungsdauern

| **Übersicht der medianen Nachbeobachtungsdauern aller Datenschnitte der für den ITC nach CA089-003[a] und den ITC Ide-Cel vs. ERRMM Kohorte aus MM-007[a] herangezogenen Kohorten** | | |
|---|---|---|
| | **Datenschnitt** | **Nachbeobachtungsdauer Median (Min; Max)** |
| **Ide-Cel Studien** | | |
| **KarMMa** Leukapherese Analyse-Set (ITT) (N = 136) | **16.10.2019[b,c]** | **12,5** (1,0; 19,7) |
| | 14.01.2020 | 14,3 (1,0; 22,6) |
| | 07.04.2020 | 16,5 (1,0; 25,8) |
| | 21.12.2020 | 19,9 (1,0; 33,8) |
| **CRB-401** Leukapherese Analyse-Set (ITT) (N = 42) | **22.07.2019[b,c]** | **9,9** (1,0; 32,0) |
| | 14.01.2020 | 12,1 (1,0; 39,4) |
| | 07.04.2020 | 11,5 (1,0; 42,3) |
| **Konventionelle Therapieoptionen** | | |
| **NDS-MM-003** ERRMM Kohorte (N = 190) | **30.10.2019[b]** | **10,2** (0,2; 24,0) |
| **MM-007** ERRMM Kohorte (N = 41) | **15.09.2018[c]** | **4,3** (0,9: 20,2) |

a: Für den ITC nach CA089-003 (Leukapherese Analyse-Sets der Studien KarMMa und CRB vs. ERRMM Kohorte der Studie NDS-MM-003) und den ITC Ide-Cel vs. ERRMM Kohorte der Studie MM-007 (Leukapherese Analyse-Sets der Studien KarMMa und CRB vs. ERRMM Kohorte der Studie MM-007) wurden die Nachbeobachtungszeiten wie folgt definiert:

Definition der Nachbeobachtungszeit der Leukapherese Analyse-Sets der Studien KarMMa und CRB-401 in Monaten: ((Letzter Zeitpunkt, zu dem bekannt war, dass der Patient noch lebte, oder Zeitpunkt des Todes, jenachdem was früher eintrat) – Zeitpunkt der Leukapherese + 1) / 30.4375

Definition der Nachbeobachtungszeit der ERRMM Kohorte der Studie NDS-MM-007 und MM-007 in Monaten: ((Letzter Zeitpunkt, zudem bekannt war, dass der Patient noch lebte oder Zeitpunkt des Todes) – Indexdatum + 1) / 30.4375

b: herangezogen für ITC nach CA089-003, da vergleichbarste Datenschnitte in Hinblick auf Median der Nachbeobachtungsdauer

c: herangezogen für ITC Ide-Cel vs. ERRMM Kohorte der Studie MM-007, da vergleichbarste Datenschnitte in Hinblick auf Median der Nachbeobachtungsdauer

Abkürzungen: Ide-Cel: Idecabtagen vicleucel; ERRMM: Eligible RRMM; ITC: Indirect Treatment Comparison (im Dossier vereinfachend genutzt für indirekter Vergleich ohne Brückenkomparator); ITT: Intention-to-Treat; Max: Maximum; Min: Minimum; N: Anzahl Patienten; RRMM: Rezidiviertes und/oder refraktäres Multiples Myelom

| **Übersicht der medianen Nachbeobachtungsdauern aller Datenschnitte der für den ITC nach CA089-007[a] herangezogenen Kohorten** | | |
|---|---|---|
| | **Datenschnitt** | **Nachbeobachtungsdauer Median (Min; Max)** |
| **Ide-Cel Studien** | | |
| **KarMMa** Leukapherese Analyse-Set (ITT) (N = 136) | 16.10.2019 | 15,0 (11,1; 21,0) |
| | 14.01.2020 | 18,0 (14,1; 24,0) |
| | 07.04.2020 | 20,7 (16,8; 26,7) |
| | **21.12.2020[b]** | **29,2** (25,5; 35,2) |
| **CRB-401** Leukapherese Analyse-Set (ITT) (N = 42) | 22.07.2019 | 17,7 (7,6; 36,7) |
| | 14.01.2020 | 23,4 (13,4; 42,5) |
| | **07.04.2020[b]** | **26,2** (16,2; 45,0) |
| **Konventionelle Therapieoptionen** | | |
| **PREAMBLE** ERRMM Kohorte (N = 43) | **16.09.2020[c]** | **25,6** (4,6; 48,3) |

a: Für den ITC nach CA089-007 (Leukapherese Analyse-Sets der Studien KarMMa und CRB vs. ERRMM Kohorte der Studie PREAMBLE) wurden die Nachbeobachtungszeiten wie folgt definiert:

Definition der Nachbeobachtungszeit der Leukapherese Analyse-Sets der Studien KarMMa und CRB-401 in Monaten: ((Letzter Zeitpunkt, zu dem bekannt war, dass der Patient noch lebte, oder Zeitpunkt des Todes, jenachdem was früher eintrat) – Zeitpunkt der Leukapherese + 1) / 30,4375

Definition der minimalen potenziellen Beobachtungszeit in Monaten der ERRMM Kohorte der Studie PREAMBLE in Monaten: ((Letzter Zeitpunkt, zudem bekannt war, dass der Patient noch lebte oder Zeitpunkt des Todes) – Indexdatum + 1) / 30,4375

b: herangezogen für ITC nach CA089-007, da vergleichbarste Datenschnitte in Hinblick auf Median der Nachbeobachtungsdauer

Abkürzungen: Ide-Cel: Idecabtagen vicleucel; ERRMM: Eligible RRMM; ITC: Indirect Treatment Comparison (im Dossier vereinfachend genutzt für indirekter Vergleich ohne Brückenkomparator); ITT: Intention-to-Treat; Max: Maximum; Min: Minimum; N: Anzahl Patienten; RRMM: Rezidiviertes und/oder refraktäres Multiples Myelom

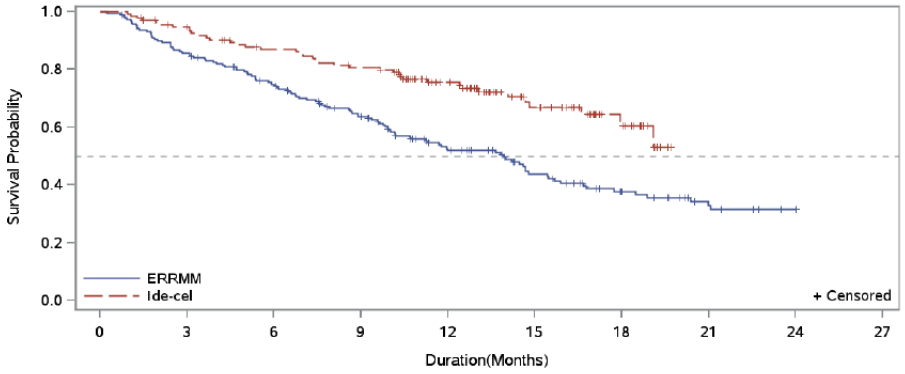
# 15. Gesamtüberleben (Kaplan-Meier Kurven für Sensitivitätsanalysen)

## 15.1 Indirekter Vergleich ohne Brückenkomparator nach CA089-003

Bristol Myers Squibb
Protocol: CA-089-003

Page 1 of 1
Data Cut Off Date: 30Oct2019(RW) 16OCT2019(MM-001)

Figure 1.2.2
Overall Survival (OS) Without Adjustment by Confounders of RW ERRMM and BB2121 ITT Cohorts




Number of subjects at risk

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| ERRMM | 190 | 162 | 137 | 111 | 77 | 53 | 36 | 24 | 19 | 0 |
| Ide-cel | 136 | 124 | 110 | 101 | 72 | 36 | 16 | 0 | | |

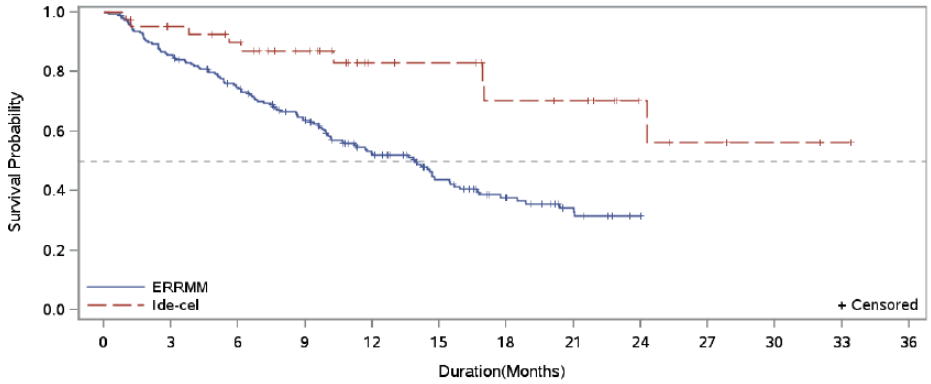
ITT: Enrolled subjects who underwent leukapheresis, excluding 150 x 10^6 dose group.
OS: Time from index date to all-cause death or censorship.
Program Path: /u02/projects/bb_2121/bb_2121_nds_mm_003/deliverables/d006_german_2021/programs/graphs/final/f_1_2_2.sas
Run Date: 12FEB2021

Kaplan-Meier Kurve für den **ITC nach CA089-003 des Leukapherese Analyse-Set (ITT) der Studie KarMMa vs. ERRMM Kohorte der Studie NDS-MM-003** für das **Gesamtüberleben:** Ergebnisse des naiven Vergleichs
Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat

Bristol Myers Squibb
Protocol: CA-089-003

Page 1 of 1
Data Cut Off Date: 30Oct2019(RW),22JUL2019(CRB-401)

Figure 1.2.1
Overall Survival (OS) Without Adjustment by Confounders of RW ERRMM and CRB-401 ITT Cohorts




Number of subjects at risk

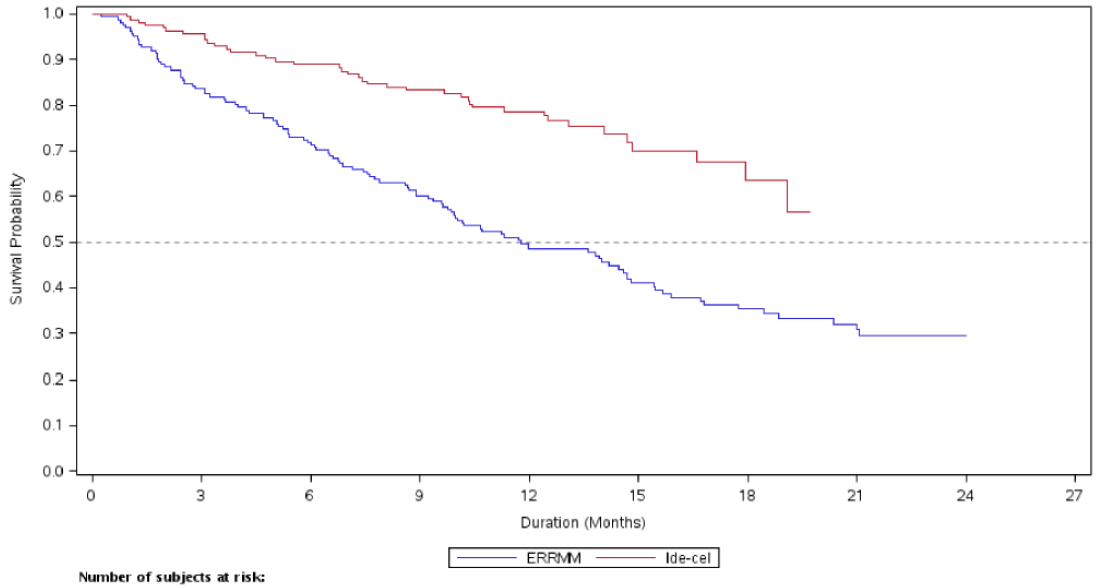
| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ERRMM | 190 | 162 | 137 | 111 | 77 | 53 | 36 | 24 | 19 | 0 | | | |
| Ide-cel | 42 | 37 | 33 | 26 | 16 | 15 | 11 | 10 | 5 | 3 | 2 | 1 | 0 |

ITT: Enrolled subjects who underwent leukapheresis, excluding 150 x 10^6 dose group.
OS: Time from index date to all-cause death or censorship.
Program Path: /u02/projects/bb_2121/bb_2121_nds_mm_003/deliverables/d006_german_2021/programs/graphs/final/f_1_2_1.sas
Run Date: 12FEB2021

Kaplan-Meier Kurve für den **ITC nach CA089-003 des Leukapherese Analyse-Set (ITT) der Studie CRB-401 vs. ERRMM Kohorte der Studie NDS-MM-003** für das **Gesamtüberleben:** Ergebnisse des naiven Vergleichs
Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat

Bristol Myers Squibb
CA-089-003
Page 1 of 1
Cutoff date: 30Oct2019(RW) 16OCT2019(MM-001)

Figure 1.3.2
Overall Survival (OS) Adjusted By Confounders of RW ERRMM and BB2121 ITT Cohort




Number of subjects at risk:

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| ERRMM | 190 | 162 | 137 | 111 | 77 | 53 | 36 | 24 | 19 | 0 |
| Ide-cel | 136 | 124 | 110 | 101 | 72 | 36 | 16 | 0 | 0 | 0 |

ITT: Enrolled subjects who underwent leukapheresis, excluding 150 x 10^6 dose group.
OS: Time from index date to all-cause death or censorship.
Program:
/u02/projects/bb_2121/bb_2121_nds_mm_003/deliverables/d006_german_2021/programs/graphs/final/f_os_adj_multvar_enrolled.sas
Data Source: ADTTE
Run date: 11FEB21:21:02

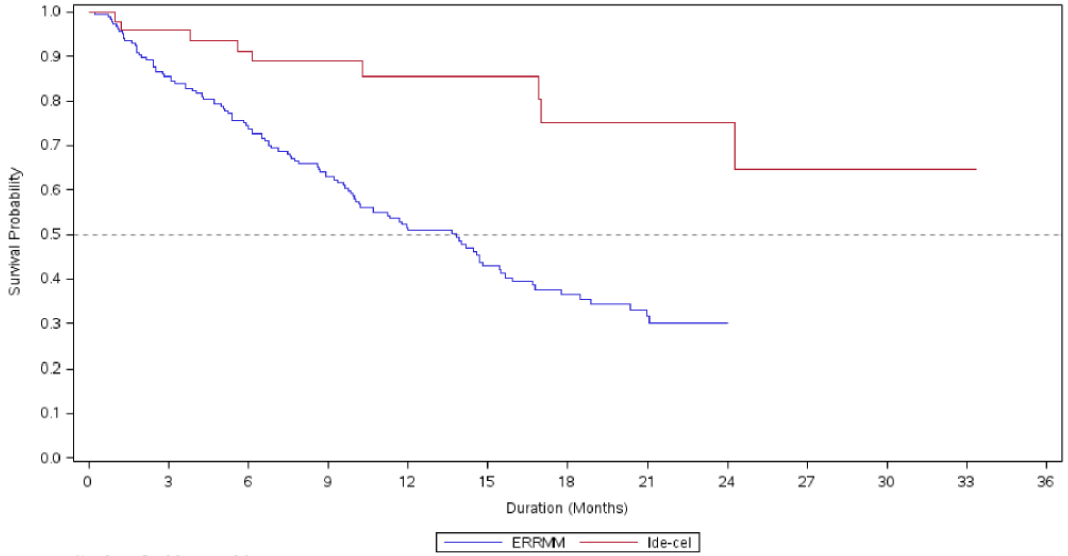
Kaplan-Meier Kurve für den **ITC nach CA089-003 des Leukapherese Analyse-Set (ITT) der Studie KarMMa vs. ERRMM Kohorte der Studie NDS-MM-003** für das **Gesamtüberleben:** Ergebnisse des Multivariaten Cox-Proportional-Hazards-Modell (mit Adjustierung für Confounder)

Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat

Bristol Myers Squibb
CA-089-003

Page 1 of 1
Cutoff date: 30Oct2019(RW) 22JUL2019(CRB-401)

Figure 1.3.1
Overall Survival (OS) Adjusted By Confounders of RW ERRMM and CRB401 ITT Cohort




**Number of subjects at risk:**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ERRMM | 190 | 162 | 137 | 111 | 77 | 53 | 36 | 24 | 19 | 0 | 0 | 0 | 0 |
| Ide-cel | 42 | 37 | 33 | 26 | 16 | 15 | 11 | 10 | 5 | 3 | 2 | 1 | 0 |

ITT: Enrolled subjects who underwent leukapheresis, excluding 150 x 10^6 dose group.
OS: Time from index date to all-cause death or censorship.
Program:
/u02/projects/bb_2121/bb_2121_nds_mm_003/deliverables/d006_german_2021/programs/graphs/final/f_os_adj_multvar_enrolled.sas
Data Source: ADTTE

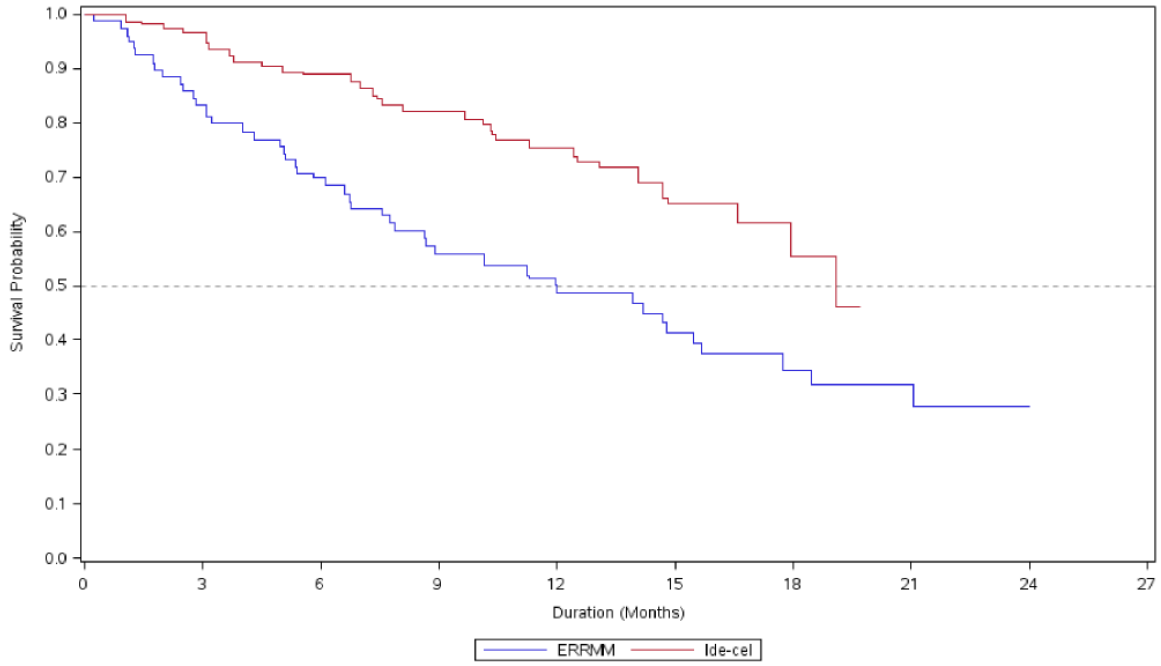
Run date: 11FEB21:21:02

Kaplan-Meier Kurve für den **ITC nach CA089-003 des Leukapherese Analyse-Set (ITT) der Studie CRB-401 vs. ERRMM Kohorte der Studie NDS-MM-003** für das **Gesamtüberleben:** Ergebnisse des Multivariaten Cox-Proportional-Hazards-Modell (mit Adjustierung für Confounder)

Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat

Bristol Myers Squibb
CA-089-003
Page 1 of 1
Cutoff date: 30Oct2019(RW) 16OCT2019(MM-001)

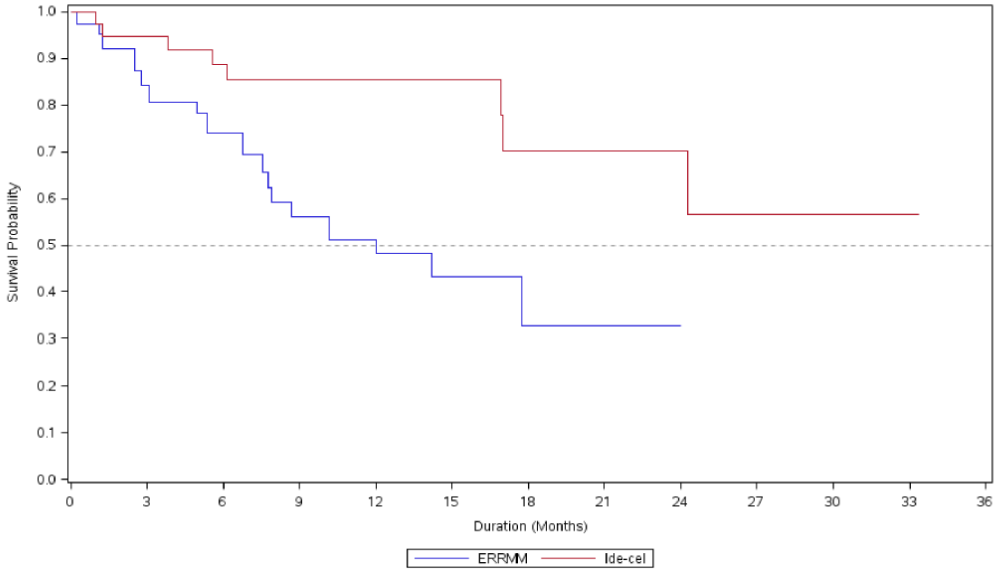
Figure 1.5.2
Overall Survival (OS) Adjusted for Matching of RW ERRMM and BB2121 ITT Cohort




ITT: Enrolled subjects who underwent leukapheresis, excluding 150 x 10^6 dose group.
OS: Time from index date to all-cause death or censorship.
Program:
/u02/projects/bb_2121/bb_2121_nds_mm_003/deliverables/d006_german_2021/programs/graphs/final/f_os_matched_enrolled.sas
Data Source: ADTTE
Run date: 11FEB21:21:00

Kaplan-Meier Kurve für den **ITC nach CA089-003 des Leukapherese Analyse-Set (ITT) der Studie KarMMa vs. ERRMM Kohorte der Studie NDS-MM-003** für das **Gesamtüberleben:** Ergebnisse des Propensity Score Matching
Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat

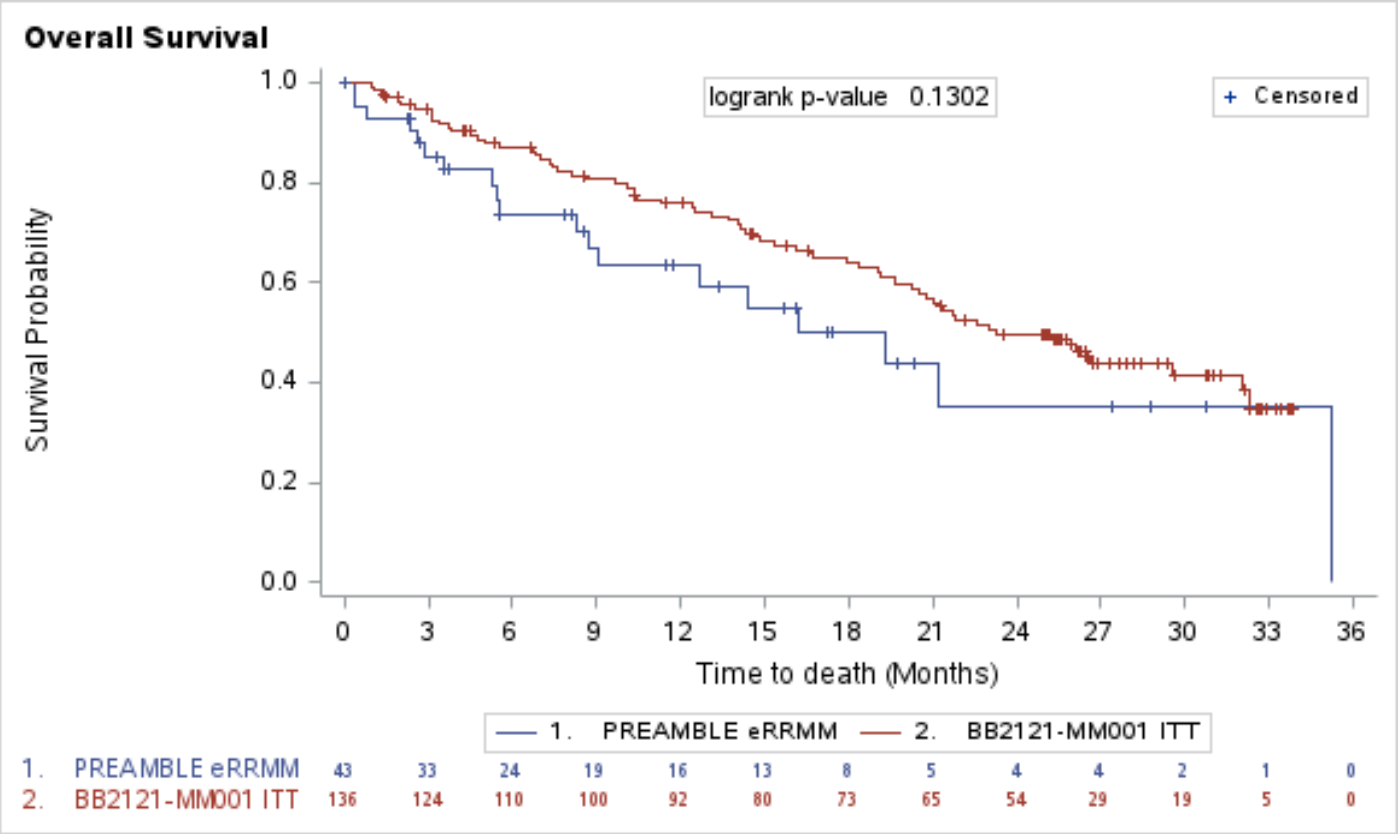
Bristol Myers Squibb
CA-089-003
Page 1 of 1
Cutoff date: 30Oct2019(RW) 22JUL2019(CRB-401)
Figure 1.5.1
Overall Survival (OS) Adjusted for Matching of RW ERRMM and CRB401 ITT Cohort



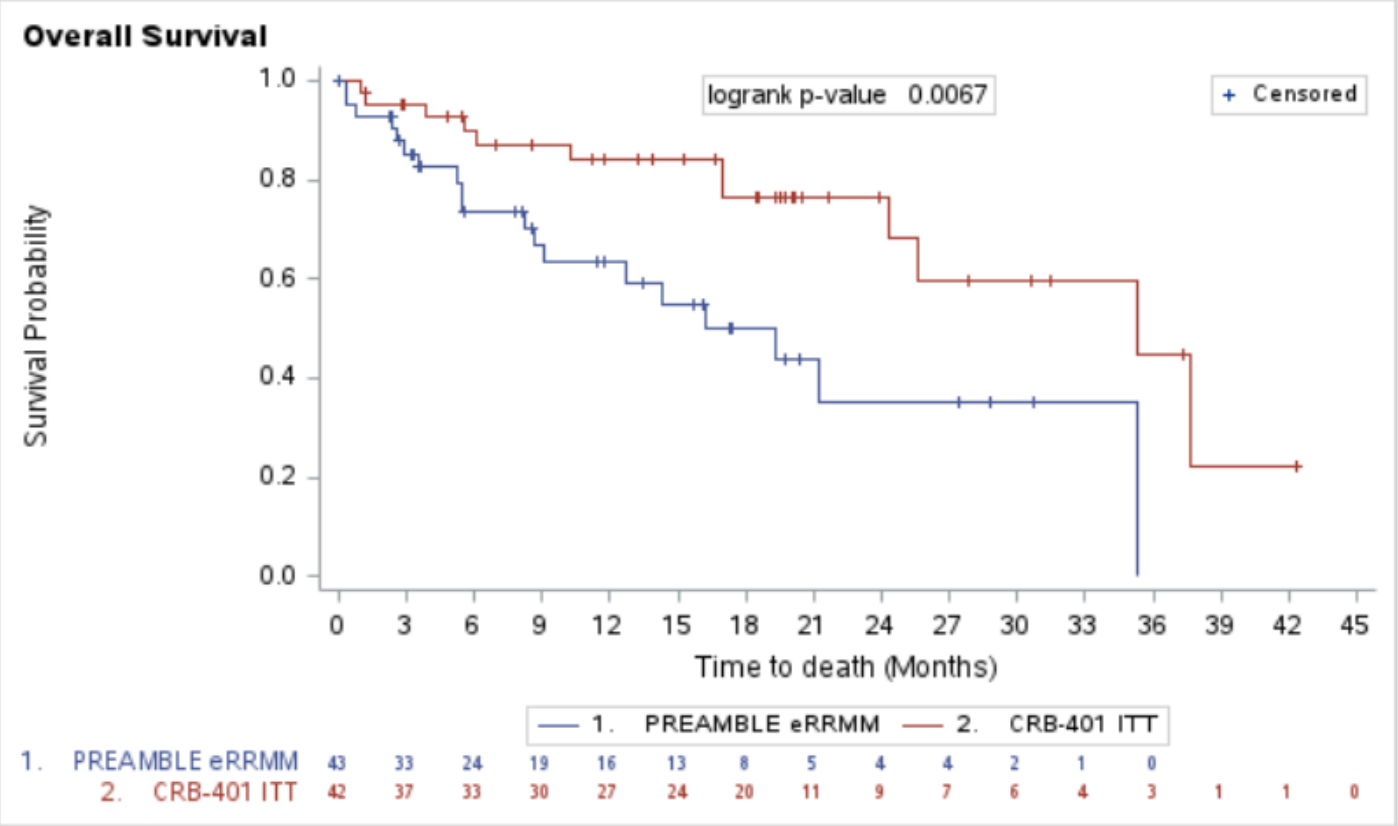

ITT: Enrolled subjects who underwent leukapheresis, excluding 150 x 10^6 dose group.
OS: Time from index date to all-cause death or censorship.
Program:
/u02/projects/bb_2121/bb_2121_nds_mm_003/deliverables/d006_german_2021/programs/graphs/final/f_os_matched_enrolled.sas
Data Source: ADTTE
Run date: 11FEB21:21:00

Kaplan-Meier Kurve für den **ITC nach CA089-003 des Leukapherese Analyse-Set (ITT) der Studie CRB-401 vs. ERRMM Kohorte der Studie NDS-MM-003** für das **Gesamtüberleben:** Ergebnisse des Propensity Score Matching
Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat

## 15.2 Indirekter Vergleich ohne Brückenkomparator nach CA089-007

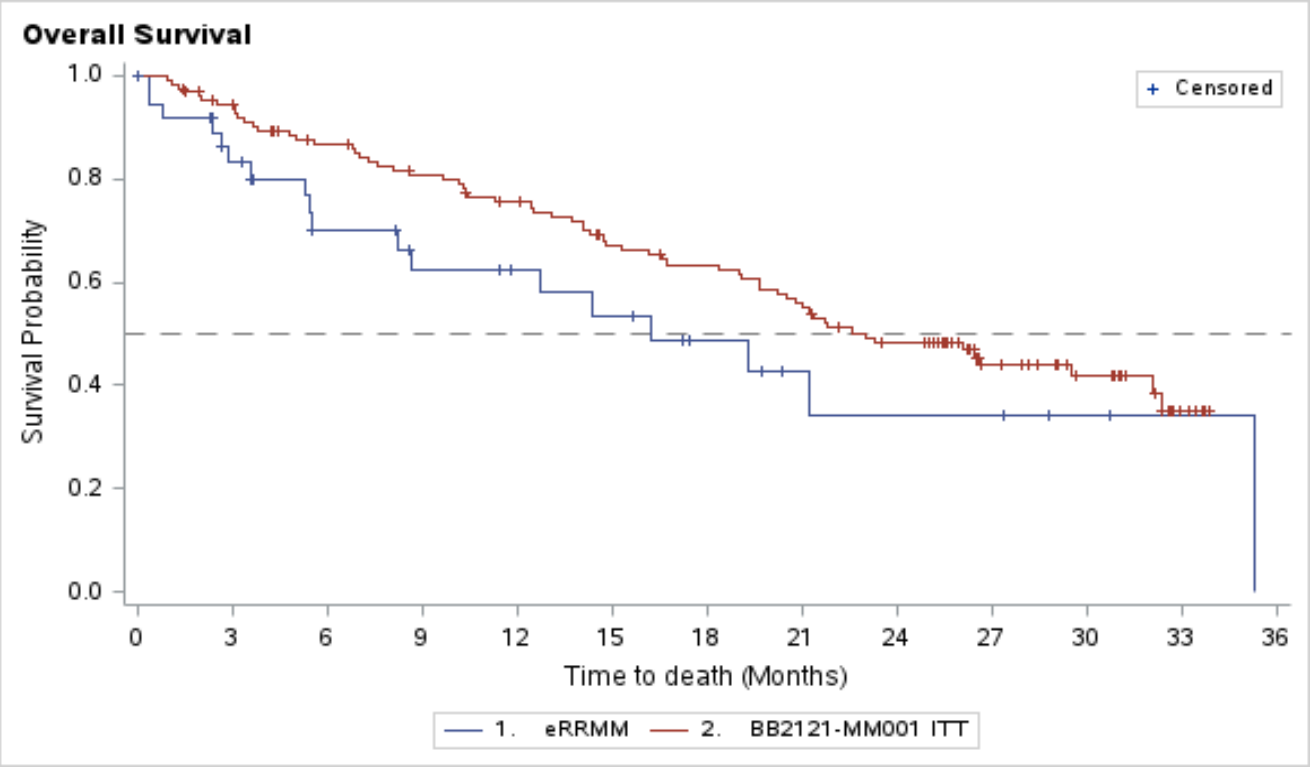



Kaplan-Meier Kurve für den **ITC nach CA089-007 des Leukapherese Analyse-Set (ITT) der Studie KarMMa vs. ERRMM Kohorte der Studie PREAMBLE** für das **Gesamtüberleben:** Ergebnisse des naiven Vergleichs
Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat



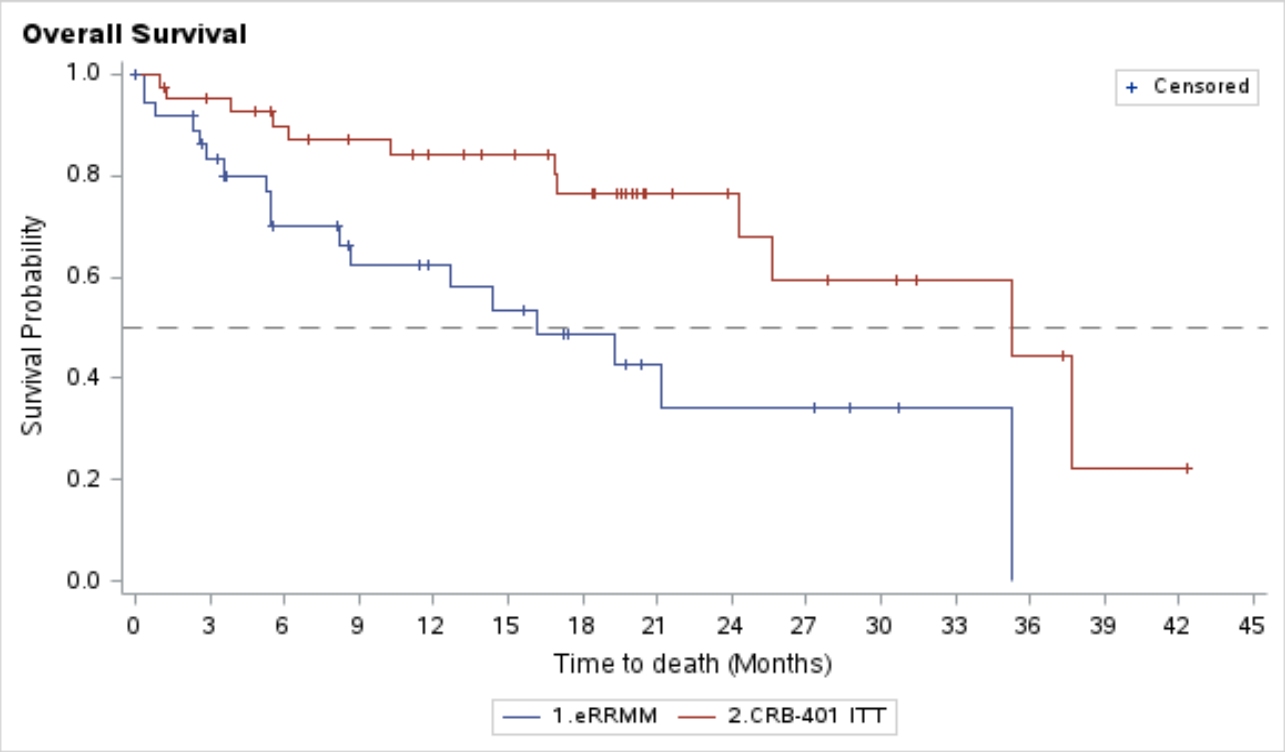

Kaplan-Meier Kurve für den **ITC nach CA089-007 des Leukapherese Analyse-Set (ITT) der Studie CRB-401 vs. ERRMM Kohorte der Studie PREAMBLE** für das **Gesamtüberleben:** Ergebnisse des naiven Vergleichs

Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat.



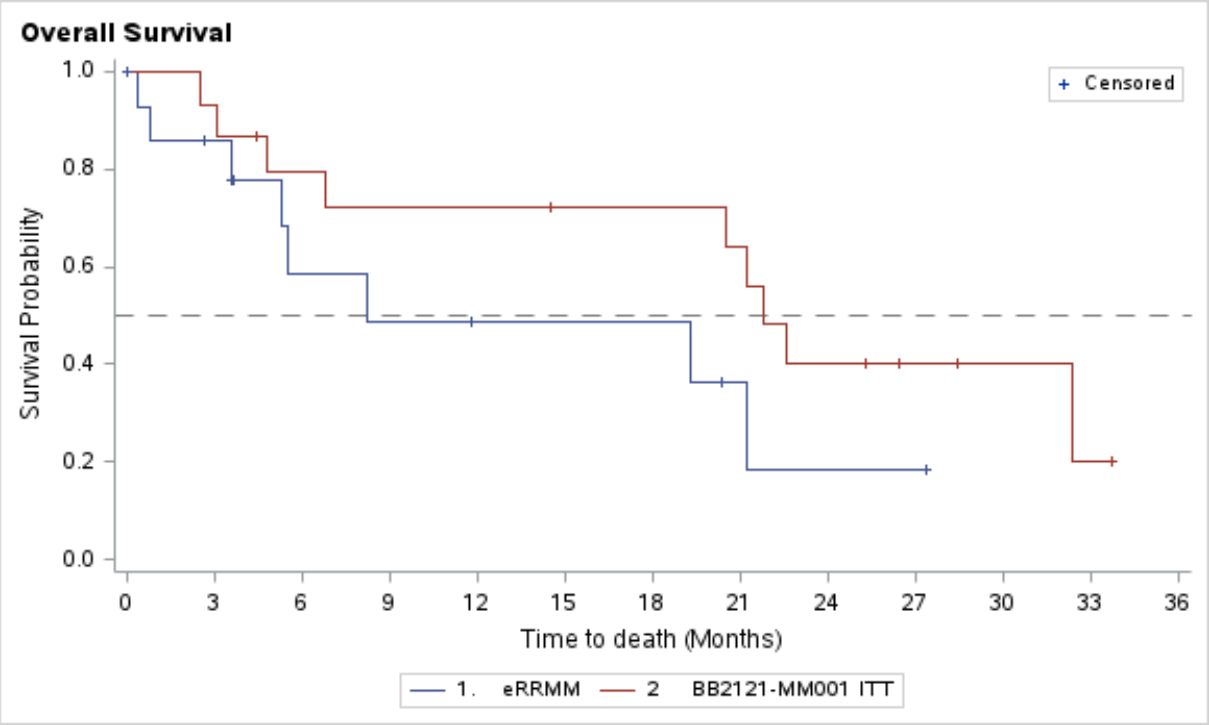

Kaplan-Meier Kurve für den **ITC nach CA089-007 des Leukapherese Analyse-Set (ITT) der Studie KarMMa vs. ERRMM Kohorte der Studie PREAMBLE** für das **Gesamtüberleben:** Ergebnisse des Multivariaten Cox-Proportional-Hazards-Modell (mit Adjustierung für Confounder)

Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat

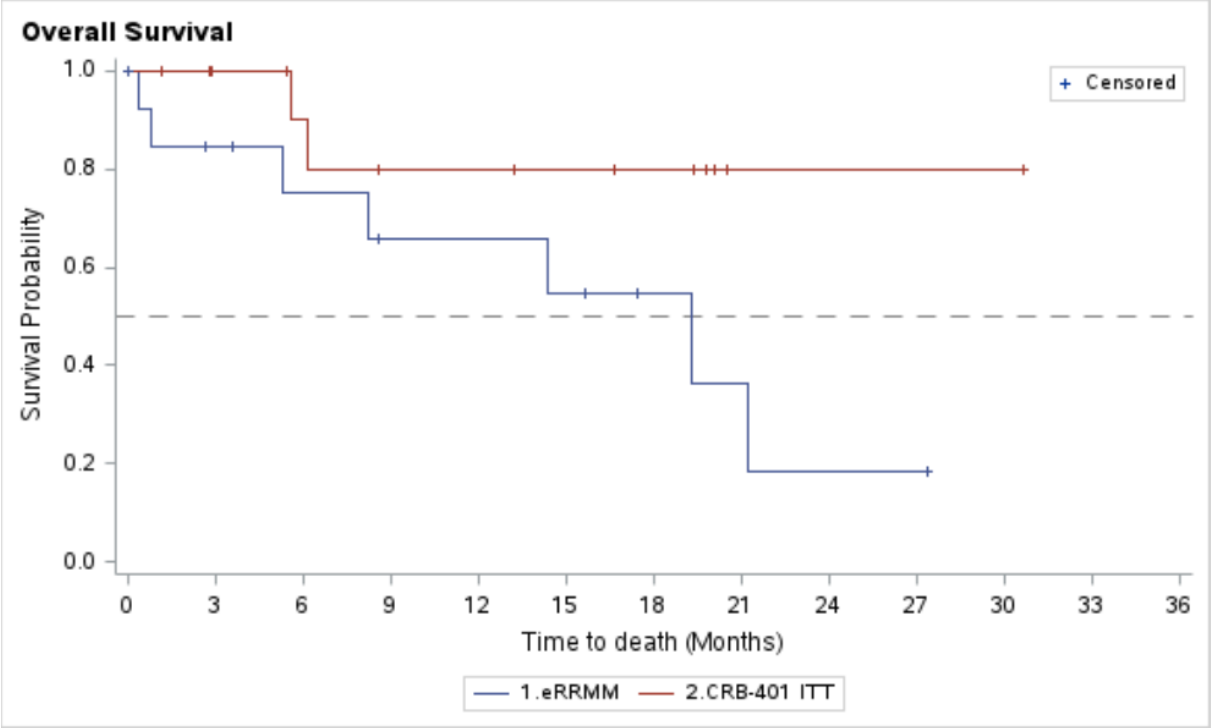



Kaplan-Meier Kurve für den **ITC nach CA089-007 des Leukapherese Analyse-Set (ITT) der Studie CRB-401 vs. ERRMM Kohorte der Studie PREAMBLE** für das **Gesamtüberleben:** Ergebnisse des Multivariaten Cox-Proportional-Hazards-Modell (mit Adjustierung für Confounder)

Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat

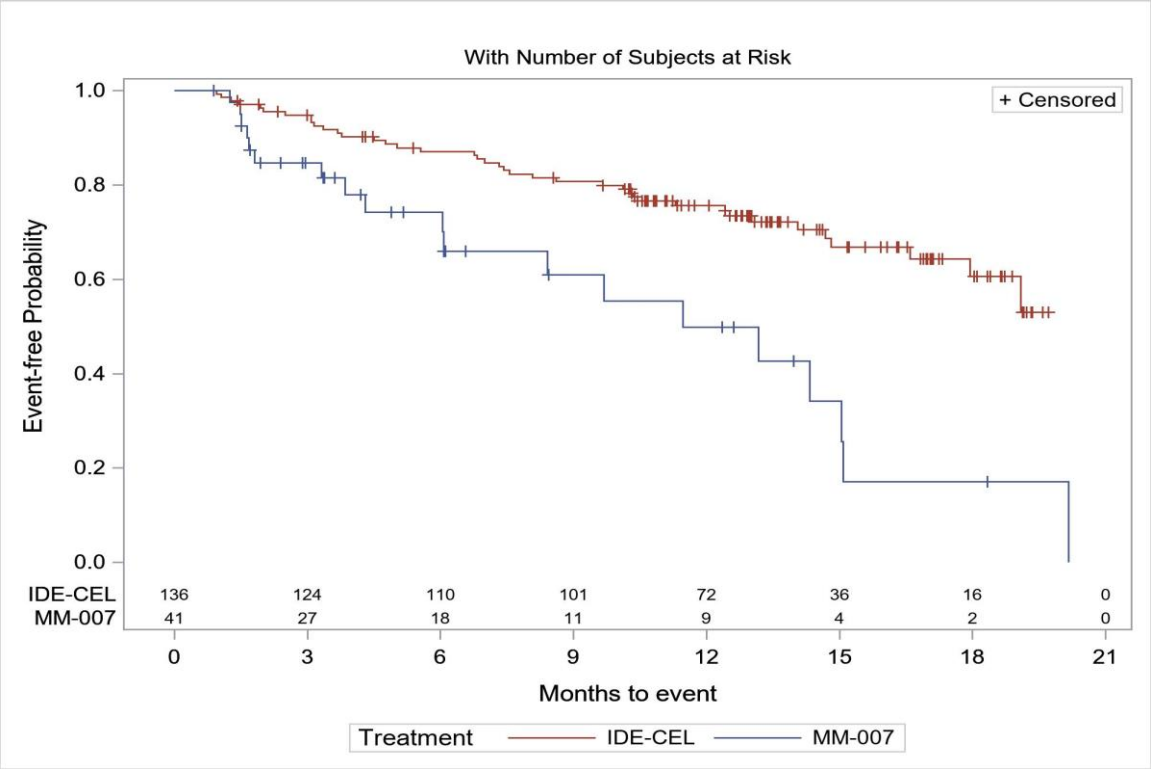



Kaplan-Meier Kurve für den **ITC nach CA089-007 des Leukapherese Analyse-Set (ITT) der Studie KarMMa vs. ERRMM Kohorte der Studie PREAMBLE** für das **Gesamtüberleben:** Ergebnisse des Propensity Score Matching
Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat

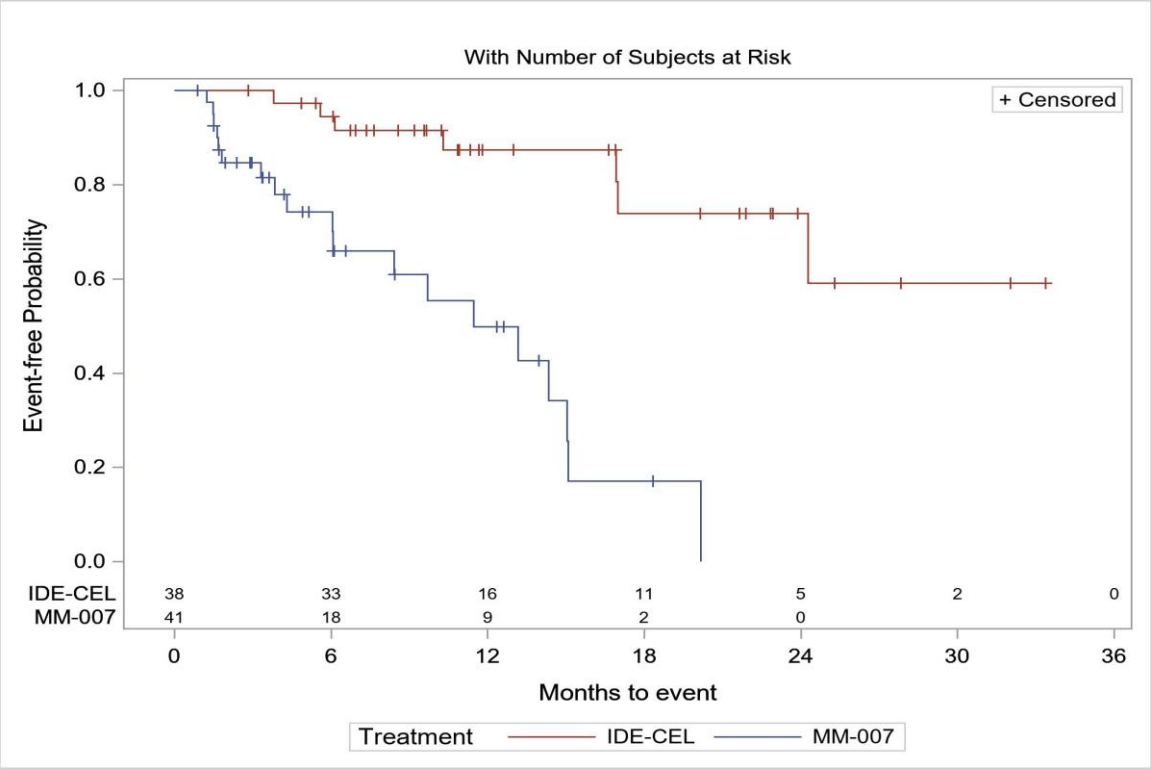



Kaplan-Meier Kurve für den **ITC nach CA089-007 des Leukapherese Analyse-Set (ITT) der Studie CRB-401 vs. ERRMM Kohorte der Studie PREAMBLE** für das **Gesamtüberleben:** Ergebnisse des Propensity Score Matching
Abkürzungen: eRRMM: Eligible RRMM; ITT: Intention-to-Treat

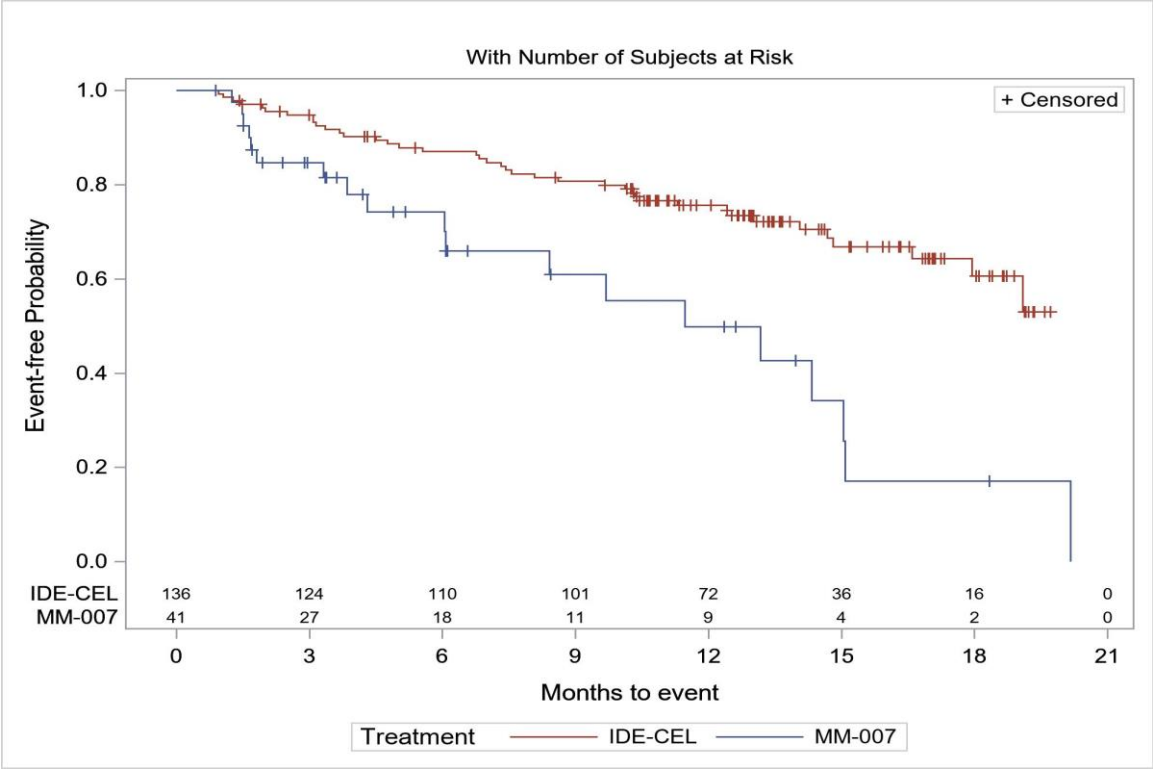
## 15.3 Indirekter Vergleich ohne Brückenkomparator Ide-Cel vs. ERRMM Kohorte aus MM-007



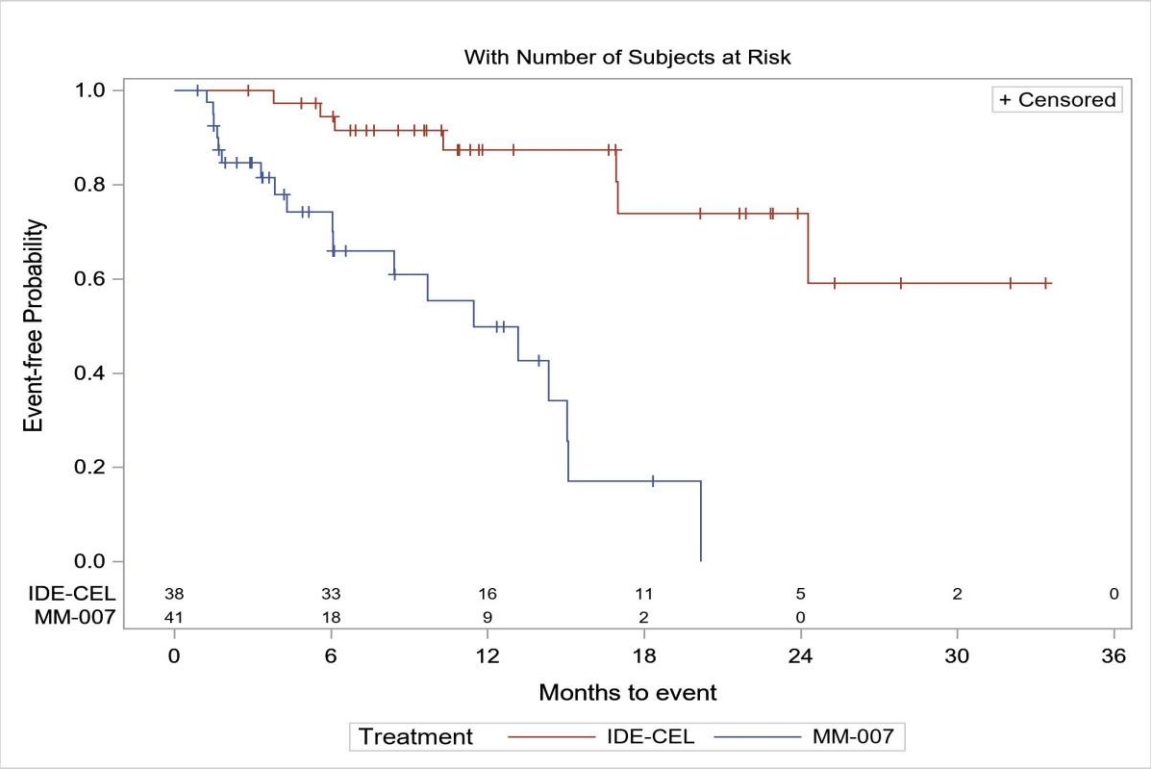

Kaplan-Meier Kurve für den **ITC des Leukapherese Analyse-Set (ITT) der Studie KarMMa vs. ERRMM Kohorte aus der Studie MM-007** für das **Gesamtüberleben**: Ergebnisse des naiven Vergleichs



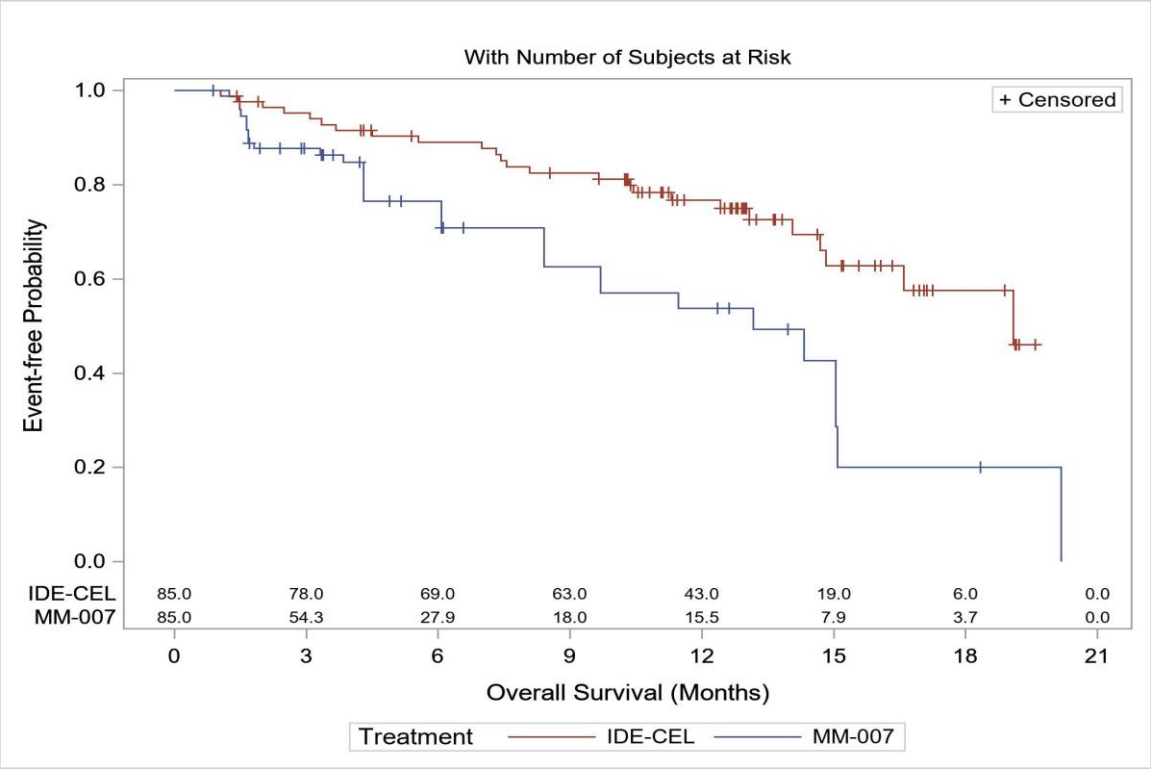

Kaplan-Meier Kurve für den **ITC des Leukapherese Analyse-Set (ITT) der Studie CRB-401 vs. ERRMM Kohorte aus der Studie MM-007** für das **Gesamtüberleben**: Ergebnisse des naiven Vergleichs



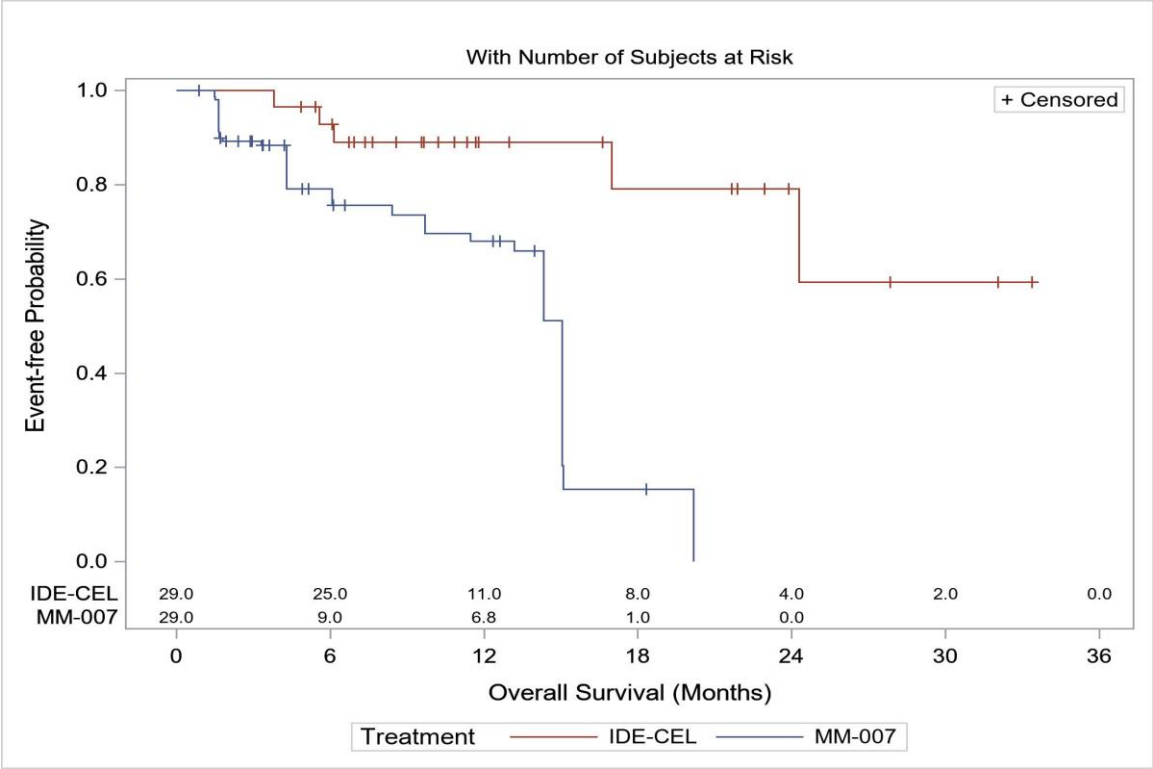

Kaplan-Meier Kurve für den **ITC des Leukapherese Analyse-Set (ITT) der Studie KarMMa vs. ERRMM Kohorte der Studie MM-007** für das **Gesamtüberleben:** Ergebnisse des Multivariaten Cox-Proportional-Hazards-Modell (mit Adjustierung für Confounder)




Kaplan-Meier Kurve für den **ITC des Leukapherese Analyse-Set (ITT) der Studie CRB-401 vs. ERRMM Kohorte der Studie MM-007** für das **Gesamtüberleben:** Ergebnisse des Multivariaten Cox-Proportional-Hazards-Modell (mit Adjustierung für Confounder)




Kaplan-Meier Kurve für den **ITC des Leukapherese Analyse-Set (ITT) der Studie KarMMa vs. ERRMM Kohorte aus der Studie MM-007** für das **Gesamtüberleben**: Ergebnisse nach Propensity Score Matching (Greedy Nearest Neighbor Matching)




Kaplan-Meier Kurve für den **ITC des Leukapherese Analyse-Set (ITT) der Studie CRB-401 vs. ERRMM Kohorte aus der Studie MM-007** für das **Gesamtüberleben**: Ergebnisse nach Propensity Score Matching (Greedy Nearest Neighbor Matching)

# 16. Symptomatik

## 16.1 Indirekter Vergleich ohne Brückenkomparator nach CA089-007

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Fatigue des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 72,3 [41,7; 102,8] | 122 | 40,1 [35,7; 44,5] |
| Indexzeitpunkt | 3 | 48,1 [-15,7; 112,0] | 110 | 44,9 [40,5; 49,3] |
| Monat 1 | 7 | 70,6 [45,3; 95,9] | 107 | 41,4 [36,8; 46,0] |
| Monat 2 | 6 | 85,2 [71,1; 99,3] | 97 | 31,6 [27,0; 36,2] |
| Monat 3 | 2 | 33,3 [-107,7; 174,3] | 84 | 27,9 [23,6; 32,2] |
| Monat 4 | 4 | 52,8 [1,9; 103,6] | 78 | 28,6 [23,8; 33,4] |
| Monat 5 | 3 | 81,5 [49,7; 113,3] | 76 | 24,3 [19,4; 29,2] |
| Monat 6 | 0 | - | 75 | 24,3 [19,0; 29,7] |
| Monat 9 | 8 | 61,1 [50,0; 72,3] | 58 | 17,2 [12,6; 21,9] |
| Monat 12 | 7 | 54,0 [27,1; 80,8] | 54 | 23,0 [17,3; 28,8] |
| Monat 15 | 3 | 51,8 [19,9; 83,8] | 31 | 25,4 [15,9; 34,9] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Schmerz des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 62,5 [49,2; 75,8] | 122 | 40,7 [35,7; 45,7] |
| Indexzeitpunkt | 3 | 38,9 [-94,2; 172,0] | 110 | 36,4 [31,7; 41,1] |
| Monat 1 | 7 | 59,5 [31,6; 87,4] | 107 | 32,1 [27,1; 37,1] |
| Monat 2 | 6 | 50,0 [20,7; 79,3] | 97 | 30,6 [25,4; 35,8] |
| Monat 3 | 2 | 50,0 [-162,2; 262,2] | 84 | 27,4 [21,9; 32,9] |
| Monat 4 | 4 | 41,7 [-13,5; 96,8] | 78 | 25,9 [20,6; 31,2] |
| Monat 5 | 3 | 44,4 [-3,5; 92,3] | 76 | 25,0 [19,8; 30,3] |
| Monat 6 | 0 | - | 75 | 25,8 [20,0; 31,6] |
| Monat 9 | 8 | 45,8 [25,1; 66,6] | 58 | 21,8 [16,7; 26,9] |
| Monat 12 | 7 | 45,2 [22,2; 68,3] | 54 | 25,0 [18,6; 31,4] |
| Monat 15 | 3 | 38,9 [-24,4; 102,2] | 31 | 25,8 [17,1; 34,5] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Übelkeit und Erbrechen des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 12,5 [-12,9; 37,9] | 122 | 8,2 [5,6; 10,8] |
| Indexzeitpunkt | 3 | 5,6 [-18,4; 29,5] | 110 | 21,8 [18,0; 25,6] |
| Monat 1 | 7 | 9,5 [-2,6; 21,7] | 107 | 6,9 [4,1; 9,7] |
| Monat 2 | 6 | 13,9 [-3,3; 31,1] | 97 | 5,3 [2,8; 7,8] |
| Monat 3 | 2 | 0 [-; -] | 84 | 6,0 [2,9; 9,1] |
| Monat 4 | 4 | 12,5 [-0,8; 25,8] | 78 | 6,4 [3,0; 9,8] |
| Monat 5 | 3 | 27,8 [-58,4; 114,0] | 76 | 3,5 [1,5; 5,5] |
| Monat 6 | 0 | - | 75 | 4,9 [2,4; 7,4] |
| Monat 9 | 8 | 10,4 [0,1; 20,8] | 58 | 4,9 [1,8; 8,0] |
| Monat 12 | 7 | 11,9 [4,4; 19,5] | 54 | 5,9 [2,1; 9,7] |
| Monat 15 | 3 | 0 [-; -] | 31 | 5,4 [1,6; 9,2] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Dyspnoe des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 50,0 [19,3; 80,7] | 122 | 20,8 [16,5; 25,1] |
| Indexzeitpunkt | 3 | 11,1 [-36,7; 58,9] | 110 | 16,1 [11,4; 20,8] |
| Monat 1 | 7 | 38,1 [5,1; 71,1] | 107 | 19,3 [14,6; 24,0] |
| Monat 2 | 6 | 50,0 [13,3; 86,7] | 97 | 17,9 [13,4; 22,4] |
| Monat 3 | 2 | 33,4 [-390,4; 457,1] | 84 | 11,9 [8,0; 15,8] |
| Monat 4 | 4 | 58,3 [7,5; 109,1] | 78 | 12,4 [8,6; 16,2] |
| Monat 5 | 3 | 55,6 [-70,9; 182,1] | 76 | 8,8 [5,1; 12,6] |
| Monat 6 | 0 | - | 75 | 11,6 [7,2; 16,0] |
| Monat 9 | 8 | 52,4 [22,3; 82,5] | 58 | 8,0 [4,0; 12,0] |
| Monat 12 | 7 | 33,3 [8,1; 58,5] | 54 | 9,3 [4,9; 13,7] |
| Monat 15 | 3 | 33,4 [-390,4; 457,1] | 31 | 12,9 [4,5; 21,3] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Schlaflosigkeit des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 55,6 [7,7; 103,5] | 122 | 31,7 [26,5; 36,9] |
| Indexzeitpunkt | 3 | 55,5 [-40,1; 151,2] | 110 | 30,3 [25,2; 35,4] |
| Monat 1 | 7 | 57,2 [42,1; 72,2] | 107 | 23,4 [18,6; 28,3] |
| Monat 2 | 6 | 55,6 [19,4; 91,7] | 97 | 26,5 [20,6; 32,4] |
| Monat 3 | 2 | 50,0 [-162,2; 262,2] | 84 | 22,2 [16,7; 27,7] |
| Monat 4 | 4 | 33,3 [-; -] | 78 | 21,4 [15,3; 27,5] |
| Monat 5 | 3 | 22,2 [-73,4; 117,9] | 76 | 19,7 [14,1; 25,3] |
| Monat 6 | 0 | - | 75 | 18,2 [12,9; 23,5] |
| Monat 9 | 8 | 37,5 [19,6; 55,4] | 58 | 17,2 [11,1; 23,3] |
| Monat 12 | 7 | 23,8 [0,5; 47,1] | 54 | 21,0 [13,2; 28,8] |
| Monat 15 | 3 | 66,7 [-16,2; 149,5] | 31 | 21,5 [11,7; 31,3] |

Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Appetitlosigkeit des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 25,0 [-1,5; 51,5] | 122 | 18,6 [14,0; 23,2] |
| Indexzeitpunkt | 3 | 22,2 [-25,6; 70,0] | 110 | 37,9 [32,7; 43,1] |
| Monat 1 | 7 | 23,8 [-10,5; 58,1] | 107 | 25,9 [20,1; 31,7] |
| Monat 2 | 6 | 55,6 [13,2; 97,9] | 97 | 17,9 [12,9; 22,9] |
| Monat 3 | 2 | 0 [-; -] | 84 | 15,9 [10,5; 21,3] |
| Monat 4 | 4 | 33,3 [-10,0; 76,7] | 78 | 14,5 [8,8; 20,2] |
| Monat 5 | 3 | 55,6 [7,7; 103,5] | 76 | 10,5 [5,4; 15,6] |
| Monat 6 | 0 | - | 75 | 12,9 [8,1; 17,7] |
| Monat 9 | 8 | 25,0 [0,3; 49,7] | 58 | 6,9 [2,7; 11,1] |
| Monat 12 | 7 | 38,1 [5,1; 71,1] | 54 | 8,6 [3,4; 13,8] |
| Monat 15 | 3 | 33,3 [-49,5; 116,2] | 31 | 17,2 [6,8; 27,6] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Obstipation des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 25,0 [-25,8; 75,8] | 122 | 13,1 [9,3; 17,0] |
| Indexzeitpunkt | 3 | 33,3 [-110,1; 176,8] | 110 | 26,7 [21,1; 32,3] |
| Monat 1 | 7 | 33,3 [8,1; 58,5] | 107 | 13,1 [8,9; 17,3] |
| Monat 2 | 6 | 33,3 [-10,9; 77,6] | 97 | 9,6 [6,0; 13,2] |
| Monat 3 | 2 | 33,3 [-; -] | 84 | 7,1 [3,8; 10,4] |
| Monat 4 | 4 | 16,7 [-13,9; 47,2] | 78 | 6,4 [3,2; 9,6] |
| Monat 5 | 3 | 11,1 [-36,7; 58,9] | 76 | 7,5 [3,7; 11,3] |
| Monat 6 | 0 | - | 75 | 8,4 [4,1; 12,7] |
| Monat 9 | 8 | 25,0 [-7,5; 57,5] | 58 | 8,6 [4,2; 13,0] |
| Monat 12 | 7 | 14,3 [-2,2; 30,7] | 54 | 5,6 [1,8; 9,4] |
| Monat 15 | 3 | 0 [-; -] | 31 | 10,8 [3,1; 18,5] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Diarrhö des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 16,7 [-13,9; 47,2] | 122 | 13,7 [10,1; 17,3] |
| Indexzeitpunkt | 3 | 0 [-; -] | 110 | 14,8 [10,3; 19,3] |
| Monat 1 | 7 | 14,3 [-2,2; 30,7] | 107 | 14,0 [9,3; 18,7] |
| Monat 2 | 6 | 16,7 [-12,6; 45,9] | 97 | 16,2 [11,5; 20,9] |
| Monat 3 | 2 | 50,0 [-162,2; 262,2] | 84 | 15,5 [10,4; 20,6] |
| Monat 4 | 4 | 8,3 [-18,2; 34,8] | 78 | 14,1 [8,4; 19,8] |
| Monat 5 | 3 | 0 [-; -] | 76 | 11,8 [7,1; 16,5] |
| Monat 6 | 0 | - | 75 | 11,1 [6,7; 15,5] |
| Monat 9 | 8 | 16,7 [1,8; 31,5] | 58 | 9,2 [5,0; 13,4] |
| Monat 12 | 7 | 33,3 [8,1; 58,5] | 54 | 9,9 [5,1; 14,7] |
| Monat 15 | 3 | 11,1 [-36,7; 58,9] | 31 | 6,5 [0,9; 12,1] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Krankheitssymptome des Fragebogens EORTC QLQ-MY20 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 5 | 67,8 [32,5; 103,1] | 122 | 32,6 [28,4; 36,8] |
| Indexzeitpunkt | 3 | 31,5 [-57,1; 120,1] | 110 | 30,9 [26,8; 35,0] |
| Monat 1 | 7 | 43,5 [27,3; 59,8] | 107 | 23,3 [19,7; 26,9] |
| Monat 2 | 6 | 45,2 [15,7; 74,7] | 96 | 23,7 [19,8; 27,6] |
| Monat 3 | 2 | 22,3 [-48,3; 92,8] | 84 | 20,6 [17,0; 24,2] |
| Monat 4 | 4 | 37,5 [-14,2; 89,2] | 78 | 19,7 [16,2; 23,2] |
| Monat 5 | 3 | 38,9 [-21,3; 99,1] | 75 | 18,8 [15,5; 22,2] |
| Monat 6 | 0 | - | 74 | 20,7 [16,8; 24,6] |
| Monat 9 | 8 | 36,8 [14,3; 59,3] | 57 | 18,0 [13,8; 22,2] |
| Monat 12 | 8 | 40,3 [16,1; 64,5] | 54 | 20,3 [15,3; 25,3] |
| Monat 15 | 3 | 30,8 [-22,8; 84,4] | 31 | 21,1 [14,1; 28,1] |

Abkürzungen: EORTC QLQ-MY20: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire Multiple Myeloma Module 20; KI: Konfidenzintervall; N: Anzahl Patienten

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Nebenwirkungen des Fragebogens EORTC QLQ-MY20 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 5 | 38,7 [27,0; 50,3] | 122 | 18,2 [15,6; 20,8] |
| Indexzeitpunkt | 3 | 25,9 [-34,5; 86,3] | 110 | 19,9 [17,4; 22,4] |
| Monat 1 | 7 | 36,7 [14,5; 58,8] | 107 | 18,3 [15,1; 21,5] |
| Monat 2 | 6 | 36,0 [24,5; 47,5] | 96 | 15,3 [12,4; 18,2] |
| Monat 3 | 2 | 11,1 [-; -] | 84 | 14,0 [11,3; 16,7] |
| Monat 4 | 4 | 28,1 [-6,1; 62,2] | 78 | 14,0 [10,9; 17,1] |
| Monat 5 | 3 | 29,6 [-2,2; 61,4] | 75 | 12,0 [9,1; 14,9] |
| Monat 6 | 0 | - | 74 | 11,7 [9,2; 14,2] |
| Monat 9 | 8 | 27,1 [14,3; 39,9] | 57 | 8,6 [6,2; 11,0] |
| Monat 12 | 8 | 31,3 [16,8; 45,8] | 54 | 12,3 [8,9; 15,8] |
| Monat 15 | 3 | 28,4 [-9,9; 66,6] | 31 | 13,2 [7,9; 18,5] |
| Abkürzungen: EORTC QLQ-MY20: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire Multiple Myeloma Module 20; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

# 17. Gesundheitszustand

## 17.1 Indirekter Vergleich ohne Brückenkomparator nach CA089-007

Ergebnisse der mittleren Scorewerte ab Baseline der VAS des Fragebogens EQ 5D für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 5 | 49,3 [1,3; 97,2] | 122 | 67,2 [63,9; 70,5] |
| Indexzeitpunkt | 3 | 50,0 [-24,5; 124,5] | 111 | 67,0 [63,4; 70,6] |
| Monat 1 | 7 | 56,3 [36,2; 76,5] | 108 | 70,6 [67,1; 74,1] |
| Monat 2 | 6 | 57,0 [23,7; 90,3] | 97 | 73,3 [69,8; 76,8] |
| Monat 3 | 2 | 61,0 [-; -] | 84 | 76,0 [72,8; 79,2] |
| Monat 4 | 4 | 67,5 [25,7; 109,3] | 78 | 77,3 [74,0; 80,6] |
| Monat 5 | 3 | 55,0 [10,2; 99,8] | 76 | 79,7 [76,4; 83,0] |
| Monat 6 | 0 | - | 75 | 79,7 [76,2; 83,2] |
| Monat 9 | 8 | 51,4 [33,7; 69,1] | 58 | 82,0 [77,8; 86,2] |
| Monat 12 | 8 | 53,8 [32,0; 75,5] | 54 | 80,8 [76,9; 84,7] |
| Monat 15 | 3 | 50,0 [-; -] | 31 | 76,4 [68,5; 84,3] |
| Abkürzungen: EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Scale; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

# 18. Gesundheitsbezogene Lebensqualität

## 18.1 Indirekter Vergleich ohne Brückenkomparator nach CA089-007

Ergebnisse der mittleren Scorewerte ab Baseline der Funktionsskala Allgemeiner Gesundheitszustand des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 33,3 [4,7; 61,9] | 122 | 60,3 [56,6; 64,0] |
| Indexzeitpunkt | 3 | 52,8 [-25,5; 131,1] | 110 | 55,5 [51,6; 59,4] |
| Monat 1 | 7 | 48,8 [36,7; 61,0] | 107 | 63,9 [60,1; 67,8] |
| Monat 2 | 6 | 38,9 [14,4; 63,4] | 97 | 69,6 [65,6; 73,6] |
| Monat 3 | 2 | 83,4 [-128,2; 294,9] | 84 | 70,4 [66,5; 74,3] |
| Monat 4 | 4 | 60,4 [31,1; 89,8] | 78 | 72,5 [68,6; 76,4] |
| Monat 5 | 3 | 47,2 [23,4; 71,0] | 76 | 76,1 [72,5; 79,8] |
| Monat 6 | 0 | - | 75 | 75,6 [71,6; 79,6] |
| Monat 9 | 8 | 47,9 [27,3; 68,6] | 58 | 79,6 [75,1; 84,1] |
| Monat 12 | 7 | 58,4 [34,9; 81,8] | 54 | 77,8 [72,8; 82,9] |
| Monat 15 | 3 | 44,5 [32,6; 56,4] | 31 | 71,0 [62,1; 79,9] |

Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten

Ergebnisse der mittleren Scorewerte ab Baseline der Funktionsskala Physische Funktion des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 51,7 [28,1; 75,2] | 122 | 68,6 [64,1; 73,1] |
| Indexzeitpunkt | 3 | 66,7 [-19,4; 152,8] | 110 | 69,0 [64,7; 73,3] |
| Monat 1 | 7 | 53,3 [26,2; 80,4] | 107 | 70,2 [65,4; 75,0] |
| Monat 2 | 6 | 40,0 [31,1; 48,8] | 97 | 76,2 [72,1; 80,3] |
| Monat 3 | 2 | 70,0 [-226,1; 366,1] | 84 | 80,3 [76,6; 84,0] |
| Monat 4 | 4 | 63,4 [15,5; 111,2] | 78 | 80,8 [76,8; 84,9] |
| Monat 5 | 3 | 53,3 [36,8; 69,9] | 76 | 82,6 [78,7; 86,5] |
| Monat 6 | 0 | - | 75 | 82,8 [78,7; 86,9] |
| Monat 9 | 8 | 56,7 [50,0; 63,3] | 58 | 83,3 [78,5; 88,1] |
| Monat 12 | 7 | 59,0 [45,5; 72,6] | 54 | 82,8 [77,7; 87,9] |
| Monat 15 | 3 | 46,7 [13,5; 79,8] | 31 | 78,5 [69,6; 87,4] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Funktionsskala Rollenfunktion des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 33,4 [-27,9; 94,6] | 122 | 64,2 [58,8; 69,6] |
| Indexzeitpunkt | 3 | 66,7 [-16,18; 149,51] | 110 | 60,2 [54,4; 66,0] |
| Monat 1 | 7 | 50,0 [17,9; 82,1] | 107 | 63,6 [57,9; 69,3] |
| Monat 2 | 6 | 36,1 [4,0; 68,2] | 97 | 70,8 [65,1; 76,6] |
| Monat 3 | 2 | 50,0 [-162,2; 262,2] | 84 | 73,4 [67,3; 79,5] |
| Monat 4 | 4 | 54,2 [28,7; 79,6] | 78 | 76,3 [71,4; 81,2] |
| Monat 5 | 3 | 44,4 [-3,5; 92,3] | 76 | 80,7 [75,0; 86,4] |
| Monat 6 | 0 | - | 75 | 78,4 [72,8; 84,0] |
| Monat 9 | 8 | 41,7 [26,8; 56,6] | 58 | 84,2 [78,3; 90,1] |
| Monat 12 | 7 | 61,9 [34,2; 89,6] | 54 | 81,2 [74,3; 88,1] |
| Monat 15 | 3 | 27,8 [-58,4; 114,0] | 31 | 74,2 [61,7; 86,7] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Funktionsskala Kognitive Funktion des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 54,2 [28,7; 79,6] | 122 | 81,8 [78,1; 85,5] |
| Indexzeitpunkt | 3 | 88,9 [41,1; 136,7] | 110 | 82,4 [78,5; 86,3] |
| Monat 1 | 7 | 71,4 [46,7; 96,1] | 107 | 85,2 [81,1; 89,3] |
| Monat 2 | 6 | 63,9 [40,6; 87,2] | 97 | 88,7 [85,7; 91,7] |
| Monat 3 | 2 | 91,7 [-14,5; 197,8] | 84 | 88,1 [84,8; 91,5] |
| Monat 4 | 4 | 91,7 [76,3; 107,0] | 78 | 87,2 [83,2; 91,2] |
| Monat 5 | 3 | 66,7 [-5,0; 138,4] | 76 | 89,0 [85,2; 92,9] |
| Monat 6 | 0 | - | 75 | 88,0 [84,3; 91,7] |
| Monat 9 | 8 | 89,6 [79,2; 99,9] | 58 | 89,9 [85,8; 94,0] |
| Monat 12 | 7 | 83,3 [65,5; 101,1] | 54 | 86,4 [81,2; 91,6] |
| Monat 15 | 3 | 88,9 [64,9; 112,8] | 31 | 83,3 [75,0; 91,6] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Funktionsskala Emotionale Funktion des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 50,0 [23,5; 76,5] | 122 | 77,1 [73,3; 80,9] |
| Indexzeitpunkt | 3 | 72,2 [60,3; 84,1] | 110 | 75,5 [71,6; 79,4] |
| Monat 1 | 7 | 61,9 [48,6; 75,2] | 107 | 79,1 [75,1; 83,1] |
| Monat 2 | 6 | 59,7 [39,4; 80,0] | 97 | 83,8 [79,9; 87,7] |
| Monat 3 | 2 | 91,7 [-; -] | 84 | 85,2 [81,3; 89,1] |
| Monat 4 | 4 | 77,1 [60,4; 93,8] | 78 | 84,7 [81,0; 88,4] |
| Monat 5 | 3 | 86,1 [43,1; 129,2] | 76 | 86,3 [82,5; 90,1] |
| Monat 6 | 0 | - | 75 | 84,8 [81,1; 88,5] |
| Monat 9 | 8 | 70,8 [50,8; 90,9] | 58 | 85,2 [80,4; 90,0] |
| Monat 12 | 7 | 65,5 [38,6; 92,3] | 54 | 86,4 [82,2; 90,6] |
| Monat 15 | 3 | 69,4 [2,9; 136,0] | 31 | 85,2 [77,1; 93,3] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Funktionsskala Soziale Funktion des Fragebogens EORTC QLQ-C30 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 4 | 50,0 [-3,0; 103,1] | 122 | 64,9 [60,1; 69,7] |
| Indexzeitpunkt | 3 | 66,7 [-16,2; 149,5] | 110 | 59,4 [53,5; 65,3] |
| Monat 1 | 7 | 58,3 [40,0; 76,7] | 107 | 61,5 [55,9; 67,1] |
| Monat 2 | 6 | 38,9 [2,8; 75,0] | 97 | 71,3 [66,2; 76,5] |
| Monat 3 | 2 | 91,7 [-14,5; 197,8] | 84 | 73,8 [68,3; 79,3] |
| Monat 4 | 4 | 58,4 [31,8; 84,9] | 78 | 79,1 [73,8; 84,5] |
| Monat 5 | 3 | 55,6 [7,7; 103,5] | 76 | 83,6 [78,9; 88,3] |
| Monat 6 | 0 | - | 75 | 81,8 [77,3; 86,3] |
| Monat 9 | 8 | 54,2 [30,9; 77,4] | 58 | 84,5 [78,9; 90,1] |
| Monat 12 | 7 | 61,9 [42,6; 81,3] | 54 | 79,0 [72,8; 85,2] |
| Monat 15 | 3 | 38,9 [-24,4; 102,2] | 31 | 77,4 [67,1; 87,7] |
| Abkürzungen: EORTC QLQ-C30: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire C30; KI: Konfidenzintervall; N: Anzahl Patienten | | | | |

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Zukunftsperspektiven des Fragebogens EORTC QLQ-MY20 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 5 | 44,5 [7,9; 81,0] | 122 | 60,4 [55,9; 64,9] |
| Indexzeitpunkt | 3 | 63,0 [20,7; 105,2] | 110 | 60,6 [56,1; 65,1] |
| Monat 1 | 7 | 46,0 [22,0; 70,1] | 107 | 68,1 [63,6; 72,6] |
| Monat 2 | 6 | 40,8 [8,9; 72,6] | 96 | 72,6 [68,0; 77,3] |
| Monat 3 | 2 | 72,3 [1,7; 142,8] | 84 | 72,5 [67,9; 77,1] |
| Monat 4 | 4 | 72,3 [54,6; 89,9] | 78 | 73,4 [68,7; 78,1] |
| Monat 5 | 3 | 70,4 [-9,4; 150,1] | 75 | 77,9 [73,5; 82,3] |
| Monat 6 | 0 | - | 74 | 74,8 [69,8; 79,9] |
| Monat 9 | 8 | 69,5 [55,6; 83,3] | 57 | 76,4 [70,7; 82,1] |
| Monat 12 | 8 | 38,9 [7,9; 69,9] | 54 | 78,0 [72,7; 83,4] |
| Monat 15 | 3 | 66,7 [-; -] | 31 | 72,8 [63,7; 81,9] |

Abkürzungen: EORTC QLQ-MY20: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire Multiple Myeloma Module 20; KI: Konfidenzintervall; N: Anzahl Patienten

Ergebnisse der mittleren Scorewerte ab Baseline der Symptomskala Körperbild des Fragebogens EORTC QLQ-MY20 für den historischen Vergleich CA089-007

| **Zeitpunkt** | **PREAMBLE** | | **KarMMa** | |
|---|---|---|---|---|
| | **N** | **Mittelwert [95% KI]** | **N** | **Mittelwert [95% KI]** |
| Baseline | 5 | 46,7 [-0,5; 93,9] | 122 | 75,1 [70,4; 79,8] |
| Indexzeitpunkt | 3 | 77,8 [30,0; 125,6] | 110 | 76,6 [70,9; 82,3] |
| Monat 1 | 7 | 52,4 [22,3; 82,5] | 107 | 75,4 [70,1; 80,7] |
| Monat 2 | 6 | 66,7 [16,0; 117,4] | 96 | 80,6 [75,4; 85,8] |
| Monat 3 | 2 | 100,0 [-; -] | 84 | 81,7 [76,0; 87,4] |
| Monat 4 | 4 | 91,7 [65,2; 118,2] | 78 | 82,9 [77,1; 88,7] |
| Monat 5 | 3 | 55,6 [-70,9; 182,1] | 75 | 85,3 [80,2; 90,5] |
| Monat 6 | 0 | - | 74 | 84,2 [78,8; 89,6] |
| Monat 9 | 8 | 66,7 [45,6; 87,8] | 57 | 88,9 [82,9; 94,9] |
| Monat 12 | 8 | 66,7 [40,9; 92,5] | 54 | 87,0 [80,7; 93,3] |
| Monat 15 | 3 | 77,8 [30,0; 125,6] | 31 | 88,2 [79,3; 97,1] |

Abkürzungen: EORTC QLQ-MY20: European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire Multiple Myeloma Module 20; KI: Konfidenzintervall; N: Anzahl Patienten

# IV. Deskriptive Vergleiche der Verträglichkeit

## 19. Baseline Charakteristika

### 19.1 Baseline Charakteristika ELOQUENT-3

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Demographic Characteristics Summary
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| AGE (YEARS) | | | |
| N | 47 | 39 | 86 |
| MEAN | 66.4 | 63.7 | 65.2 |
| MEDIAN | 68.0 | 65.0 | 66.0 |
| MIN , MAX | 43 , 80 | 36 , 81 | 36 , 81 |
| Q1 , Q3 | 60.0 , 74.0 | 58.0 , 70.0 | 58.0 , 72.0 |
| STANDARD DEVIATION | 9.6 | 9.6 | 9.6 |
| AGE CATEGORIZATION (%) | | | |
| < 65 | 16 ( 34.0) | 18 ( 46.2) | 34 ( 39.5) |
| >= 65 AND < 75 | 21 ( 44.7) | 15 ( 38.5) | 36 ( 41.9) |
| >= 75 | 10 ( 21.3) | 6 ( 15.4) | 16 ( 18.6) |
| SEX (%) | | | |
| MALE | 24 ( 51.1) | 25 ( 64.1) | 49 ( 57.0) |
| FEMALE | 23 ( 48.9) | 14 ( 35.9) | 37 ( 43.0) |
| RACE (%) | | | |
| WHITE | 34 ( 72.3) | 32 ( 82.1) | 66 ( 76.7) |
| BLACK OR AFRICAN AMERICAN | 0 | 0 | 0 |
| ASIAN | 13 ( 27.7) | 6 ( 15.4) | 19 ( 22.1) |
| AMERICAN INDIAN OR ALASKA NATIVE | 0 | 0 | 0 |
| NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER | 0 | 0 | 0 |
| OTHER | 0 | 1 ( 2.6) | 1 ( 1.2) |
| ETHNICITY (%) | | | |
| HISPANIC OR LATINO | 1 ( 2.1) | 0 | 1 ( 1.2) |
| NOT HISPANIC OR LATINO | 9 ( 19.1) | 12 ( 30.8) | 21 ( 24.4) |
| NOT REPORTED | 37 ( 78.7) | 27 ( 69.2) | 64 ( 74.4) |

