



Clinical trial results:

A Phase IIa, Open-label, Multicenter Study of Single-agent MOR00208, an Fc-Optimized Anti-CD19 Antibody, in Patients with Relapsed or Refractory B-Cell Non-Hodgkin's Lymphoma

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2012-002659-41 |
| Trial protocol | BE IT HU ES DE PL |
| Global end of trial date | 06 April 2022 |

Results information

| | |
|--------------------------------|--|
| Result version number | v2 (current) |
| This version publication date | 21 April 2023 |
| First version publication date | 05 January 2019 |
| Version creation reason | • New data added to full data set Availability of final CSR |

Trial information

Trial identification

| | |
|-----------------------|------------|
| Sponsor protocol code | MOR208C201 |
|-----------------------|------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01685008 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Morphosys AG |
| Sponsor organisation address | Semmelweisstrasse 7, Planegg, Germany, 82152 |
| Public contact | Medical Information, Morphosys AG, +1 844 667-1992, medinfo@morphosys.com |
| Scientific contact | Medical Information, Morphosys AG, +1 844 667-1992, medinfo@morphosys.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 15 June 2022 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 06 April 2022 |
| Global end of trial reached? | Yes |
| Global end of trial date | 06 April 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the antitumor activity of single-agent MOR00208 in adult patients with relapsed or refractory NHL who have received at least 1 prior therapy containing rituximab as one of the treatments.

Protection of trial subjects:

This trial was designed, conducted and reported in accordance with the International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP), applicable local regulations (including European Directive 2001/20/EC), and following the ethical principles laid down in the Declaration of Helsinki. Specific ICH adopted and other relevant international guidelines and recommendations were taken into account as far as meaningfully possible. Safety monitoring for all patients enrolled in the study included laboratory safety assessments (haematology, blood chemistry, urinalysis, coagulation, and anti-MOR00208 antibodies) and clinical evaluations (physical examinations, vital signs, 12-lead ECG) as detailed in the Schedule of Assessments.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 23 April 2013 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Spain: 12 |
| Country: Number of subjects enrolled | United States: 20 |
| Country: Number of subjects enrolled | Belgium: 2 |
| Country: Number of subjects enrolled | Germany: 7 |
| Country: Number of subjects enrolled | Hungary: 16 |
| Country: Number of subjects enrolled | Italy: 19 |
| Country: Number of subjects enrolled | Poland: 16 |
| Worldwide total number of subjects | 92 |
| EEA total number of subjects | 72 |

Notes:

Subjects enrolled per age group

| | |
|--|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 | 0 |

| | |
|--|----|
| wk | |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 43 |
| From 65 to 84 years | 46 |
| 85 years and over | 3 |

Subject disposition

Recruitment

Recruitment details:

This was a Phase IIa open-label, multicenter safety and efficacy study of MOR00208, that was planned to enroll approximately 40 to 120 adult patients with refractory or relapsed NHL who have received at least 1 prior therapy containing rituximab.

Pre-assignment

Screening details:

Patients were male or female ≥ 18 years of age, with a histologically confirmed diagnosis of FL, other indolent NHL (e.g., MZL/MALT), DLBCL, or MCL. Patients must have had progression of their NHL after at least 1 prior rituximab-containing regimen, and had at least 1 site of measurable disease on an MRI or CT scan.

Period 1

| | |
|------------------------------|------------------|
| Period 1 title | Screening Period |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|-----------|----------|
| Arm title | MOR00208 |
|-----------|----------|

Arm description:

A total of 113 patients were screened; of these, 21 were screening failures and did not receive treatment with MOR00208. 92 patients completed screening and received at least one dose of study drug.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | MOR00208 |
| Investigational medicinal product code | MOR00208 |
| Other name | MOR208, XmAb5574, tafasitamab |
| Pharmaceutical forms | Solution for infusion in administration system |
| Routes of administration | Intravenous use |

Dosage and administration details:

MOR00208 drug product is a lyophilisate supplied in single-use 20 mL glass vials. Each vial contains 200 mg of MOR00208 for reconstitution with 5 mL water for injection. Intravenous infusions were administered at the study site, beginning on Cycle 1 Day 1.

| | |
|---------------------------------------|----------|
| Number of subjects in period 1 | MOR00208 |
| Started | 92 |
| Completed | 92 |

Period 2

| | |
|------------------------------|-----------------------------------|
| Period 2 title | Main Study Treatment (Cycles 1-2) |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|--|--|
| Arm title | MOR00208 |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | MOR00208 |
| Investigational medicinal product code | MOR00208 |
| Other name | MOR208, XmaB5574, tafasitamab |
| Pharmaceutical forms | Solution for infusion in administration system |
| Routes of administration | Intravenous use |

Dosage and administration details:

MOR00208 drug product is a lyophilisate supplied in single-use 20 mL glass vials. Each vial contains 200 mg of MOR00208 for reconstitution with 5 mL water for injection. Intravenous infusions were administered at the study site, beginning on Cycle 1 Day 1.

| Number of subjects in period 2 | MOR00208 |
|---------------------------------------|----------|
| Started | 92 |
| Completed | 75 |
| Not completed | 17 |
| Adverse event, serious fatal | 4 |
| Physician decision | 2 |
| Adverse event, non-fatal | 3 |
| Progressive disease | 7 |
| Protocol deviation | 1 |

Period 3

| | |
|------------------------------|-----------------------------------|
| Period 3 title | Post Cycle 2 (C3 and Maintenance) |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|--------------------|--------------|
| Arm title | MOR00208 |
| Arm description: - | |
| Arm type | Experimental |

| | |
|--|--|
| Investigational medicinal product name | MOR00208 |
| Investigational medicinal product code | MOR00208 |
| Other name | MOR208, XmAb5574, tafasitamab |
| Pharmaceutical forms | Solution for infusion in administration system |
| Routes of administration | Intravenous use |

Dosage and administration details:

MOR00208 drug product is a lyophilisate supplied in single-use 20 mL glass vials. Each vial contains 200 mg of MOR00208 for reconstitution with 5 mL water for injection. Intravenous infusions were administered at the study site, beginning on Cycle 1 Day 1.

| Number of subjects in period 3 | MOR00208 |
|---------------------------------------|-----------------|
| Started | 75 |
| Started Cycle 3 Treatment | 50 |
| Started Maintenance Phase Treatment | 16 |
| Completed | 1 |
| Not completed | 74 |
| Adverse event, serious fatal | 1 |
| Consent withdrawn by subject | 4 |
| Physician decision | 10 |
| Other | 5 |
| New cancer therapy | 7 |
| Unspecified | 1 |
| Progressive disease | 46 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | MOR00208 |
|-----------------------|----------|

Reporting group description:

A total of 113 patients were screened; of these, 21 were screening failures and did not receive treatment with MOR00208. 92 patients completed screening and received at least one dose of study drug.

| Reporting group values | MOR00208 | Total | |
|--|----------|-------|--|
| Number of subjects | 92 | 92 | |
| Age categorical | | | |
| Age (years) | | | |
| Units: Subjects | | | |
| Adults (18-64 Years) | 43 | 43 | |
| Adults (65 and over) | 49 | 49 | |
| Age continuous | | | |
| Age mean and SD | | | |
| Units: years | | | |
| arithmetic mean | 65.57 | | |
| standard deviation | ± 12.225 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 36 | 36 | |
| Male | 56 | 56 | |
| Race | | | |
| Units: Subjects | | | |
| Asian | 1 | 1 | |
| Black or African American | 1 | 1 | |
| White | 87 | 87 | |
| Other | 3 | 3 | |
| NHL Subtype | | | |
| Units: Subjects | | | |
| Follicular lymphoma | 34 | 34 | |
| Diffuse large B-cell lymphoma | 35 | 35 | |
| Mantle cell lymphoma | 12 | 12 | |
| Other indolent NHL | 11 | 11 | |
| Weight | | | |
| Units: kg | | | |
| arithmetic mean | 77.10 | | |
| standard deviation | ± 17.012 | - | |
| Height | | | |
| n=90 for this characteristic, as height was not collected at Screening (minor protocol noncompliance) for 2 patients in the Safety Population. | | | |
| Units: cm | | | |
| arithmetic mean | 169.30 | | |
| standard deviation | ± 11.954 | - | |
| BMI | | | |
| n=90 for this characteristic, as height was not collected at Screening (minor protocol noncompliance) for 2 patients in the Safety Population. | | | |