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Baseline Physical Measurements Summary
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| BASELINE | | | |
| WEIGHT (KG) | | | |
| N | 47 | 39 | 86 |
| MEAN | 70.27 | 72.80 | 71.42 |
| MEDIAN | 66.00 | 71.90 | 69.50 |
| MIN , MAX | 40.0 , 114.0 | 29.9 , 110.0 | 29.9 , 114.0 |
| Q1 , Q3 | 60.50 , 79.00 | 60.00 , 84.00 | 60.00 , 81.00 |
| STANDARD DEVIATION | 15.41 | 16.50 | 15.87 |
| PERFORMANCE STATUS (ECOG) (%) | | | |
| 0 | 23 ( 48.9) | 20 ( 51.3) | 43 ( 50.0) |
| 1 | 21 ( 44.7) | 15 ( 38.5) | 36 ( 41.9) |
| 2 | 3 ( 6.4) | 4 ( 10.3) | 7 ( 8.1) |

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Baseline Myeloma Risk Factors Summary
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| RISK CATEGORY | | | |
| HIGH RISK | 5 ( 10.6) | 6 ( 15.4) | 11 ( 12.8) |
| LOW RISK | 1 ( 2.1) | 1 ( 2.6) | 2 ( 2.3) |
| STANDARD RISK | 36 ( 76.6) | 29 ( 74.4) | 65 ( 75.6) |
| NOT EVALUABLE | 5 ( 10.6) | 3 ( 7.7) | 8 ( 9.3) |
| ISS STAGE AT STUDY ENTRY (CRF) | | | |
| STAGE I | 26 ( 55.3) | 22 ( 56.4) | 48 ( 55.8) |
| STAGE II | 17 ( 36.2) | 13 ( 33.3) | 30 ( 34.9) |
| STAGE III | 4 ( 8.5) | 4 ( 10.3) | 8 ( 9.3) |
| DEL 17P | | | |
| YES | 2 ( 4.3) | 4 ( 10.3) | 6 ( 7.0) |
| NO | 36 ( 76.6) | 28 ( 71.8) | 64 ( 74.4) |
| NOT REPORTED | 9 ( 19.1) | 7 ( 17.9) | 16 ( 18.6) |
| 1Q21 | | | |
| YES | 22 ( 46.8) | 18 ( 46.2) | 40 ( 46.5) |
| NO | 16 ( 34.0) | 11 ( 28.2) | 27 ( 31.4) |
| NOT REPORTED | 9 ( 19.1) | 10 ( 25.6) | 19 ( 22.1) |
| T(14;16) | | | |
| YES | 6 ( 12.8) | 0 | 6 ( 7.0) |
| NO | 33 ( 70.2) | 31 ( 79.5) | 64 ( 74.4) |
| NOT REPORTED | 8 ( 17.0) | 8 ( 20.5) | 16 ( 18.6) |

DBL - 22FEB2021
Positive score for each abnormality tested, except for del(17p), was assigned based on identifying at least one abnormal cell out of a required minimum of 100 cells examined. For del(17p), abnormality is defined as observing at least 60% abnormal cells out of a required minimum of 100 cells examined.
High risk: ISS stage II or III and t(4;14) or del(17p) abnormality.
Low risk: ISS stage I or II and absence of t(4;14), del(17p) and 1q21 abnormalities and age <55.
Standard risk: any subjects not meeting the definition of high or low risk.
Not Evaluable: Subjects having missing data preventing the classification in the other 3 categories.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-risk-ebr87.sas 31MAY2021:10:54:47

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Baseline Myeloma Risk Factors Summary
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| T(4;14) | | | |
| YES | 4 ( 8.5) | 8 ( 20.5) | 12 ( 14.0) |
| NO | 34 ( 72.3) | 23 ( 59.0) | 57 ( 66.3) |
| NOT REPORTED | 9 ( 19.1) | 8 ( 20.5) | 17 ( 19.8) |
| DEL 1P | | | |
| YES | 0 | 1 ( 2.6) | 1 ( 1.2) |
| NO | 37 ( 78.7) | 28 ( 71.8) | 65 ( 75.6) |
| NOT REPORTED | 10 ( 21.3) | 10 ( 25.6) | 20 ( 23.3) |
| T(11;14) | | | |
| YES | 6 ( 12.8) | 8 ( 20.5) | 14 ( 16.3) |
| NO | 33 ( 70.2) | 22 ( 56.4) | 55 ( 64.0) |
| NOT REPORTED | 8 ( 17.0) | 9 ( 23.1) | 17 ( 19.8) |

DBL - 22FEB2021
Positive score for each abnormality tested, except for del(17p), was assigned based on identifying at least one abnormal cell out of a required minimum of 100 cells examined. For del(17p), abnormality is defined as observing at least 60% abnormal cells out of a required minimum of 100 cells examined.
High risk: ISS stage II or III and t(4;14) or del(17p) abnormality.
Low risk: ISS stage I or II and absence of t(4;14), del(17p) and 1q21 abnormalities and age <55.
Standard risk: any subjects not meeting the definition of high or low risk.
Not Evaluable: Subjects having missing data preventing the classification in the other 3 categories.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-risk-ebr87.sas 31MAY2021:10:54:47

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Baseline Myeloma Characteristics Summary - SI Units
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| M-PROTEIN, SERUM (QUANTITATIVE SPE) (G/L) | | | |
| N | 47 | 39 | 86 |
| MEAN | 20.6 | 17.7 | 19.3 |
| MEDIAN | 19.0 | 15.0 | 17.5 |
| MIN , MAX | 0 , 53 | 0 , 68 | 0 , 68 |
| Q1 , Q3 | 2.0 , 32.0 | 0.0 , 28.0 | 1.0 , 32.0 |
| STANDARD DEVIATION | 17.2 | 19.0 | 18.0 |
| M-PROTEIN, URINE (G/DAY) | | | |
| N | 47 | 39 | 86 |
| MEAN | 0.360 | 0.751 | 0.538 |
| MEDIAN | 0.050 | 0.140 | 0.075 |
| MIN , MAX | 0.00 , 3.18 | 0.00 , 5.12 | 0.00 , 5.12 |
| Q1 , Q3 | 0.000 , 0.290 | 0.030 , 0.850 | 0.010 , 0.520 |
| STANDARD DEVIATION | 0.746 | 1.319 | 1.057 |
| FREE LIGHT CHAINS, SERUM (sFLC), KAPPA (MG/L) | | | |
| N | 47 | 39 | 86 |
| MEAN | 1013.035 | 934.926 | 977.614 |
| MEDIAN | 118.000 | 49.900 | 99.050 |
| MIN , MAX | 1.15 , 23600.00 | 0.90 , 11900.00 | 0.90 , 23600.00 |
| Q1 , Q3 | 15.600 , 666.000 | 6.510 , 865.000 | 9.420 , 718.000 |
| STANDARD DEVIATION | 3530.459 | 2221.089 | 2992.035 |

DBL - 22FEB2021
Imaging for extramedullary plasmacytomas was not performed. Computed tomography or MRI was to be performed at screening to assess extramedullary plasmacytomas only if clinically indicated.
Subjects for whom not all 8 sites of skeletal survey were assessed will be classified according to the number of lytic lesions reported for the sites that were assessed.
Conversion factors to US Units: Serum M-Protein x 0.1, Urine M-Protein x 1000.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-myelcharac-ebr87.sas 01JUN2021:13:27:32

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Baseline Myeloma Characteristics Summary - SI Units
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| FREE LIGHT CHAINS, SERUM (sFLC), LAMBDA (MG/L) | | | |
| N | 47 | 39 | 86 |
| MEAN | 176.744 | 789.872 | 454.791 |
| MEDIAN | 6.500 | 10.300 | 7.940 |
| MIN , MAX | 0.50 , 3700.00 | 0.50 , 12900.00 | 0.50 , 12900.00 |
| Q1 , Q3 | 1.730 , 20.800 | 1.700 , 679.000 | 1.730 , 152.000 |
| STANDARD DEVIATION | 610.449 | 2283.032 | 1620.527 |
| FREE LIGHT CHAINS, SERUM (sFLC), \|KAPPA-LAMBDA\| (MG/L) | | | |
| N | 47 | 39 | 86 |
| MEAN | 1178.616 | 1711.946 | 1420.475 |
| MEDIAN | 189.850 | 715.300 | 543.395 |
| MIN , MAX | 0.45 , 23598.27 | 9.40 , 12899.10 | 0.45 , 23598.27 |
| Q1 , Q3 | 64.900 , 724.500 | 175.100 , 1555.900 | 102.780 , 1074.930 |
| STANDARD DEVIATION | 3534.472 | 2943.344 | 3271.843 |
| FREE LIGHT CHAINS, SERUM (sFLC), KAPPA/LAMBDA RATIO | | | |
| N | 47 | 39 | 86 |
| MEAN | 859.091 | 770.444 | 818.890 |
| MEDIAN | 26.920 | 9.320 | 20.980 |
| MIN , MAX | 0.00 , 13641.62 | 0.00 , 14000.00 | 0.00 , 14000.00 |
| Q1 , Q3 | 2.090 , 227.210 | 0.010 , 143.060 | 0.090 , 143.060 |
| STANDARD DEVIATION | 2669.876 | 2511.012 | 2584.259 |

DBL - 22FEB2021
Imaging for extramedullary plasmacytomas was not performed. Computed tomography or MRI was to be performed at screening to assess extramedullary plasmacytomas only if clinically indicated.
Subjects for whom not all 8 sites of skeletal survey were assessed will be classified according to the number of lytic lesions reported for the sites that were assessed.
Conversion factors to US Units: Serum M-Protein x 0.1, Urine M-Protein x 1000.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-myelcharac-ebr87.sas 01JUN2021:13:27:32

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Baseline Myeloma Characteristics Summary - SI Units
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| NUMBER OF LYTIC BONE LESIONS | | | |
| 0 | 10 ( 21.3) | 8 ( 20.5) | 18 ( 20.9) |
| 1 - 3 | 4 ( 8.5) | 7 ( 17.9) | 11 ( 12.8) |
| > 3 | 33 ( 70.2) | 24 ( 61.5) | 57 ( 66.3) |
| PLASMACYTOMA | | | |
| YES | 4 ( 8.5) | 8 ( 20.5) | 12 ( 14.0) |
| NO | 42 ( 89.4) | 31 ( 79.5) | 73 ( 84.9) |
| UNKNOWN | 0 | 0 | 0 |
| NOT REPORTED | 1 ( 2.1) | 0 | 1 ( 1.2) |
| MYELOMA TYPE | | | |
| IGG | 26 ( 55.3) | 16 ( 41.0) | 42 ( 48.8) |
| IGA | 10 ( 21.3) | 8 ( 20.5) | 18 ( 20.9) |
| IGM | 0 | 0 | 0 |
| LIGHT CHAIN DISEASE | 9 ( 19.1) | 14 ( 35.9) | 23 ( 26.7) |
| BICLONAL | 1 ( 2.1) | 1 ( 2.6) | 2 ( 2.3) |
| TRICLONAL | 0 | 0 | 0 |
| NOT CLASSIFIED | 1 ( 2.1) | 0 | 1 ( 1.2) |

DBL - 22FEB2021
Imaging for extramedullary plasmacytomas was not performed. Computed tomography or MRI was to be performed at screening to assess extramedullary plasmacytomas only if clinically indicated.
Subjects for whom not all 8 sites of skeletal survey were assessed will be classified according to the number of lytic lesions reported for the sites that were assessed.
Conversion factors to US Units: Serum M-Protein x 0.1, Urine M-Protein x 1000.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-myelcharac-ebr87.sas 01JUN2021:13:27:32

Protocol: CA204125 Page 4 of 4

Baseline Myeloma Characteristics Summary - SI Units
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| ISS STAGE AT DIAGNOSIS (CRF) | | | |
| STAGE I | 27 ( 57.4) | 16 ( 41.0) | 43 ( 50.0) |
| STAGE II | 9 ( 19.1) | 12 ( 30.8) | 21 ( 24.4) |
| STAGE III | 11 ( 23.4) | 10 ( 25.6) | 21 ( 24.4) |
| NOT REPORTED | 0 | 1 ( 2.6) | 1 ( 1.2) |
| ISS STAGE AT STUDY ENTRY (CRF) | | | |
| STAGE I | 26 ( 55.3) | 22 ( 56.4) | 48 ( 55.8) |
| STAGE II | 17 ( 36.2) | 13 ( 33.3) | 30 ( 34.9) |
| STAGE III | 4 ( 8.5) | 4 ( 10.3) | 8 ( 9.3) |

DBL - 22FEB2021
Imaging for extramedullary plasmacytomas was not performed. Computed tomography or MRI was to be performed at screening to assess extramedullary plasmacytomas only if clinically indicated.
Subjects for whom not all 8 sites of skeletal survey were assessed will be classified according to the number of lytic lesions reported for the sites that were assessed.
Conversion factors to US Units: Serum M-Protein x 0.1, Urine M-Protein x 1000.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-myelcharac-ebr87.sas 01JUN2021:13:27:32

Protocol: CA204125 Page 1 of 1

Prior Therapy Summary: Number of Lines and Refractory Status
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| NUMBER OF PRIOR LINES OF THERAPY | | | |
| 3 | 22 ( 46.8) | 18 ( 46.2) | 40 ( 46.5) |
| >= 4 | 25 ( 53.2) | 21 ( 53.8) | 46 ( 53.5) |
| REFRACTORY STATUS TO PRIOR LINES OF THERAPY | | | |
| LENALIDOMIDE | | | |
| REFRACTORY TO LENALIDOMIDE | 41 ( 87.2) | 29 ( 74.4) | 70 ( 81.4) |
| RELAPSED AND REFRACTORY TO LENALIDOMIDE | 6 ( 12.8) | 8 ( 20.5) | 14 ( 16.3) |
| PROTEASOME INHIBITOR (PI) | | | |
| REFRACTORY TO PI | 39 ( 83.0) | 30 ( 76.9) | 69 ( 80.2) |
| RELAPSED AND REFRACTORY TO PI | 8 ( 17.0) | 7 ( 17.9) | 15 ( 17.4) |
| BORTEZOMIB | | | |
| REFRACTORY TO BORTEZOMIB | 33 ( 70.2) | 22 ( 56.4) | 55 ( 64.0) |
| RELAPSED AND REFRACTORY TO BORTEZOMIB | 10 ( 21.3) | 8 ( 20.5) | 18 ( 20.9) |
| CARFILZOMIB | | | |
| REFRACTORY TO CARFILZOMIB | 8 ( 17.0) | 15 ( 38.5) | 23 ( 26.7) |
| RELAPSED AND REFRACTORY TO CARFILZOMIB | 0 | 1 ( 2.6) | 1 ( 1.2) |
| IXAZOMIB | | | |
| REFRACTORY TO IXAZOMIB | 3 ( 6.4) | 0 | 3 ( 3.5) |
| RELAPSED AND REFRACTORY TO IXAZOMIB | 0 | 0 | 0 |
| BOTH PI AND LENALIDOMIDE | | | |
| REFRACTORY TO BOTH | 33 ( 70.2) | 24 ( 61.5) | 57 ( 66.3) |
| RELAPSED AND REFRACTORY TO BOTH | 0 | 4 ( 10.3) | 4 ( 4.7) |
| REFRACTORY TO ONE; RELAPSED AND REFRACTORY TO THE OTHER | 14 ( 29.8) | 7 ( 17.9) | 21 ( 24.4) |

DBL - 22FEB2021
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-priorther-ebr87.sas 31MAY2021:11:29:49

Protocol: CA204125 Page 1 of 1

Time from Diagnosis to Randomization Summary
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| TIME FROM DISEASE DIAGNOSIS TO RANDOMIZATION (MONTHS) | | | |
| N | 45 | 38 | 83 |
| MEAN | 80.29 | 76.11 | 78.37 |
| MEDIAN | 72.05 | 62.65 | 70.87 |
| MIN , MAX | 17.9 , 262.8 | 19.7 , 209.7 | 17.9 , 262.8 |
| Q1 , Q3 | 39.92 , 101.09 | 42.71 , 103.00 | 42.05 , 103.00 |
| STANDARD DEVIATION | 51.06 | 43.69 | 47.59 |

DBL - 22FEB2021
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-diag-ebr87.sas 26MAY2021:14:30:56

Protocol: CA204125 Page 1 of 1

Prior Therapy for Multiple Myeloma Summary
All Randomized Subjects with at Least 3 Lines of Prior Therapy

| | E-Pd N = 47 | Pd N = 39 | Total N = 86 |
|---|---|---|---|
| NUMBER OF SUBJECTS WITH AT LEAST ONE PRIOR SYSTEMIC THERAPY | 47 (100.0) | 39 (100.0) | 86 (100.0) |
| NUMBER OF REGIMENS | | | |
| MEDIAN | 4.0 | 4.0 | 4.0 |
| MIN, MAX | 3, 8 | 3, 8 | 3, 8 |
| NUMBER OF REGIMENS | | | |
| 2 | 0 | 0 | 0 |
| 3 | 22 ( 46.8) | 18 ( 46.2) | 40 ( 46.5) |
| >=4 | 25 ( 53.2) | 21 ( 53.8) | 46 ( 53.5) |
| PRIOR THERAPY | | | |
| STEM CELL TRANSPLANT | 27 ( 57.4) | 27 ( 69.2) | 54 ( 62.8) |
| RADIOTHERAPY | 13 ( 27.7) | 9 ( 23.1) | 22 ( 25.6) |
| SURGERY | 7 ( 14.9) | 8 ( 20.5) | 15 ( 17.4) |
| TYPE OF SURGERY | | | |
| KYPHOPLASTY | 1 ( 2.1) | 1 ( 2.6) | 2 ( 2.3) |
| ORTHOPEDIC SURGERY | 3 ( 6.4) | 5 ( 12.8) | 8 ( 9.3) |
| DEBULKING SURGERY | 1 ( 2.1) | 1 ( 2.6) | 2 ( 2.3) |
| OTHER | 2 ( 4.3) | 2 ( 5.1) | 4 ( 4.7) |

DBL - 22FEB2021
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-th-priormm-ebr87.sas 31MAY2021:11:30:27

## 19.2 Baseline Charakteristika MM-007

Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| Age (years) | n | 65 | 76 | 141 |
| | Mean | 67.4 | 64.3 | 65.7 |
| | SD | 8.17 | 10.65 | 9.68 |
| | Median | 68.0 | 66.0 | 66.0 |
| | Min, Max | 50, 86 | 36, 85 | 36, 86 |
| Age group 1 | | | | |
| <=75 | n (%) | 55 ( 84.6) | 65 ( 85.5) | 120 ( 85.1) |
| >75 | n (%) | 10 ( 15.4) | 11 ( 14.5) | 21 ( 14.9) |
| Age group 2 | | | | |
| <=65 | n (%) | 26 ( 40.0) | 36 ( 47.4) | 62 ( 44.0) |
| >65 | n (%) | 39 ( 60.0) | 40 ( 52.6) | 79 ( 56.0) |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities; del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive.
Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
SOURCE: X:\Numerus\Studies\CLG\CLG107\Analysis\Prod\Progs\Tab_4.SAS
Date/time of run: 24AUG2021 15:46
Analysis Plan: 12MAY2021 Confidential Page 1 of 12

Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| Sex | | | | |
| Male | n (%) | 36 ( 55.4) | 43 ( 56.6) | 79 ( 56.0) |
| Female | n (%) | 29 ( 44.6) | 33 ( 43.4) | 62 ( 44.0) |
| Race | | | | |
| American Indian/Alaska Native | n (%) | 0 | 0 | 0 |
| Asian | n (%) | 0 | 1 ( 1.3) | 1 ( 0.7) |
| Black or African American | n (%) | 2 ( 3.1) | 2 ( 2.6) | 4 ( 2.8) |
| Native Hawaiian or Other Pacific Islander | n (%) | 0 | 0 | 0 |
| White | n (%) | 54 ( 83.1) | 66 ( 86.8) | 120 ( 85.1) |
| Not Collected or Reported | n (%) | 8 ( 12.3) | 5 ( 6.6) | 13 ( 9.2) |
| Other | n (%) | 1 ( 1.5) | 2 ( 2.6) | 3 ( 2.1) |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities; del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive.
Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
SOURCE: X:\Numerus\Studies\CLG\CLG107\Analysis\Prod\Progs\Tab_4.SAS
Date/time of run: 24AUG2021 15:46
Analysis Plan: 12MAY2021 Confidential Page 2 of 12

Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| Region | | | | |
| US | n (%) | 6 ( 9.2) | 7 ( 9.2) | 13 ( 9.2) |
| Non-US | n (%) | 59 ( 90.8) | 69 ( 90.8) | 128 ( 90.8) |
| Weight (kg) | n | 65 | 76 | 141 |
| | Mean | 74.38 | 77.18 | 75.89 |
| | SD | 13.418 | 15.795 | 14.762 |
| | Median | 73.40 | 76.90 | 75.00 |
| | Min, Max | 48.0, 110.3 | 42.0, 123.1 | 42.0, 123.1 |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities;
del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive.
Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
SOURCE: X:\Numerus\Studies\CLG\CLG107\Analysis\Prod\Progs\Tab_4.SAS
Date/time of run: 24AUG2021 15:46
Analysis Plan: 12MAY2021 Confidential Page 3 of 12

Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| ECOG Performance Status | | | | |
| 0 | n (%) | 26 ( 40.0) | 36 ( 47.4) | 62 ( 44.0) |
| 1 | n (%) | 36 ( 55.4) | 35 ( 46.1) | 71 ( 50.4) |
| 2 | n (%) | 3 ( 4.6) | 5 ( 6.6) | 8 ( 5.7) |
| 3 | n (%) | 0 | 0 | 0 |
| 4 | n (%) | 0 | 0 | 0 |
| Time Since Initial Diagnosis (years) | n | 65 | 76 | 141 |
| | Mean | 7.65 | 6.46 | 7.01 |
| | SD | 4.339 | 2.827 | 3.639 |
| | Median | 6.40 | 6.15 | 6.30 |
| | Min, Max | 1.5, 19.9 | 0.6, 14.7 | 0.6, 19.9 |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities;
del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive.
Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
SOURCE: X:\Numerus\Studies\CLG\CLG107\Analysis\Prod\Progs\Tab_4.SAS
Date/time of run: 24AUG2021 15:46
Analysis Plan: 12MAY2021 Confidential Page 4 of 12

Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| International Staging System at Study Entry [a] | | | | |
| Stage I | n (%) | 28 ( 43.1) | 31 ( 40.8) | 59 ( 41.8) |
| Stage II | n (%) | 25 ( 38.5) | 26 ( 34.2) | 51 ( 36.2) |
| Stage III | n (%) | 12 ( 18.5) | 19 ( 25.0) | 31 ( 22.0) |
| Prior Stem Cell Transplant | | | | |
| Yes | n (%) | 44 ( 67.7) | 58 ( 76.3) | 102 ( 72.3) |
| Allogeneic | n (%) | 1 ( 1.5) | 1 ( 1.3) | 2 ( 1.4) |
| Autologous | n (%) | 43 ( 66.2) | 57 ( 75.0) | 100 ( 70.9) |
| Both | n (%) | 0 | 0 | 0 |
| No | n (%) | 21 ( 32.3) | 18 ( 23.7) | 39 ( 27.7) |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities;
del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive.
Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
SOURCE: X:\Numerus\Studies\CLG\CLG107\Analysis\Prod\Progs\Tab_4.SAS
Date/time of run: 24AUG2021 15:46
Analysis Plan: 12MAY2021 Confidential Page 5 of 12

Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| Number of Prior Anti-Myeloma Regimens | n | 65 | 76 | 141 |
| | Mean | 3.0 | 3.0 | 3.0 |
| | SD | 0.25 | 0.11 | 0.19 |
| | Median | 3.0 | 3.0 | 3.0 |
| | Min, Max | 3, 5 | 3, 4 | 3, 5 |
| Number of Prior Anti-Myeloma Lines [b] | n | 65 | 76 | 141 |
| | Mean | 2.8 | 2.7 | 2.8 |
| | SD | 0.44 | 0.58 | 0.52 |
| | Median | 3.0 | 3.0 | 3.0 |
| | Min, Max | 1, 3 | 1, 4 | 1, 4 |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities; del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive.
Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
SOURCE: X:\Numerus\Studies\CLG\CLG107\Analysis\Prod\Progs\Tab_4.SAS
Date/time of run: 24AUG2021 15:46
Analysis Plan: 12MAY2021 Confidential Page 6 of 12

Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| Cytogenetic Abnormality [c] | | | | |
| High Risk | n (%) | 14 ( 21.5) | 14 ( 18.4) | 28 ( 19.9) |
| Non-high Risk | n (%) | 33 ( 50.8) | 33 ( 43.4) | 66 ( 46.8) |
| Missing | n (%) | 18 ( 27.7) | 29 ( 38.2) | 47 ( 33.3) |
| Heavy Chain Type [d] | | | | |
| IgA | n (%) | 15 ( 23.1) | 15 ( 19.7) | 30 ( 21.3) |
| IgD | n (%) | 0 | 0 | 0 |
| IgE | n (%) | 0 | 0 | 0 |
| IgG | n (%) | 44 ( 67.7) | 53 ( 69.7) | 97 ( 68.8) |
| IgM | n (%) | 0 | 0 | 0 |
| Not Detected | n (%) | 4 ( 6.2) | 6 ( 7.9) | 10 ( 7.1) |
| Missing | n (%) | 2 ( 3.1) | 2 ( 2.6) | 4 ( 2.8) |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities;
del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive.
Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
SOURCE: X:\Numerus\Studies\CLG\CLG107\Analysis\Prod\Progs\Tab_4.SAS
Date/time of run: 24AUG2021 15:46
Analysis Plan: 12MAY2021 Confidential Page 7 of 12

Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| Presence of Bone Lesions | | | | |
| Yes | n (%) | 48 ( 73.8) | 49 ( 64.5) | 97 ( 68.8) |
| No | n (%) | 17 ( 26.2) | 27 ( 35.5) | 44 ( 31.2) |
| Presence of Plasmacytoma | | | | |
| Yes | n (%) | 4 ( 6.2) | 5 ( 6.6) | 9 ( 6.4) |
| No | n (%) | 61 ( 93.8) | 71 ( 93.4) | 132 ( 93.6) |
| Baseline Beta-2-Microglobulin (mg/L) | n | 65 | 76 | 141 |
| | Mean | 4.3125 | 4.6669 | 4.5035 |
| | SD | 2.37285 | 3.02222 | 2.73833 |
| | Median | 3.6200 | 3.7565 | 3.6990 |
| | Min, Max | 1.640, 14.306 | 1.340, 16.722 | 1.340, 16.722 |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities;
del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive.
Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
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Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| Baseline Beta-2-Microglobulin Distribution | | | | |
| < 3.5 mg/L | n (%) | 30 ( 46.2) | 34 ( 44.7) | 64 ( 45.4) |
| >= 3.5 mg/L to <= 5.5 mg/L | n (%) | 23 ( 35.4) | 23 ( 30.3) | 46 ( 32.6) |
| > 5.5 mg/L | n (%) | 12 ( 18.5) | 19 ( 25.0) | 31 ( 22.0) |
| Baseline Albumin (g/dL) | n | 65 | 76 | 141 |
| | Mean | 3.77 | 3.82 | 3.80 |
| | SD | 0.493 | 0.559 | 0.528 |
| | Median | 3.80 | 3.85 | 3.80 |
| | Min, Max | 2.6, 4.7 | 2.0, 5.2 | 2.0, 5.2 |
| Baseline Albumin Distribution (g/dL) | | | | |
| < 3.5 | n (%) | 14 ( 21.5) | 17 ( 22.4) | 31 ( 22.0) |
| >= 3.5 | n (%) | 51 ( 78.5) | 59 ( 77.6) | 110 ( 78.0) |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities;
del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive.
Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
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Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| Baseline Lactate Dehydrogenase (LDH) > ULN | | | | |
| Yes | n (%) | 12 ( 18.5) | 16 ( 21.1) | 28 ( 19.9) |
| No | n (%) | 53 ( 81.5) | 60 ( 78.9) | 113 ( 80.1) |
| Baseline Hemoglobin (g/dL) | n | 65 | 76 | 141 |
| | Mean | 111.1 | 108.7 | 109.8 |
| | SD | 16.81 | 17.85 | 17.36 |
| | Median | 109.0 | 109.5 | 109.0 |
| | Min, Max | 80, 158 | 63, 146 | 63, 158 |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities; del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive. Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.

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Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| Baseline Platelets ($x10^9$/L) | n | 65 | 76 | 141 |
| | Mean | 186.8 | 171.6 | 178.6 |
| | SD | 86.98 | 76.64 | 81.63 |
| | Median | 180.0 | 162.0 | 173.0 |
| | Min, Max | 31, 436 | 30, 379 | 30, 436 |
| Baseline Renal Function (CGCRCL) (mL/min) | | | | |
| < 30 | n (%) | 3 ( 4.6) | 2 ( 2.6) | 5 ( 3.5) |
| 30 - < 45 | n (%) | 8 ( 12.3) | 7 ( 9.2) | 15 ( 10.6) |
| 45 - < 60 | n (%) | 13 ( 20.0) | 11 ( 14.5) | 24 ( 17.0) |
| 60 - < 80 | n (%) | 18 ( 27.7) | 24 ( 31.6) | 42 ( 29.8) |
| >= 80 | n (%) | 23 ( 35.4) | 32 ( 42.1) | 55 ( 39.0) |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities; del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive. Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
SOURCE: X:\Numerus\Studies\CLG\CLG107\Analysis\Prod\Progs\Tab_4.SAS
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Celgene: CC-4047-MM-007

Table 4: Baseline Characteristics
(Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| Characteristic | Statistic(s) | POM+BTZ+LD-DEX (N=65) | BTZ+LD-DEX (N=76) | All Subjects (N=141) |
|---|---|---|---|---|
| Prior Refractory Status [e] | | | | |
| Immunomodulatory Agents | n (%) | 57 ( 87.7) | 61 ( 80.3) | 118 ( 83.7) |
| Lenalidomide | n (%) | 56 ( 86.2) | 59 ( 77.6) | 115 ( 81.6) |
| Thalidomide | n (%) | 9 ( 13.8) | 5 ( 6.6) | 14 ( 9.9) |
| Proteasome Inhibitors | n (%) | 12 ( 18.5) | 15 ( 19.7) | 27 ( 19.1) |
| Bortezomib | n (%) | 6 ( 9.2) | 12 ( 15.8) | 18 ( 12.8) |
| Carfilzomib | n (%) | 5 ( 7.7) | 2 ( 2.6) | 7 ( 5.0) |
| Ixazomib | n (%) | 1 ( 1.5) | 2 ( 2.6) | 3 ( 2.1) |
| Refractory to Both Immunomodulatory Agent and Proteasome Inhibitor [e] | | | | |
| Yes | n (%) | 9 ( 13.8) | 13 ( 17.1) | 22 ( 15.6) |
| No | n (%) | 56 ( 86.2) | 63 ( 82.9) | 119 ( 84.4) |

N = Number of patients in the analysis set. Percentages are calculated based upon N.
CGCRCL = Cockcroft Gault Creatinine Clearance; ECOG = Eastern Cooperative Oncology Group; Max = Maximum; Min = Minimum; SD = Standard Deviation; ULN = Upper Limit of Normal.
[a] International Staging System is calculated using baseline values of Albumin and Beta-2-microglobulin.
[b] A therapeutic line is defined by subject's progression status. Only a regimen after disease progression is counted as a new line of therapy.
[c] High-risk is defined as presence of cytogenetic abnormality in at least one or more of the following cytogenetic abnormalities;
del(17p)(including monosomy 17), t(4;14) and/or t(14;16). Non-high risk is absence of high risk cytogenetic abnormalities.
[d] Heavy chain type is based on the serum immunofixation information if available, if serum immunofixation is not available, urine immunofixation is used.
[e] Refractory is defined as disease that is nonresponsive on therapy, or progresses within 60 days of last dose, inclusive.
Nonresponsive disease is defined as either failure to achieve minimal response or development of progressive disease while on therapy.
Refractory to each drug refers to refractory to the last (i.e., most recent) time the respective drug was received.
Refractory to each class of drugs refers to being refractory to at least one drug in that respective class.
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## 19.3 Baseline Charakteristika MM-003

Celgene: CC-4047-MM-003
Table 4: Demographic and Baseline Characteristics (Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| | POM+BTZ+LD-DEX (N=292) | HD-DEX (N=146) | All Subjects (N=438) |
|---|---|---|---|
| Age (years) | | | |
| n | 292 | 146 | 438 |
| Mean | 63.5 | 63.7 | 63.5 |
| SD | 9.25 | 9.44 | 9.30 |
| Median | 64.0 | 65.0 | 64.0 |
| Min, Max | 35.0, 84.0 | 35.0, 87.0 | 35.0, 87.0 |
| Stratification Factor 1: Age n(%) | | | |
| <= 75 Years Old | 270 ( 92.5) | 136 ( 93.2) | 406 ( 92.7) |
| > 75 Years Old | 22 ( 7.5) | 10 ( 6.8) | 32 ( 7.3) |
| Age Distribution n(%) | | | |
| <= 65 | 163 ( 55.8) | 78 ( 53.4) | 241 ( 55.0) |
| > 65 | 129 ( 44.2) | 68 ( 46.6) | 197 ( 45.0) |

N: Number of patients in the analysis set. Percentages are calculated based upon N.
[a] Disease Population Group 1 is defined as refractory subjects who have progressed on or within 60 days of both lenalidomide and bortezomib based treatments. Disease Population Group 2 is defined as relapsed and refractory subjects who achieved at least PR and progressed within 6months after stopping treatment with lenalidomide and/or bortezomib. Disease Population Group 3 is defined as refractory/intolerant subjects who have developed intolerance/toxicity after a minimum of 2 cycles of bortezomib.
[b] High risk is defined as any cytogenetic abnormality in 13q14, 17p13, 4p16/14q32 or 14q32/16q23.
[c] Heavy chain type is based on the serum immunofixation information if available,if serum immunofixation is not available, urine immunofixation is used.
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Celgene: CC-4047-MM-003
Table 4: Demographic and Baseline Characteristics (Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| | POM+BTZ+LD-DEX (N=292) | HD-DEX (N=146) | All Subjects (N=438) |
|---|---|---|---|
| Sex n(%) | | | |
| Male | 174 ( 59.6) | 82 ( 56.2) | 256 ( 58.4) |
| Female | 118 ( 40.4) | 64 ( 43.8) | 182 ( 41.6) |
| Race n(%) | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 4 ( 1.4) | 0 | 4 ( 0.9) |
| Black or African American | 4 ( 1.4) | 2 ( 1.4) | 6 ( 1.4) |
| Native Hawaiian or Other Pacific Islanders | 0 | 0 | 0 |
| White | 239 ( 81.8) | 109 ( 74.7) | 348 ( 79.5) |
| Other | 2 ( 0.7) | 2 ( 1.4) | 4 ( 0.9) |
| Not Collected | 43 ( 14.7) | 33 ( 22.6) | 76 ( 17.4) |
| Stratification Factor 2: Disease Population [a] n(%) | | | |
| Disease Population Group 1 | 241 ( 82.5) | 120 ( 82.2) | 361 ( 82.4) |
| Disease Population Group 2 | 8 ( 2.7) | 5 ( 3.4) | 13 ( 3.0) |
| Disease Population Group 3 | 43 ( 14.7) | 21 ( 14.4) | 64 ( 14.6) |

N: Number of patients in the analysis set. Percentages are calculated based upon N.
[a] Disease Population Group 1 is defined as refractory subjects who have progressed on or within 60 days of both lenalidomide and bortezomib based treatments. Disease Population Group 2 is defined as relapsed and refractory subjects who achieved at least PR and progressed within 6months after stopping treatment with lenalidomide and/or bortezomib. Disease Population Group 3 is defined as refractory/intolerant subjects who have developed intolerance/toxicity after a minimum of 2 cycles of bortezomib.
[b] High risk is defined as any cytogenetic abnormality in 13q14, 17p13, 4p16/14q32 or 14q32/16q23.
[c] Heavy chain type is based on the serum immunofixation information if available,if serum immunofixation is not available, urine immunofixation is used.
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Celgene: CC-4047-MM-003
Table 4: Demographic and Baseline Characteristics (Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| | POM+BTZ+LD-DEX (N=292) | HD-DEX (N=146) | All Subjects (N=438) |
|---|---|---|---|
| Weight (kg) | | | |
| n | 291 | 146 | 437 |
| Mean | 74.7 | 73.3 | 74.3 |
| SD | 15.34 | 15.74 | 15.47 |
| Median | 74.5 | 71.1 | 74.0 |
| Min, Max | 41.0, 127.0 | 42.0, 121.0 | 41.0, 127.0 |
| Baseline ECOG Performance Status n(%) | | | |
| 0 | 104 ( 35.6) | 35 ( 24.0) | 139 ( 31.7) |
| 1 | 134 ( 45.9) | 82 ( 56.2) | 216 ( 49.3) |
| 2 | 52 ( 17.8) | 23 ( 15.8) | 75 ( 17.1) |
| 3 | 0 | 3 ( 2.1) | 3 ( 0.7) |
| Missing | 2 ( 0.7) | 3 ( 2.1) | 5 ( 1.1) |

N: Number of patients in the analysis set. Percentages are calculated based upon N.
[a] Disease Population Group 1 is defined as refractory subjects who have progressed on or within 60 days of both lenalidomide and bortezomib based treatments. Disease Population Group 2 is defined as relapsed and refractory subjects who achieved at least PR and progressed within 6months after stopping treatment with lenalidomide and/or bortezomib. Disease Population Group 3 is defined as refractory/intolerant subjects who have developed intolerance/toxicity after a minimum of 2 cycles of bortezomib.
[b] High risk is defined as any cytogenetic abnormality in 13q14, 17p13, 4p16/14q32 or 14q32/16q23.
[c] Heavy chain type is based on the serum immunofixation information if available,if serum immunofixation is not available, urine immunofixation is used.

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Celgene: CC-4047-MM-003
Table 4: Demographic and Baseline Characteristics (Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| | POM+BTZ+LD-DEX (N=292) | HD-DEX (N=146) | All Subjects (N=438) |
|---|---|---|---|
| Multiple Myeloma Stage before Study Entry n(%) | | | |
| I | 21 ( 7.2) | 11 ( 7.5) | 32 ( 7.3) |
| II | 94 ( 32.2) | 35 ( 24.0) | 129 ( 29.5) |
| III | 168 ( 57.5) | 99 ( 67.8) | 267 ( 61.0) |
| Missing | 9 ( 3.1) | 1 ( 0.7) | 10 ( 2.3) |
| Autologous SCT n(%) | | | |
| Yes | 212 ( 72.6) | 103 ( 70.5) | 315 ( 71.9) |
| No | 80 ( 27.4) | 43 ( 29.5) | 123 ( 28.1) |
| Prior Anti-Myeloma Therapies given? n(%) | | | |
| Yes | 292 (100.0) | 146 (100.0) | 438 (100.0) |
| Number of Prior Anti-myeloma Regimen | | | |
| n | 292 | 146 | 438 |
| Mean | 5.2 | 5.3 | 5.2 |
| SD | 1.94 | 2.15 | 2.01 |
| Median | 5.0 | 5.0 | 5.0 |
| Min, Max | 3.0, 14.0 | 3.0, 17.0 | 3.0, 17.0 |

N: Number of patients in the analysis set. Percentages are calculated based upon N.
[a] Disease Population Group 1 is defined as refractory subjects who have progressed on or within 60 days of both lenalidomide and bortezomib based treatments. Disease Population Group 2 is defined as relapsed and refractory subjects who achieved at least PR and progressed within 6months after stopping treatment with lenalidomide and/or bortezomib. Disease Population Group 3 is defined as refractory/intolerant subjects who have developed intolerance/toxicity after a minimum of 2 cycles of bortezomib.
[b] High risk is defined as any cytogenetic abnormality in 13q14, 17p13, 4p16/14q32 or 14q32/16q23.
[c] Heavy chain type is based on the serum immunofixation information if available,if serum immunofixation is not available, urine immunofixation is used.
SOURCE: X:\Numerus\Studies\CLG\CLG106\Analysis\Prod\Progs\Tab_4.SAS
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Celgene: CC-4047-MM-003
Table 4: Demographic and Baseline Characteristics (Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| | POM+BTZ+LD-DEX (N=292) | HD-DEX (N=146) | All Subjects (N=438) |
|---|---|---|---|
| Stratification Factor 3: Number of Prior Anti-MM Therapies n(%) | | | |
| 2 Prior Anti-Mm Therapies | 7 ( 2.4) | 3 ( 2.1) | 10 ( 2.3) |
| >2 Prior Anti-Mm Therapies | 285 ( 97.6) | 143 ( 97.9) | 428 ( 97.7) |
| Cytogenetic Abnormality [b] n(%) | | | |
| High Risk | 126 ( 43.2) | 55 ( 37.7) | 181 ( 41.3) |
| Non-High Risk | 90 ( 30.8) | 45 ( 30.8) | 135 ( 30.8) |
| Missing | 76 ( 26.0) | 46 ( 31.5) | 122 ( 27.9) |
| Heavy Chain Type [c] n(%) | | | |
| Any Heavy Chain | 257 ( 88.0) | 119 ( 81.5) | 376 ( 85.8) |
| IgA | 73 ( 25.0) | 30 ( 20.5) | 103 ( 23.5) |
| IgG | 181 ( 62.0) | 85 ( 58.2) | 266 ( 60.7) |
| IgM | 1 ( 0.3) | 0 | 1 ( 0.2) |
| IgD | 2 ( 0.7) | 4 ( 2.7) | 6 ( 1.4) |
| Not Detected | 35 ( 12.0) | 27 ( 18.5) | 62 ( 14.2) |

N: Number of patients in the analysis set. Percentages are calculated based upon N.
[a] Disease Population Group 1 is defined as refractory subjects who have progressed on or within 60 days of both lenalidomide and bortezomib based treatments. Disease Population Group 2 is defined as relapsed and refractory subjects who achieved at least PR and progressed within 6months after stopping treatment with lenalidomide and/or bortezomib. Disease Population Group 3 is defined as refractory/intolerant subjects who have developed intolerance/toxicity after a minimum of 2 cycles of bortezomib.
[b] High risk is defined as any cytogenetic abnormality in 13q14, 17p13, 4p16/14q32 or 14q32/16q23.
[c] Heavy chain type is based on the serum immunofixation information if available,if serum immunofixation is not available, urine immunofixation is used.

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Celgene: CC-4047-MM-003
Table 4: Demographic and Baseline Characteristics (Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| | POM+BTZ+LD-DEX (N=292) | HD-DEX (N=146) | All Subjects (N=438) |
|---|---|---|---|
| Presence of Bone Lesions n(%) | | | |
| Yes | 196 ( 67.1) | 94 ( 64.4) | 290 ( 66.2) |
| No | 96 ( 32.9) | 52 ( 35.6) | 148 ( 33.8) |
| Presence of Plasmacytoma n(%) | | | |
| Yes | 27 ( 9.2) | 13 ( 8.9) | 40 ( 9.1) |
| No | 265 ( 90.8) | 133 ( 91.1) | 398 ( 90.9) |
| Baseline Beta-2-microglobulin (mg/L) | | | |
| n | 279 | 139 | 418 |
| Mean | 5.3 | 5.5 | 5.4 |
| SD | 3.33 | 3.46 | 3.37 |
| Median | 4.6 | 4.5 | 4.6 |
| Min, Max | 1.6, 31.8 | 1.6, 30.0 | 1.6, 31.8 |

N: Number of patients in the analysis set. Percentages are calculated based upon N.
[a] Disease Population Group 1 is defined as refractory subjects who have progressed on or within 60 days of both lenalidomide and bortezomib based treatments. Disease Population Group 2 is defined as relapsed and refractory subjects who achieved at least PR and progressed within 6months after stopping treatment with lenalidomide and/or bortezomib. Disease Population Group 3 is defined as refractory/intolerant subjects who have developed intolerance/toxicity after a minimum of 2 cycles of bortezomib.
[b] High risk is defined as any cytogenetic abnormality in 13q14, 17p13, 4p16/14q32 or 14q32/16q23.
[c] Heavy chain type is based on the serum immunofixation information if available,if serum immunofixation is not available, urine immunofixation is used.