| | | | |
|--------------------|---------|---|--|
| Units: kg/m2 | | | |
| arithmetic mean | 26.86 | | |
| standard deviation | ± 5.133 | - | |

End points

End points reporting groups

| | |
|--|----------|
| Reporting group title | MOR00208 |
| Reporting group description: A total of 113 patients were screened; of these, 21 were screening failures and did not receive treatment with MOR00208. 92 patients completed screening and received at least one dose of study drug. | |
| Reporting group title | MOR00208 |
| Reporting group description: - | |
| Reporting group title | MOR00208 |
| Reporting group description: - | |

Primary: Overall Response Rate (ORR)

| | |
|---|--|
| End point title | Overall Response Rate (ORR) ^[1] |
| End point description: Proportion of Patients with Complete Remission (CR) or Partial Remission (PR), assessed as per the 2007 International Working Group (IWG) response criteria | |
| End point type | Primary |
| End point timeframe: From first dose until Follow-up Visit 12, up to 4.5 years | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The primary endpoint for this open-label study was a count of responders; no statistical analyses or comparisons are applicable.

| End point values | MOR00208 | | | |
|-----------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 92 | | | |
| Units: patients | | | | |
| Complete remission | 6 | | | |
| Partial remission | 16 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Stable Disease (SD) Rate

| | |
|---|--------------------------|
| End point title | Stable Disease (SD) Rate |
| End point description: Proportion of Patients with Stable Disease | |
| End point type | Secondary |
| End point timeframe: From first dose until Follow-up Visit 12, up to 4.5 years | |

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 92 | | | |
| Units: patients | 31 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DoR)

| | |
|--|----------------------------|
| End point title | Duration of Response (DoR) |
| End point description: Time from first response (CR or PR) to first documentation of relapse/progression, for patients who had any response during the study. | |
| End point type | Secondary |
| End point timeframe: From first dose until Follow-up Visit 12, up to 4.5 years | |

| | | | | |
|----------------------------------|------------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 22 ^[2] | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 24.0 (11.1 to 1000000) | | | |

Notes:

[2] - The upper CI was not reached; "1000000" entered as numerical value required.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Progression (TTP)

| | |
|--|---------------------------|
| End point title | Time to Progression (TTP) |
| End point description: Time from first dosing until documentation of progression or death due to lymphoma | |
| End point type | Secondary |
| End point timeframe: From first dose until Follow-up Visit 12, up to 4.5 years | |

| | | | | |
|----------------------------------|-------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 76 ^[3] | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 5.4 (3.4 to 12.0) | | | |

Notes:

[3] - Patients with documented progression of disease.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS)

| | |
|------------------------|--|
| End point title | Progression-free Survival (PFS) |
| End point description: | Time from first dosing until progression or death due to any cause |
| End point type | Secondary |
| End point timeframe: | From first dose until Follow-up Visit 12, up to 4.5 years |

| | | | | |
|----------------------------------|-------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 80 ^[4] | | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 5.4 (3.2 to 9.9) | | | |

Notes:

[4] - Patients with documented progression or death from any cause.

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence and Severity of Adverse Events (AEs)

| | |
|------------------------|---|
| End point title | Incidence and Severity of Adverse Events (AEs) |
| End point description: | Number of patients with treatment-emergent AEs rated Mild, Moderate, and Severe |
| End point type | Secondary |
| End point timeframe: | From first dose until 30 days after last dose of MOR00208, up to 8.5 years |

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 92 | | | |
| Units: patients | | | | |
| Mild | 29 | | | |
| Moderate | 20 | | | |
| Severe | 6 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number and Proportion of Patients Who Potentially Developed Anti-MOR00208 Antibodies and Semiquantitative Anti-MOR00208 Antibody Assessments

| | |
|-----------------|--|
| End point title | Number and Proportion of Patients Who Potentially Developed Anti-MOR00208 Antibodies and Semiquantitative Anti-MOR00208 Antibody Assessments |
|-----------------|--|

End point description:

Number of patients with at least one positive (+ve) post-Baseline sample containing positive anti-MOR00208 antibodies; Baseline (pre-dose) sample has to be tested negative (-ve)

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

End point timeframe:

From first dose until Follow-up Visit 3, up to 7 months

| | | | | |
|--|-----------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 92 | | | |
| Units: patients | | | | |
| Yes (≥ 1 +ve sample post-Baseline inc last sample) | 0 | | | |
| No (Baseline and all post-Baseline samples -ve) | 82 | | | |
| Transient (≥ 1 +ve post-Baseline, -ve last sample) | 0 | | | |
| Not evaluable (pre-dose sample tested +ve) | 5 | | | |
| Missing (no post-Baseline measurement available) | 5 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetic (PK) Parameter: Maximum Serum Concentration Observed (C_{max}) of MOR00208

| | |
|-----------------|---|
| End point title | Pharmacokinetic (PK) Parameter: Maximum Serum |
|-----------------|---|

End point description:

The highest concentration of MOR00208 measured in serum

End point type Secondary

End point timeframe:

Estimated from first dose (samples taken on first day of dosing at pre-dose, end of infusion, after 1 hour, 4 hours, 24 hours, and pre-dose on Day 8)

| End point values | MOR00208 | | | |
|--------------------------------------|-------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 85 ^[5] | | | |
| Units: µg/mL | | | | |
| arithmetic mean (standard deviation) | 263.1 (± 111.35) | | | |

Notes:

[5] - PK parameters were calculated as data permitted for the PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Time to Maximum Serum Concentration Observed (Tmax) of MOR00208

End point title PK Parameter: Time to Maximum Serum Concentration Observed (Tmax) of MOR00208

End point description:

The time to highest concentration of MOR00208 measured in serum

End point type Secondary

End point timeframe:

Estimated from first dose (samples taken on first day of dosing at pre-dose, end of infusion, after 1 hour, 4 hours, 24 hours, and pre-dose on Day 8)

| End point values | MOR00208 | | | |
|--------------------------------------|-------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 85 ^[6] | | | |
| Units: hours | | | | |
| arithmetic mean (standard deviation) | 5.8 (± 17.46) | | | |

Notes:

[6] - PK parameters were calculated as data permitted for the PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Apparent Trough Serum Concentration Before Dosing (Clast) of MOR00208

| | |
|------------------------|---|
| End point title | PK Parameter: Apparent Trough Serum Concentration Before Dosing (Clast) of MOR00208 |
| End point description: | The last quantifiable concentration from the first dose of MOR00208 |
| End point type | Secondary |
| End point timeframe: | Estimated from first dose (samples taken on first day of dosing at pre-dose, end of infusion, after 1 hour, 4 hours, 24 hours, and pre-dose on Day 8) |

| | | | | |
|--------------------------------------|-------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 85 ^[7] | | | |
| Units: µg/mL | | | | |
| arithmetic mean (standard deviation) | 81.0 (± 36.66) | | | |

Notes:

[7] - PK parameters were calculated as data permitted for the PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Area Under the Concentration Curve From Dose Time Zero to the Time the Last Quantifiable Concentration is Observed (AUC[0-t]) of MOR00208

| | |
|------------------------|--|
| End point title | PK Parameter: Area Under the Concentration Curve From Dose Time Zero to the Time the Last Quantifiable Concentration is Observed (AUC[0-t]) of MOR00208 |
| End point description: | Area under the concentration curve. The time curve from time zero (0) to the time that the last concentration above the lower limit of quantification (LLQ) is observed. |
| End point type | Secondary |
| End point timeframe: | Estimated from first dose (samples taken on first day of dosing at pre-dose, end of infusion, after 1 hour, 4 hours, 24 hours, and pre-dose on Day 8) |

| | | | | |
|--------------------------------------|----------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 85 ^[8] | | | |
| Units: h*µg/mL | | | | |
| arithmetic mean (standard deviation) | 21942.5 (± 11847.35) | | | |