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Celgene: CC-4047-MM-003
Table 4: Demographic and Baseline Characteristics (Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| | POM+BTZ+LD-DEX (N=292) | HD-DEX (N=146) | All Subjects (N=438) |
|---|---|---|---|
| Baseline Beta-2-microglobulin Distribution n(%) | | | |
| < 3.5 mg/L | 85 ( 29.1) | 41 ( 28.1) | 126 ( 28.8) |
| 3.5 - <5.5 mg/L | 103 ( 35.3) | 44 ( 30.1) | 147 ( 33.6) |
| >= 5.5 mg/L | 91 ( 31.2) | 54 ( 37.0) | 145 ( 33.1) |
| Missing | 13 ( 4.5) | 7 ( 4.8) | 20 ( 4.6) |
| Baseline Albumin (g/dL) | | | |
| n | 291 | 145 | 436 |
| Mean | 3.6 | 3.6 | 3.6 |
| SD | 0.62 | 0.63 | 0.62 |
| Median | 3.7 | 3.7 | 3.7 |
| Min, Max | 1.6, 5.2 | 1.8, 4.8 | 1.6, 5.2 |
| Baseline Albumin Distribution n(%) | | | |
| < 3.5 g/dL | 102 ( 34.9) | 56 ( 38.4) | 158 ( 36.1) |
| >= 3.5 g/dL | 189 ( 64.7) | 89 ( 61.0) | 278 ( 63.5) |
| Missing | 1 ( 0.3) | 1 ( 0.7) | 2 ( 0.5) |

N: Number of patients in the analysis set. Percentages are calculated based upon N.
[a] Disease Population Group 1 is defined as refractory subjects who have progressed on or within 60 days of both lenalidomide and bortezomib based treatments. Disease Population Group 2 is defined as relapsed and refractory subjects who achieved at least PR and progressed within 6months after stopping treatment with lenalidomide and/or bortezomib. Disease Population Group 3 is defined as refractory/intolerant subjects who have developed intolerance/toxicity after a minimum of 2 cycles of bortezomib.
[b] High risk is defined as any cytogenetic abnormality in 13q14, 17p13, 4p16/14q32 or 14q32/16q23.
[c] Heavy chain type is based on the serum immunofixation information if available,if serum immunofixation is not available, urine immunofixation is used.

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Celgene: CC-4047-MM-003
Table 4: Demographic and Baseline Characteristics (Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| | POM+BTZ+LD-DEX (N=292) | HD-DEX (N=146) | All Subjects (N=438) |
|---|---|---|---|
| Baseline LDH >= 1.5xULN n(%) | | | |
| Yes | 25 ( 8.6) | 18 ( 12.3) | 43 ( 9.8) |
| No | 266 ( 91.1) | 127 ( 87.0) | 393 ( 89.7) |
| Missing | 1 ( 0.3) | 1 ( 0.7) | 2 ( 0.5) |
| Baseline Hemoglobin (g/dL) | | | |
| n | 292 | 146 | 438 |
| Mean | 10.0 | 9.9 | 10.0 |
| SD | 1.57 | 1.45 | 1.53 |
| Median | 9.8 | 9.8 | 9.8 |
| Min, Max | 7.0, 16.6 | 6.3, 13.9 | 6.3, 16.6 |
| Baseline Platelets (10^9/L) | | | |
| n | 292 | 146 | 438 |
| Mean | 138.2 | 137.0 | 137.8 |
| SD | 77.53 | 74.45 | 76.44 |
| Median | 130.5 | 127.0 | 129.0 |
| Min, Max | 12.0, 461.0 | 13.0, 447.0 | 12.0, 461.0 |

N: Number of patients in the analysis set. Percentages are calculated based upon N.
[a] Disease Population Group 1 is defined as refractory subjects who have progressed on or within 60 days of both lenalidomide and bortezomib based treatments. Disease Population Group 2 is defined as relapsed and refractory subjects who achieved at least PR and progressed within 6months after stopping treatment with lenalidomide and/or bortezomib. Disease Population Group 3 is defined as refractory/intolerant subjects who have developed intolerance/toxicity after a minimum of 2 cycles of bortezomib.
[b] High risk is defined as any cytogenetic abnormality in 13q14, 17p13, 4p16/14q32 or 14q32/16q23.
[c] Heavy chain type is based on the serum immunofixation information if available,if serum immunofixation is not available, urine immunofixation is used.

SOURCE: X:\Numerus\Studies\CLG\CLG106\Analysis\Prod\Progs\Tab_4.SAS
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Celgene: CC-4047-MM-003
Table 4: Demographic and Baseline Characteristics (Intent-to-treat Population with at least 3 Prior Anti-Myeloma Regimens)

| | POM+BTZ+LD-DEX (N=292) | HD-DEX (N=146) | All Subjects (N=438) |
|---|---|---|---|
| Baseline Renal Function (Creatinine Clearance) n(%) | | | |
| < 30 ml/min | 2 ( 0.7) | 2 ( 1.4) | 4 ( 0.9) |
| 30-<45 ml/min | 27 ( 9.2) | 15 ( 10.3) | 42 ( 9.6) |
| 45-<60 ml/min | 61 ( 20.9) | 40 ( 27.4) | 101 ( 23.1) |
| 60-<80 ml/min | 96 ( 32.9) | 37 ( 25.3) | 133 ( 30.4) |
| >=80 ml/min | 104 ( 35.6) | 51 ( 34.9) | 155 ( 35.4) |
| Missing | 2 ( 0.7) | 1 ( 0.7) | 3 ( 0.7) |

N: Number of patients in the analysis set. Percentages are calculated based upon N.
[a] Disease Population Group 1 is defined as refractory subjects who have progressed on or within 60 days of both lenalidomide and bortezomib based treatments. Disease Population Group 2 is defined as relapsed and refractory subjects who achieved at least PR and progressed within 6months after stopping treatment with lenalidomide and/or bortezomib. Disease Population Group 3 is defined as refractory/intolerant subjects who have developed intolerance/toxicity after a minimum of 2 cycles of bortezomib.
[b] High risk is defined as any cytogenetic abnormality in 13q14, 17p13, 4p16/14q32 or 14q32/16q23.
[c] Heavy chain type is based on the serum immunofixation information if available,if serum immunofixation is not available, urine immunofixation is used.

SOURCE: X:\Numerus\Studies\CLG\CLG106\Analysis\Prod\Progs\Tab_4.SAS
Date/time of run: 23AUG2021 09:42. Cut Date: 01SEP2013
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# 20. Deskriptiver Vergleich UE nach SOC und PT

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. MM-007 (PVd)

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-007 (PVd) (N = 63)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 127 (93,4) | 48 (76,2) |
| Anämie | 96 (70,6) | 25 (39,7) |
| Leukopenie | 59 (43,4) | 8 (12,7) |
| Lymphopenie | 39 (28,7) | 3 (4,8) |
| Neutropenie | 121 (89,0) | 35 (55,6) |
| Thrombozytopenie | 87 (64,0) | 29 (46,0) |
| **Erkrankungen des Gastrointestinaltrakts (Für SOC-Differenz < 15%)** | | |
| Brechreiz | 76 (55,9) | 15 (23,8) |

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-007 (PVd) (N = 63)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort (Für SOC-Differenz < 15%)** | | |
| Asthenie | 22 (16,2) | 20 (31,7) |
| **Erkrankungen des Immunsystems** | 110 (80,9) | 2 (3,2) |
| Zytokin-Freisetzungssyndrom | 105 (77,2) | 1 (1,6) |
| Hypogammaglobulinämie | 27 (19,9) | 1 (1,6) |
| **Untersuchungen** | 75 (55,1) | 14 (22,2) |
| Aspartataminotransferase erhöht | 26 (19,1) | 2 (3,2) |
| **Stoffwechsel- und Ernährungsstörungen** | 101 (74,3) | 33 (52,4) |
| Hyperglykämie | 8 (5,9) | 14 (22,2) |
| Hypokalzämie | 37 (27,2) | 2 (3,2) |
| Hypokaliämie | 52 (38,2) | 6 (9,5) |

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-007 (PVd) (N = 63)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Hypomagnesiämie | 32 (23,5) | 3 (4,8) |
| Hyponatriämie | 27 (19,9) | 1 (1,6) |
| Hypophosphatämie | 41 (30,1) | 6 (9,5) |
| **Erkrankungen des Nervensystems (Für SOC-Differenz < 15%)** | | |
| Kopfschmerzen | 39 (28,7) | 5 (7,9) |
| Periphere sensorische Neuropathie | 4 (2,9) | 28 (44,4) |
| Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); PVd: Pomalidomid + Bortezomib + Dexamethason; SOC: Systemorganklasse; | | |

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs derStudie KarMMa (Ide-Cel) vs. MM-007 (Vd)

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-007 (Vd) (N = 75)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 127 (93,4) | 44 (58,7) |
| Anämie | 96 (70,6) | 25 (33,3) |
| Febrile Neutropenie | 22 (16,2) | 0 (0) |
| Leukopenie | 59 (43,4) | 3 (4) |
| Lymphopenie | 39 (28,7) | 3 (4) |
| Neutropenie | 121 (89) | 3 (4) |
| Thrombozytopenie | 87 (64) | 34 (45,3) |
| **Erkrankungen des Gastrointestinaltrakts** | 117 (86) | 43 (57,3) |
| Brechreiz | 76 (55,9) | 13 (17,3) |

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-007 (Vd) (N = 75)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Immunsystems** | 110 (80,9) | 1 (1,3) |
| Zytokin-Freisetzungssyndrom | 105 (77,2) | 0 (0) |
| Hypogammaglobulinämie | 27 (19,9) | 0 (0) |
| **Untersuchungen** | 75 (55,1) | 20 (26,7) |
| Aspartataminotransferase erhöht | 26 (19,1) | 0 (0) |
| **Stoffwechsel- und Ernährungsstörungen** | 101 (74,3) | 33 (44) |
| Appetit vermindert | 35 (25,7) | 7 (9,3) |
| Hypoalbuminämie | 22 (16,2) | 0 (0) |
| Hypokalzämie | 37 (27,2) | 0 (0) |
| Hypokaliämie | 52 (38,2) | 6 (8) |
| Hypomagnesiämie | 32 (23,5) | 3 (4) |

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-007 (Vd) (N = 75)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Hyponatriämie | 27 (19,9) | 2 (2,7) |
| Hypophosphatämie | 41 (30,1) | 3 (4) |
| **Erkrankungen des Nervensystems (Für SOC-Differenz < 15%)** | | |
| Kopfschmerzen | 39 (28,7) | 6 (8) |
| Periphere sensorische Neuropathie | 4 (2,9) | 24 (32) |
| **Gefäßerkrankungen (Für SOC-Differenz < 15%)** | | |
| Hypotonie | 24 (17,6) | 1 (1,3) |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort** | 107 (78,7) | 45 (60) |
| **Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen** | 81 (59,6) | 31 (41,3) |
| **Erkrankungen der Nieren und Harnwege** | 40 (29,4) | 9 (12) |
| Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse; Vd: Bortezomib + Dexamethason; | | |

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. MM-003 (Pd)

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-003 (Pd) (N = 290)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 127 (93,4) | 223 (76,9) |
| Anämie | 96 (70,6) | 151 (52,1) |
| Leukopenie | 59 (43,4) | 37 (12,8) |
| Lymphopenie | 39 (28,7) | 12 (4,1) |
| Neutropenie | 121 (89,0) | 151 (52,1) |
| Thrombozytopenie | 87 (64,0) | 88 (30,3) |
| **Erkrankungen des Gastrointestinaltrakts** | 117 (86,0) | 176 (60,7) |
| Brechreiz | 76 (55,9) | 48 (16,6) |
| **Erkrankungen des Immunsystems** | 110 (80,9) | 9 (3,1) |
| Hypogammaglobulinämie | 27 (19,9) | 1 (0,3) |

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-003 (Pd) (N = 290)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Untersuchungen** | 75 (55,1) | 86 (29,7) |
| Aspartataminotransferase erhöht | 26 (19,1) | 4 (1,4) |
| **Stoffwechsel- und Ernährungsstörungen** | 101 (74,3) | 118 (40,7) |
| Hypokalzämie | 37 (27,2) | 11 (3,8) |
| Hypokaliämie | 52 (38,2) | 29 (10,0) |
| Hypomagnesiämie | 32 (23,5) | 6 (2,1) |
| Hyponatriämie | 27 (19,9) | 12 (4,1) |
| Hypophosphatämie | 41 (30,1) | 3 (1,0) |
| **Erkrankungen des Nervensystems (Für SOC-Differenz < 15%)** | | |
| Kopfschmerzen | 39 (28,7) | 24 (8,3) |
| Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; Pd: Pomalidomid + Dexamethason; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse | | |

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. MM-003 (HD-Dex)

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-003 (Hd-Dex) (N = 143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 127 (93,4) | 96 (67,1) |
| Anämie | 96 (70,6) | 74 (51,7) |
| Febrile Neutropenie | 22 (16,2) | 0 (0) |
| Leukopenie | 59 (43,4) | 8 (5,6) |
| Lymphopenie | 39 (28,7) | 6 (4,2) |
| Neutropenie | 121 (89,0) | 33 (23,1) |
| Thrombozytopenie | 87 (64,0) | 43 (30,1) |
| **Erkrankungen des Gastrointestinaltrakts** | 117 (86) | 58 (40,6) |
| Diarrhö | 52 (38,2) | 27 (18,9) |
| Brechreiz | 76 (55,9) | 16 (11,2) |

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-003 (Hd-Dex) (N = 143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Erbrechen | 29 (21,3) | 7 (4,9) |
| **Erkrankungen des Immunsystems** | 110 (80,9) | 3 (2,1) |
| Hypogammaglobulinämie | 27 (19,9) | 0 (0) |
| **Untersuchungen** | 75 (55,1) | 29 (20,3) |
| Aspartataminotransferase erhöht | 26 (19,1) | 2 (1,4) |
| **Stoffwechsel- und Ernährungsstörungen** | 101 (74,3) | 61 (42,7) |
| Appetit vermindert | 35 (25,7) | 11 (7,7) |
| Hypokalzämie | 37 (27,2) | 9 (6,3) |
| Hypokaliämie | 52 (38,2) | 11 (7,7) |
| Hypomagnesiämie | 32 (23,5) | 3 (2,1) |
| Hyponatriämie | 27 (19,9) | 4 (2,8) |

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-003 (Hd-Dex) (N = 143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Hypophosphatämie | 41 (30,1) | 0 (0) |
| **Erkrankungen des Nervensystems** | 78 (57,4) | 55 (38,5) |
| Kopfschmerzen | 39 (28,7) | 7 (4,9) |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort** | 107 (78,7) | 89 (62,2) |
| **Infektionen und parasitäre Erkrankungen** | 95 (69,9) | 77 (53,8) |
| **Erkrankungen der Atemwege, des Brustraums und Mediastinums** | 71 (52,2) | 48 (33,6) |
| **Erkrankungen der Haut und des Unterhautgewebes** | 50 (36,8) | 25 (17,5) |
| **Gefäßerkrankungen** | 42 (30,9) | 20 (14) |
| Abkürzungen: HD-Dex: Hochdosiertes Dexamethason (High Dose Dexamethasone); Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse | | |

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. ELOQUENT-3 (EPd)

| | **KarMMa (Ide-Cel) (N = 136)** | **ELOQUENT-3 (EPd) (N = 47)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 127 (93,4) | 29 (61,7) |
| Anämie | 96 (70,6) | 13 (27,7) |
| Leukopenie | 59 (43,4) | 5 (10,6) |
| Lymphopenie | 39 (28,7) | 6 (12,8) |
| Neutropenie | 121 (89,0) | 13 (27,7) |
| Thrombozytopenie | 87 (64,0) | 8 (17,0) |
| **Erkrankungen des Gastrointestinaltrakts** | 117 (86,0) | 9 (19,1) |
| Brechreiz | 76 (55,9) | 2 (4,3) |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort** | 107 (78,7) | 28 (59,6) |
| Ermüdung | 54 (39,7) | 10 (21,3) |

| | **KarMMa (Ide-Cel) (N = 136)** | **ELOQUENT-3 (EPd) (N = 47)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Infektionen und parasitäre Erkrankungen (Für SOC-Differenz < 15%)** | | |
| Bronchitis | 4 (2,9) | 10 (21,3) |
| Nasopharyngitis | 7 (5,1) | 14 (29,8) |
| **Untersuchungen** | 75 (55,1) | 9 (19,1) |
| **Stoffwechsel- und Ernährungsstörungen** | 101 (74,3) | 20 (42,6) |
| Appetit vermindert | 35 (25,7) | 5 (10,6) |
| Hypokaliämie | 52 (38,2) | 5 (10,6) |
| **Erkrankungen des Nervensystems** | 78 (57,4) | 14 (29,8) |
| **Erkrankungen der Nieren und Harnwege** | 40 (29,4) | 6 (12,8) |
| **Erkrankungen der Haut und des Unterhautgewebes** | 50 (36,8) | 10 (21,3) |
| Abkürzungen: EPd: Elotuzumab + Pomalidomid + Dexamethason; Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse | | |

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. ELOQUENT-3 (Pd)

| | **KarMMa (Ide-Cel) (N = 136)** | **ELOQUENT-3 (Pd) (N = 38)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 127 (93,4) | 24 (63,2) |
| Anämie | 96 (70,6) | 15 (39,5) |
| Leukopenie | 59 (43,4) | 4 (10,5) |
| Lymphopenie | 39 (28,7) | 1 (2,6) |
| Neutropenie | 121 (89,0) | 10 (26,3) |
| Thrombozytopenie | 87 (64,0) | 7 (18,4) |
| **Erkrankungen des Gastrointestinaltrakts** | 117 (86,0) | 17 (44,7) |
| Brechreiz | 76 (55,9) | 5 (13,2) |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort** | 107 (78,7) | 19 (50,0) |
| Ermüdung | 54 (39,7) | 5 (13,2) |

| | **KarMMa (Ide-Cel) (N = 136)** | **ELOQUENT-3 (Pd) (N = 38)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Infektionen und parasitäre Erkrankungen (Für SOC-Differenz < 15%)** | | |
| Bronchitis | 4 (2,9) | 5 (13,2) |
| Nasopharyngitis | 7 (5,1) | 8 (21,1) |
| **Untersuchungen** | 75 (55,1) | 12 (31,6) |
| **Stoffwechsel- und Ernährungsstörungen** | 101 (74,3) | 17 (44,7) |
| Appetit vermindert | 35 (25,7) | 3 (7,9) |
| Hypokaliämie | 52 (38,2) | 6 (15,8) |
| **Erkrankungen des Nervensystems** | 78 (57,4) | 10 (26,3) |
| **Psychiatrische Erkrankungen** | 53 (39) | 8 (21,1) |
| **Erkrankungen der Atemwege, des Brustraums und Mediastinums** | 71 (52,2) | 12 (31,6) |
| **Gefäßerkrankungen** | 42 (30,9) | 4 (10,5) |

| | **KarMMa (Ide-Cel) (N = 136)** | **ELOQUENT-3 (Pd) (N = 38)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; Pd: Pomalidomid + Dexamethason; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse | | |

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. MM-007 (PVd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-007 (PVd) (N = 63)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 40 (95,2) | 48 (76,2) |
| Anämie | 32 (76,2) | 25 (39,7) |
| Febrile Neutropenie | 9 (21,4) | 2 (3,2) |
| Leukopenie | 24 (57,1) | 8 (12,7) |
| Lymphopenie | 20 (47,6) | 3 (4,8) |
| Neutropenie | 36 (85,7) | 35 (55,6) |
| Thrombozytopenie | 31 (73,8) | 29 (46,0) |
| **Erkrankungen des Gastrointestinaltrakts** | 37 (88,1) | 46 (73,0) |
| Brechreiz | 27 (64,3) | 15 (23,8) |
| Erbrechen | 14 (33,3) | 11 (17,5) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-007 (PVd) (N = 63)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort** | 37 (88,1) | 46 (73,0) |
| Asthenie | 5 (11,9) | 20 (31,7) |
| Schüttelfrost | 12 (28,6) | 1 (1,6) |
| Ermüdung | 24 (57,1) | 19 (30,2) |
| Fieber | 16 (38,1) | 13 (20,6) |
| **Erkrankungen des Immunsystems** | 35 (83,3) | 2 (3,2) |
| Zytokin-Freisetzungssyndrom | 35 (83,3) | 1 (1,6) |
| **Untersuchungen** | 25 (59,5) | 14 (22,2) |
| Alkalische Phosphatase im Blut erhöht | 8 (19,0) | 1 (1,6) |
| **Stoffwechsel- und Ernährungsstörungen** | 33 (78,6) | 33 (52,4) |
| Hypoalbuminämie | 13 (31,0) | 2 (3,2) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-007 (PVd) (N = 63)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Hypokalzämie | 13 (31,0) | 2 (3,2) |
| Hypokaliämie | 19 (45,2) | 6 (9,5) |
| Hypomagnesiämie | 9 (21,4) | 3 (4,8) |
| Hyponatriämie | 8 (19,0) | 1 (1,6) |
| Hypophosphatämie | 16 (38,1) | 6 (9,5) |
| **Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen** | 34 (81,0) | 34 (54,0) |
| Arthralgie | 16 (38,1) | 7 (11,1) |
| **Erkrankungen des Nervensystems (Für SOC-Differenz < 15%)** | | |
| Kopfschmerzen | 14 (33,3) | 5 (7,9) |
| Periphere sensorische Neuropathie | 1 (2,4) | 28 (44,4) |
| **Erkrankungen der Atemwege, des Brustraums und Mediastinums** | 33 (78,6) | 28 (44,4) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-007 (PVd) (N = 63)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Husten | 19 (45,2) | 10 (15,9) |
| Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term);<br>PVd: Pomalidomid + Bortezomib + Dexamethason; SOC: Systemorganklasse | | |