Notes:

[8] - PK parameters were calculated as data permitted for the PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Apparent Terminal Rate Constant (λ_z) of MOR00208

| | |
|-----------------|---|
| End point title | PK Parameter: Apparent Terminal Rate Constant (λ_z) of MOR00208 |
|-----------------|---|

End point description:

Apparent terminal rate constant calculated from the regression analysis (slope) from the log-transformed measured concentrations on the terminal phase of the time-point concentration curve

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

End point timeframe:

Estimated from final dose (samples collected on the last day of Cycle 3 [C3D28; each cycle is 28 days long], and Follow-up Visits 1 [C3D28 + 4 weeks], 2 [C3D28 + 10 weeks], and 3 [C3D28 + 16 weeks])

| | | | | |
|--------------------------------------|---------------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 12 ^[9] | | | |
| Units: 1/h | | | | |
| arithmetic mean (standard deviation) | 0.00214 (\pm 0.000665) | | | |

Notes:

[9] - PK parameters were calculated as data permitted for the PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Apparent Terminal Half-life ($t_{1/2}$) of MOR00208

| | |
|-----------------|---|
| End point title | PK Parameter: Apparent Terminal Half-life ($t_{1/2}$) of MOR00208 |
|-----------------|---|

End point description:

Apparent terminal half-life calculated from $\ln(2)/\lambda_z$

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

End point timeframe:

Estimated from final dose (samples collected on the last day of Cycle 3 [C3D28; each cycle is 28 days long], and Follow-up Visits 1 [C3D28 + 4 weeks], 2 [C3D28 + 10 weeks], and 3 [C3D28 + 16 weeks])

| | | | | |
|--------------------------------------|----------------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 12 ^[10] | | | |
| Units: days | | | | |
| arithmetic mean (standard deviation) | 14.75111 (\pm 4.680075) | | | |

Notes:

[10] - PK parameters were calculated as permitted for the PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in Measurements of B-cell Populations

| | |
|-----------------|---|
| End point title | Absolute Change From Baseline in Measurements of B-cell Populations |
|-----------------|---|

End point description:

Actual change from baseline will be summarized descriptively by visit for the pharmacodynamic parameter: B-cell populations

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

End point timeframe:

Cycle 1 Day 1 (Baseline) to Cycle 1: Days 8, 15, and 22; Cycles 2 and 3: Days 1, 15, and 28 (each cycle is 28 days); End of Study (up to 7.5 years)

| | | | | |
|------------------------------------|-----------------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 70 ^[11] | | | |
| Units: 10 ⁶ /L | | | | |
| median (confidence interval 95%) | | | | |
| Cycle 1 Day 8 | -13.60 (-50.250 to -1.000) | | | |
| Cycle 1 Day 15 | -15.00 (-55.940 to -3.000) | | | |
| Cycle 1 Day 22 | -14.00 (-57.000 to -4.500) | | | |
| Cycle 2 Day 1 | -14.00 (-51.710 to -3.600) | | | |
| Cycle 2 Day 15 | -24.00 (-61.000 to -12.000) | | | |
| Cycle 2 Day 28 | -27.68 (-59.000 to -8.000) | | | |
| Cycle 3 Day 1 | -36.00 (-117.990 to 0.000) | | | |
| Cycle 3 Day 15 | -36.50 (-135.720 to 0.000) | | | |
| Cycle 3 Day 28 | -46.00 (-94.000 to -8.370) | | | |
| Study Completion/Early Termination | -15.00 (-69.820 to 4.000) | | | |

Notes:

[11] - Pharmacodynamic samples were collected at timepoints through the study where possible.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Measurements of B-cell Populations

| | |
|---|--|
| End point title | Percent Change From Baseline in Measurements of B-cell Populations |
| End point description: Relative change from baseline will be summarized descriptively by visit for the pharmacodynamic parameter: B-cell populations | |
| End point type | Secondary |
| End point timeframe: Cycle 1 Day 1 (Baseline) to Cycle 1: Days 8, 15, and 22; Cycles 2 and 3: Days 1, 15, and 28 (each cycle is 28 days); End of Study (up to 7.5 years) | |

| End point values | MOR00208 | | | |
|--|-----------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 70 ^[12] | | | |
| Units: percentage change from baseline | | | | |
| median (confidence interval 95%) | | | | |
| Cycle 1 Day 8 | -42.07 (-70.588 to -2.793) | | | |
| Cycle 1 Day 15 | -50.00 (-79.422 to -32.353) | | | |
| Cycle 1 Day 22 | -55.88 (-82.625 to -27.500) | | | |
| Cycle 2 Day 1 | -55.63 (-80.000 to -27.273) | | | |
| Cycle 2 Day 15 | -73.80 (-83.542 to -57.407) | | | |
| Cycle 2 Day 28 | -76.47 (-86.458 to -38.095) | | | |
| Cycle 3 Day 1 | -79.63 (-94.585 to -3.666) | | | |
| Cycle 3 Day 15 | -72.07 (-93.953 to -33.333) | | | |
| Cycle 3 Day 28 | -80.00 (-95.833 to -53.191) | | | |
| Study Completion/Early Termination | -49.31 (-85.444 to 2.941) | | | |

Notes:

[12] - Pharmacodynamic samples were collected at timepoints through the study where possible.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in Measurements of T-cell Populations

| | |
|---|---|
| End point title | Absolute Change From Baseline in Measurements of T-cell Populations |
| End point description: Actual change from baseline will be summarized descriptively by visit for the pharmacodynamic parameter: T-cell populations | |
| End point type | Secondary |
| End point timeframe: Cycle 1 Day 1 (Baseline) to Cycle 1: Days 8, 15, and 22; Cycles 2 and 3: Days 1, 15, and 28 (each cycle is 28 days); End of Study (up to 7.5 years) | |

| | | | | |
|------------------------------------|------------------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 71 ^[13] | | | |
| Units: 10 ⁶ /L | | | | |
| median (confidence interval 95%) | | | | |
| Cycle 1 Day 8 | 41.00 (-3.460 to 89.000) | | | |
| Cycle 1 Day 15 | 12.00 (-67.000 to 80.000) | | | |
| Cycle 1 Day 22 | -10.00 (-70.880 to 34.000) | | | |
| Cycle 2 Day 1 | 17.50 (-100.000 to 61.000) | | | |
| Cycle 2 Day 15 | 88.00 (-9.000 to 152.000) | | | |
| Cycle 2 Day 28 | 99.00 (-17.000 to 250.000) | | | |
| Cycle 3 Day 1 | 58.00 (-69.000 to 158.500) | | | |
| Cycle 3 Day 15 | 110.00 (-27.000 to 318.000) | | | |
| Cycle 3 Day 28 | 102.45 (-40.000 to 243.000) | | | |
| Study Completion/Early Termination | -57.50 (-137.000 to 144.000) | | | |

Notes:

[13] - Pharmacodynamic samples were collected at timepoints through the study where possible.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Measurements of T-cell Populations

| | |
|---|--|
| End point title | Percent Change From Baseline in Measurements of T-cell Populations |
| End point description: Relative change from baseline will be summarized descriptively by visit for the pharmacodynamic parameter: T-cell populations | |