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. MM-007 (Vd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-007 (Vd) (N = 75)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 40 (95,2) | 44 (58,7) |
| Anämie | 32 (76,2) | 25 (33,3) |
| Febrile Neutropenie | 9 (21,4) | 0 (0) |
| Leukopenie | 24 (57,1) | 3 (4,0) |
| Lymphopenie | 20 (47,6) | 3 (4,0) |
| Neutropenie | 36 (85,7) | 3 (4,0) |
| Thrombozytopenie | 31 (73,8) | 34 (45,3) |
| **Erkrankungen des Gastrointestinaltrakts** | 37 (88,1) | 43 (57,3) |
| Abdominalschmerz | 8 (19) | 3 (4,0) |
| Diarrhö | 19 (45,2) | 19 (25,3) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-007 (Vd) (N = 75)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Brechreiz | 27 (64,3) | 13 (17,3) |
| Erbrechen | 14 (33,3) | 7 (9,3) |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort** | 37 (88,1) | 45 (60,0) |
| Schüttelfrost | 12 (28,6) | 2 (2,7) |
| Ermüdung | 24 (57,1) | 23 (30,7) |
| Ödem peripher | 16 (38,1) | 15 (20,0) |
| Fieber | 16 (38,1) | 11 (14,7) |
| **Erkrankungen des Immunsystems** | 35 (83,3) | 1 (1,3) |
| Zytokin-Freisetzungssyndrom | 35 (83,3) | 0 (0) |
| **Untersuchungen** | 25 (59,5) | 20 (26,7) |
| Alkalische Phosphatase im Blut erhöht | 8 (19,0) | 0 (0) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-007 (Vd) (N = 75)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Stoffwechsel- und Ernährungsstörungen** | 33 (78,6) | 33 (44,0) |
| Hypoalbuminämie | 13 (31,0) | 0 (0) |
| Hypokalzämie | 13 (31,0) | 0 (0) |
| Hypokaliämie | 19 (45,2) | 6 (8,0) |
| Hypomagnesiämie | 9 (21,4) | 3 (4,0) |
| Hyponatriämie | 8 (19,0) | 2 (2,7) |
| Hypophosphatämie | 16 (38,1) | 3 (4,0) |
| **Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen** | 34 (81,0) | 31 (41,3) |
| Arthralgie | 16 (38,1) | 5 (6,7) |
| **Erkrankungen des Nervensystems** | 31 (73,8) | 44 (58,7) |
| Kopfschmerzen | 14 (33,3) | 6 (8,0) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-007 (Vd) (N = 75)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Periphere sensorische Neuropathie | 1 (2,4) | 24 (32,0) |
| **Erkrankungen der Atemwege, des Brustraums und Mediastinums** | 33 (78,6) | 30 (40,0) |
| Husten | 19 (45,2) | 12 (16,0) |
| **Herzerkrankungen** | 16 (38,1) | 10 (13,3) |
| **Erkrankungen der Haut und des Unterhautgewebes** | 21 (50) | 19 (25,3) |
| **Gefäßerkrankungen** | 19 (45,2) | 15 (20) |
| Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse; Vd: Bortezomib + Dexamethason | | |

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. MM-003 (Pd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (Pd) (N = 290)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 40 (95,2) | 223 (76,9) |
| Anämie | 32 (76,2) | 151 (52,1) |
| Leukopenie | 24 (57,1) | 37 (12,8) |
| Lymphopenie | 20 (47,6) | 12 (4,1) |
| Neutropenie | 36 (85,7) | 151 (52,1) |
| Thrombozytopenie | 31 (73,8) | 88 (30,3) |
| **Erkrankungen des Gastrointestinaltrakts** | 37 (88,1) | 176 (60,7) |
| Diarrhö | 19 (45,2) | 69 (23,8) |
| Brechreiz | 27 (64,3) | 48 (16,6) |
| Erbrechen | 14 (33,3) | 25 (8,6) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (Pd) (N = 290)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort (Für SOC-Differenz < 15%)** | | |
| Schüttelfrost | 12 (28,6) | 16 (5,5) |
| Ermüdung | 24 (57,1) | 102 (35,2) |
| Ödem peripher | 16 (38,1) | 55 (19,0) |
| **Infektionen und parasitäre Erkrankungen (Für SOC-Differenz < 15%)** | | |
| Infektion der oberen Atemwege | 14 (33,3) | 48 (16,6) |
| **Untersuchungen** | 25 (59,5) | 86 (29,7) |
| Alkalische Phosphatase im Blut erhöht | 8 (19,0) | 1 (0,3) |
| **Stoffwechsel- und Ernährungsstörungen** | 33 (78,6) | 118 (40,7) |
| Hyperglykämie | 9 (21,4) | 18 (6,2) |
| Hypoalbuminämie | 13 (31,0) | 10 (3,4) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (Pd) (N = 290)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Hypokalzämie | 13 (31,0) | 11 (3,8) |
| Hypokaliämie | 19 (45,2) | 29 (10,0) |
| Hypomagnesiämie | 9 (21,4) | 6 (2,1) |
| Hypophosphatämie | 16 (38,1) | 3 (1,0) |
| **Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen** | 34 (81,0) | 163 (56,2) |
| Arthralgie | 16 (38,1) | 28 (9,7) |
| **Erkrankungen des Nervensystems** | 31 (73,8) | 126 (43,4) |
| Kopfschmerzen | 14 (33,3) | 24 (8,3) |
| **Erkrankungen der Atemwege, des Brustraums und Mediastinums** | 33 (78,6) | 147 (50,7) |
| Husten | 19 (45,2) | 60 (20,7) |
| Hypoxie | 7 (16,7) | 1 (0,3) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (Pd) (N = 290)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Nasenverstopfung | 11 (26,2) | 4 (1,4) |
| **Herzerkrankungen** | 16 (38,1) | 51 (17,6) |
| **Erkrankungen des Immunsystems** | 35 (83,3) | 9 (3,1) |
| **Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen** | 14 (33,3) | 42 (14,5) |
| **Erkrankungen der Haut und des Unterhautgewebes** | 21 (50) | 97 (33,4) |
| **Gefäßerkrankungen** | 19 (45,2) | 57 (19,7) |
| Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; Pd: Pomalidomid + Dexamethason; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse | | |

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. MM-003 (HD-Dex)

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (HD-Dex) (N = 143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 40 (95,2) | 96 (67,1) |
| Anämie | 32 (76,2) | 74 (51,7) |
| Febrile Neutropenie | 9 (21,4) | 0 (0) |
| Leukopenie | 24 (57,1) | 8 (5,6) |
| Lymphopenie | 20 (47,6) | 6 (4,2) |
| Neutropenie | 36 (85,7) | 33 (23,1) |
| Thrombozytopenie | 31 (73,8) | 43 (30,1) |
| **Erkrankungen des Gastrointestinaltrakts** | 37 (88,1) | 58 (40,6) |
| Abdominalschmerz | 8 (19,0) | 5 (3,5) |
| Konstipation | 14 (33,3) | 20 (14,0) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (HD-Dex) (N = 143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Diarrhö | 19 (45,2) | 27 (18,9) |
| Brechreiz | 27 (64,3) | 16 (11,2) |
| Erbrechen | 14 (33,3) | 7 (4,9) |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort** | 37 (88,1) | 89 (62,2) |
| Schüttelfrost | 12 (28,6) | 2 (1,4) |
| Ermüdung | 24 (57,1) | 39 (27,3) |
| Ödem peripher | 16 (38,1) | 16 (11,2) |
| **Infektionen und parasitäre Erkrankungen** | 30 (71,4) | 77 (53,8) |
| Infektion der oberen Atemwege | 14 (33,3) | 10 (7,0) |
| **Untersuchungen** | 25 (59,5) | 29 (20,3) |
| Alkalische Phosphatase im Blut erhöht | 8 (19,0) | 1 (0,7) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (HD-Dex) (N = 143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Untersuchungen | 25 (59,5) | 29 (20,3) |
| **Stoffwechsel- und Ernährungsstörungen** | 33 (78,6) | 61 (42,7) |
| Hypoalbuminämie | 13 (31,0) | 3 (2,1) |
| Hypokalzämie | 13 (31,0) | 9 (6,3) |
| Hypokaliämie | 19 (45,2) | 11 (7,7) |
| Hypomagnesiämie | 9 (21,4) | 3 (2,1) |
| Hyponatriämie | 8 (19,0) | 4 (2,8) |
| Hypophosphatämie | 16 (38,1) | 0 (0) |
| **Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen** | 34 (81,0) | 81 (56,6) |
| Arthralgie | 16 (38,1) | 6 (4,2) |
| **Erkrankungen des Nervensystems** | 31 (73,8) | 55 (38,5) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (HD-Dex) (N = 143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Kopfschmerzen | 14 (33,3) | 7 (4,9) |
| **Erkrankungen der Atemwege, des Brustraums und Mediastinums** | 33 (78,6) | 48 (33,6) |
| Husten | 19 (45,2) | 15 (10,5) |
| Hypoxie | 7 (16,7) | 1 (0,7) |
| Nasenverstopfung | 11 (26,2) | 1 (0,7) |
| Husten mit Auswurf | 7 (16,7) | 1 (0,7) |
| **Gefäßerkrankungen** | 19 (45,2) | 20 (14,0) |
| Hypertonie | 8 (19,0) | 4 (2,8) |
| **Herzerkrankungen** | 16 (38,1) | 22 (15,4) |
| **Erkrankungen des Ohrs und des Labyrinths** | 7 (16,7) | 2 (1,4) |
| **Erkrankungen des Immunsystems** | 35 (83,3) | 3 (2,1) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (HD-Dex) (N = 143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen** | 14 (33,3) | 17 (11,9) |
| **Erkrankungen der Haut und des Unterhautgewebes** | 21 (50) | 25 (17,5) |
| Abkürzungen: HD-Dex: Hochdosiertes Dexamethason (High Dose Dexamethasone); Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse | | |

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. ELOQUENT-3 (EPd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **ELOQUENT-3 (EPd) (N = 47)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 40 (95,2) | 29 (61,7) |
| Anämie | 32 (76,2) | 13 (27,7) |
| Leukopenie | 24 (57,1) | 5 (10,6) |
| Lymphopenie | 20 (47,6) | 6 (12,8) |
| Neutropenie | 36 (85,7) | 13 (27,7) |
| Thrombozytopenie | 31 (73,8) | 8 (17,0) |
| **Erkrankungen des Gastrointestinaltrakts** | 37 (88,1) | 24 (51,1) |
| Diarrhö | 19 (45,2) | 14 (29,8) |
| Brechreiz | 27 (64,3) | 2 (4,3) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **ELOQUENT-3 (EPd) (N = 47)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort** | 37 (88,1) | 28 (59,6) |
| Ermüdung | 24 (57,1) | 10 (21,3) |
| Ödem peripher | 16 (38,1) | 8 (17,0) |
| **Infektionen und parasitäre Erkrankungen (Für SOC-Differenz < 15%)** | | |
| Bronchitis | 2 (4,8) | 10 (21,3) |
| Nasopharyngitis | 3 (7,1) | 14 (29,8) |
| Infektion der oberen Atemwege | 14 (33,3) | 7 (14,9) |
| **Untersuchungen** | 25 (59,5) | 9 (19,1) |
| **Stoffwechsel- und Ernährungsstörungen** | 33 (78,6) | 20 (42,6) |
| Hypokaliämie | 19 (45,2) | 5 (10,6) |
| **Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen** | 34 (81,0) | 26 (55,3) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **ELOQUENT-3 (EPd) (N = 47)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| Arthralgie | 16 (38,1) | 4 (8,5) |
| **Erkrankungen der Atemwege, des Brustraums und Mediastinums** | 33 (78,6) | 18 (38,3) |
| Husten | 19 (45,2) | 5 (10,6) |
| **Herzerkrankungen** | 16 (38,1) | 6 (12,8) |
| **Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen** | 14 (33,3) | 6 (12,8) |
| **Erkrankungen des Nervensystems** | 31 (73,8) | 14 (29,8) |
| **Erkrankungen der Haut und des Unterhautgewebes** | 21 (50) | 10 (21,3) |
| **Gefäßerkrankungen** | 19 (45,2) | 8 (17,0) |

Abkürzungen: EPd: Elotuzumab + Pomalidomid + Dexamethason; Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse

Ergebnisse zu unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. ELOQUENT-3 (Pd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **ELOQUENT-3 (Pd) (N = 38)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 40 (95,2) | 24 (63,2) |
| Anämie | 32 (76,2) | 15 (39,5) |
| Leukopenie | 24 (57,1) | 4 (10,5) |
| Lymphopenie | 20 (47,6) | 1 (2,6) |
| Neutropenie | 36 (85,7) | 10 (26,3) |
| Thrombozytopenie | 31 (73,8) | 7 (18,4) |
| **Erkrankungen des Gastrointestinaltrakts** | 37 (88,1) | 17 (44,7) |
| Diarrhö | 19 (45,2) | 5 (13,2) |
| Brechreiz | 27 (64,3) | 5 (13,2) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **ELOQUENT-3 (Pd) (N = 38)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort** | 37 (88,1) | 19 (50,0) |
| Ermüdung | 24 (57,1) | 5 (13,2) |
| Ödem peripher | 16 (38,1) | 4 (10,5) |
| **Untersuchungen** | 25 (59,5) | 12 (31,6) |
| **Stoffwechsel- und Ernährungsstörungen** | 33 (78,6) | 17 (44,7) |
| Hypokaliämie | 19 (45,2) | 6 (15,8) |
| **Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen** | 34 (81,0) | 18 (47,4) |
| Arthralgie | 16 (38,1) | 5 (13,2) |
| **Erkrankungen der Atemwege, des Brustraums und Mediastinums** | 33 (78,6) | 12 (31,6) |
| Husten | 19 (45,2) | 4 (10,5) |
| **Herzerkrankungen** | 16 (38,1) | 6 (15,8) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **ELOQUENT-3 (Pd) (N = 38)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Augenerkrankungen** | 9 (21,4) | 2 (5,3) |
| **Erkrankungen des Nervensystems** | 31 (73,8) | 10 (26,3) |
| **Erkrankungen der Haut und des Unterhautgewebes** | 21 (50) | 10 (26,3) |
| **Gefäßerkrankungen** | 19 (45,2) | 4 (10,5) |
| Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; Pd: Pomalidomid + Dexamethason; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse | | |

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. MM-007 (PVd)

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-007 (PVd) (N = 63)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 126 (92,6) | 44 (69,8) |
| Anämie | 85 (62,5) | 13 (20,6) |
| Leukopenie | 55 (40,4) | 4 (6,3) |
| Lymphopenie | 38 (27,9) | 3 (4,8) |
| Neutropenie | 117 (86,0) | 32 (50,8) |
| Thrombozytopenie | 72 (52,9) | 23 (36,5) |
| **Stoffwechsel- und Ernährungsstörungen (Für SOC-Differenz < 15%)** | | |
| Hyperglykämie | 1 (0,7) | 11 (17,5) |
| Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); PVd: Pomalidomid + Bortezomib + Dexamethason; SOC: Systemorganklasse | | |

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. MM-007 (Vd)

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-007 (Vd) (N = 75)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 126 (92,6) | 36 (48,0) |
| Anämie | 85 (62,5) | 16 (21,3) |
| Febrile Neutropenie | 21 (15,4) | 0 (0) |
| Leukopenie | 55 (40,4) | 2 (2,7) |
| Lymphopenie | 38 (27,9) | 3 (4,0) |
| Neutropenie | 117 (86,0) | 3 (4,0) |
| Thrombozytopenie | 72 (52,9) | 27 (36,0) |
| **Stoffwechsel- und Ernährungsstoerungen** | 47 (34,6) | 14 (18,7) |

Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse; Vd: Bortezomib + Dexamethason

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. MM-003 (Pd)

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-003 (Pd) (N = 290)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 126 (92,6) | 196 (67,6) |
| Anämie | 85 (62,5) | 94 (32,4) |
| Leukopenie | 55 (40,4) | 26 (9,0) |
| Lymphopenie | 38 (27,9) | 10 (3,4) |
| Neutropenie | 117 (86,0) | 142 (49,0) |
| Thrombozytopenie | 72 (52,9) | 66 (22,8) |

Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; Pd: Pomalidomid + Dexamethason; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. MM-003 (HD-Dex)

| | **KarMMa (Ide-Cel) (N = 136)** | **MM-003 (HD-Dex) (N = 143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 126 (92,6) | 82 (57,3) |
| Anämie | 85 (62,5) | 55 (38,5) |
| Febrile Neutropenie | 21 (15,4) | 0 (0) |
| Leukopenie | 55 (40,4) | 5 (3,5) |
| Lymphopenie | 38 (27,9) | 5 (3,5) |
| Neutropenie | 117 (86,0) | 26 (18,2) |
| Thrombozytopenie | 72 (52,9) | 38 (26,6) |

Abkürzungen: HD-Dex: Hochdosiertes Dexamethason (High Dose Dexamethasone); Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse;

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. ELOQUENT-3 (EPd)

| | **KarMMa (Ide-Cel) (N = 136)** | **ELOQUENT-3 (EPd) (N = 47)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 126 (92,6) | 22 (46,8) |
| Anämie | 85 (62,5) | 5 (10,6) |
| Leukopenie | 55 (40,4) | 5 (10,6) |
| Lymphopenie | 38 (27,9) | 5 (10,6) |
| Neutropenie | 117 (86,0) | 8 (17,0) |
| Thrombozytopenie | 72 (52,9) | 5 (10,6) |
| **Stoffwechsel- und Ernährungsstörungen** | 47 (34,6) | 7 (14,9) |

Abkürzungen: EPd: Elotuzumab + Pomalidomid + Dexamethason; Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie KarMMa (Ide-Cel) vs. ELOQUENT-3 (Pd)

| | **KarMMa (Ide-Cel) (N = 136)** | **ELOQUENT-3 (Pd) (N = 38)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 126 (92,6) | 17 (44,7) |
| Anämie | 85 (62,5) | 10 (26,3) |
| Leukopenie | 55 (40,4) | 2 (5,3) |
| Lymphopenie | 38 (27,9) | 1 (2,6) |
| Neutropenie | 117 (86,0) | 9 (23,7) |
| Thrombozytopenie | 72 (52,9) | 2 (5,3) |

Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; Pd: Pomalidomid + Dexamethason; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. MM-007 (PVd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-007 (PVd) (N = 63)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 39 (92,9) | 44 (69,8) |
| Anämie | 25 (59,5) | 13 (20,6) |
| Febrile Neutropenie | 8 (19,0) | 2 (3,2) |
| Leukopenie | 23 (54,8) | 4 (6,3) |
| Lymphopenie | 19 (45,2) | 3 (4,8) |
| Neutropenie | 34 (81,0) | 32 (50,8) |
| **Untersuchungen** | 10 (23,8) | 3 (4,8) |
| **Stoffwechsel- und Ernährungsstörungen (Für SOC-Differenz < 15%)** | | |
| Hypophosphatämie | 9 (21,4) | 4 (6,3) |

Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term);
PVd: Pomalidomid + Bortezomib + Dexamethason; SOC: Systemorganklasse

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. MM-007 (Vd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-007 (Vd) (N =75)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 39 (92,9) | 36 (48,0) |
| Anämie | 25 (59,5) | 16 (21,3) |
| Febrile Neutropenie | 8 (19,0) | 0 (0) |
| Leukopenie | 23 (54,8) | 2 (2,7) |
| Lymphopenie | 19 (45,2) | 3 (4,0) |
| Neutropenie | 34 (81,0) | 3 (4,0) |
| **Untersuchungen** | 10 (23,8) | 4 (5,3) |
| **Stoffwechsel- und Ernährungsstörungen (Für SOC-Differenz < 15%)** | | |
| Hypophosphatämie | 9 (21,4) | 1 (1,3) |

Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse; Vd: Bortezomib + Dexamethason

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. MM-003 (Pd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (Pd) (N = 290)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 39 (92,9) | 196 (67,6) |
| Anämie | 25 (59,5) | 94 (32,4) |
| Leukopenie | 23 (54,8) | 26 (9,0) |
| Lymphopenie | 19 (45,2) | 10 (3,4) |
| Neutropenie | 34 (81) | 142 (49) |
| Thrombozytopenie | 21 (50,0) | 66 (22,8) |
| **Stoffwechsel- und Ernährungsstörungen (Für SOC-Differenz < 15%)** | | |
| Hypophosphatämie | 9 (21,4) | 2 (0,7) |
| Abkürzungen: Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; Pd: Pomalidomid + Dexamethason; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse | | |

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. MM-003 (HD-Dex)

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (HD-Dex) (N =143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 39 (92,9) | 82 (57,3) |
| Anämie | 25 (59,5) | 55 (38,5) |
| Febrile Neutropenie | 8 (19,0) | 0 (0) |
| Leukopenie | 23 (54,8) | 5 (3,5) |
| Lymphopenie | 19 (45,2) | 5 (3,5) |
| Neutropenie | 34 (81,0) | 26 (18,2) |
| Thrombozytopenie | 21 (50,0) | 38 (26,6) |
| **Untersuchungen** | 10 (23,8) | 12 (8,4) |
| **Stoffwechsel- und Ernährungsstörungen (Für SOC-Differenz < 15%)** | | |
| Hypophosphatämie | 9 (21,4) | 0 (0) |

| | **CRB-401 (Ide-Cel) (N = 42)** | **MM-003 (HD-Dex) (N =143)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen** | 1 (2,4) | 30 (21) |
| Abkürzungen: HD-Dex: Hochdosiertes Dexamethason (High Dose Dexamethasone); Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; SOC: Systemorganklasse; PT: Bevorzugter Begriff (Preferred Term) | | |

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. ELOQUENT-3 (EPd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **ELOQUENT-3 (EPd) (N =47)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 39 (92,9) | 22 (46,8) |
| Anämie | 25 (59,5) | 5 (10,6) |
| Leukopenie | 23 (54,8) | 5 (10,6) |
| Lymphopenie | 19 (45,2) | 5 (10,6) |
| Neutropenie | 34 (81,0) | 8 (17,0) |
| Thrombozytopenie | 21 (50,0) | 5 (10,6) |
| **Untersuchungen** | 10 (23,8) | 4 (8,5) |
| **Stoffwechsel- und Ernaehrungsstoerungen** | 14 (33,3) | 7 (14,9) |

Abkürzungen: EPd: Elotuzumab + Pomalidomid + Dexamethason; Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse

Ergebnisse zu schweren unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. ELOQUENT-3 (Pd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **ELOQUENT-3 (Pd) (N = 38)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Erkrankungen des Blutes und des Lymphsystems** | 39 (92,9) | 17 (44,7) |
| Anämie | 25 (59,5) | 10 (26,3) |
| Leukopenie | 23 (54,8) | 2 (5,3) |
| Lymphopenie | 19 (45,2) | 1 (2,6) |
| Neutropenie | 34 (81,0) | 9 (23,7) |
| Thrombozytopenie | 21 (50,0) | 2 (5,3) |

Abkürzungen: Pd: Pomalidomid + Dexamethason; Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; SOC: Systemorganklasse; PT: Bevorzugter Begriff (Preferred Term)

Ergebnisse zu schwerwiegenden unerwünschten Ereignissen nach SOC und PT des deskriptiven Vergleichs der Studie CRB-401 (Ide-Cel) vs. ELOQUENT-3 (EPd)

| | **CRB-401 (Ide-Cel) (N = 42)** | **ELOQUENT-3 (EPd) (N = 47)** |
|---|---|---|
| | **Patienten mit Ereignis n (%)** | **Patienten mit Ereignis n (%)** |
| **Allgemeine Erkrankungen und Beschwerden am Verabreichungsort** | 9 (21,4) | 2 (4,3) |

Abkürzungen: EPd: Elotuzumab + Pomalidomid + Dexamethason; Ide-Cel: Idecabtagen vicleucel; KI: Konfidenzintervall; N: Anzahl Patienten; n: Anzahl Patienten mit Ereignis; n.b.: nicht berechenbar; PT: Bevorzugter Begriff (Preferred Term); SOC: Systemorganklasse