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Cycle 1 Day 1 (Baseline) to Cycle 1: Days 8, 15, and 22; Cycles 2 and 3: Days 1, 15, and 28 (each cycle is 28 days); End of Study (up to 7.5 years) | |

| | | | | |
|--|---------------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 71 ^[14] | | | |
| Units: percentage change from baseline | | | | |
| median (confidence interval 95%) | | | | |
| Cycle 1 Day 8 | 7.28 (-0.394 to 16.991) | | | |
| Cycle 1 Day 15 | 1.75 (-9.999 to 12.312) | | | |
| Cycle 1 Day 22 | -1.63 (-10.213 to 6.436) | | | |
| Cycle 2 Day 1 | 2.93 (-12.484 to 12.025) | | | |
| Cycle 2 Day 15 | 10.39 (-1.170 to 22.944) | | | |
| Cycle 2 Day 28 | 9.91 (-3.321 to 30.339) | | | |
| Cycle 3 Day 1 | 12.99 (-6.114 to 23.810) | | | |
| Cycle 3 Day 15 | 20.09 (-7.627 to 34.934) | | | |
| Cycle 3 Day 28 | 17.34 (-9.783 to 26.905) | | | |
| Study Completion/Early Termination | -8.07 (-14.994 to 26.912) | | | |

Notes:

[14] - Pharmacodynamic samples were collected at timepoints through the study where possible.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in Measurements of NK Cell Populations

| | |
|---|--|
| End point title | Absolute Change From Baseline in Measurements of NK Cell Populations |
| End point description: | |
| Actual change from baseline will be summarized descriptively by visit for the pharmacodynamic parameter: NK cell populations | |
| End point type | Secondary |
| End point timeframe: | |
| Cycle 1 Day 1 (Baseline) to Cycle 1: Days 8, 15, and 22; Cycles 2 and 3: Days 1, 15, and 28 (each cycle is 28 days); End of Study (up to 7.5 years) | |

| | | | | |
|------------------------------------|----------------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 71 ^[15] | | | |
| Units: 10 ⁶ /L | | | | |
| median (confidence interval 95%) | | | | |
| Cycle 1 Day 8 | -2.20 (-21.000 to 15.000) | | | |
| Cycle 1 Day 15 | -23.00 (-43.000 to 11.000) | | | |
| Cycle 1 Day 22 | -18.00 (-38.000 to 7.550) | | | |
| Cycle 2 Day 1 | -16.32 (-33.000 to 9.890) | | | |
| Cycle 2 Day 15 | -19.00 (-32.000 to 16.800) | | | |
| Cycle 2 Day 28 | -1.00 (-18.000 to 51.000) | | | |
| Cycle 3 Day 1 | -23.00 (-66.000 to -3.000) | | | |
| Cycle 3 Day 15 | -33.00 (-70.000 to -2.000) | | | |
| Cycle 3 Day 28 | -15.00 (-32.000 to 11.000) | | | |
| Study Completion/Early Termination | -11.00 (-35.000 to 2.000) | | | |

Notes:

[15] - Pharmacodynamic samples were collected at timepoints through the study where possible.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Measurements of NK Cell Populations

| | |
|---|---|
| End point title | Percent Change From Baseline in Measurements of NK Cell Populations |
| End point description: Relative change from baseline will be summarized descriptively by visit for the pharmacodynamic parameter: NK cell populations | |
| End point type | Secondary |
| End point timeframe: Cycle 1 Day 1 (Baseline) to Cycle 1: Days 8, 15, and 22; Cycles 2 and 3: Days 1, 15, and 28 (each cycle is 28 days); End of Study (up to 7.5 years) | |

| | | | | |
|--|----------------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 71 ^[16] | | | |
| Units: percentage change from baseline | | | | |
| median (confidence interval 95%) | | | | |
| Cycle 1 Day 8 | -1.62 (-18.261 to 11.429) | | | |
| Cycle 1 Day 15 | -18.85 (-24.046 to 11.364) | | | |
| Cycle 1 Day 22 | -13.38 (-29.688 to 3.027) | | | |
| Cycle 2 Day 1 | -11.17 (-23.478 to 5.634) | | | |
| Cycle 2 Day 15 | -8.11 (-22.467 to 20.314) | | | |
| Cycle 2 Day 28 | -1.92 (-14.762 to 29.730) | | | |
| Cycle 3 Day 1 | -14.08 (-26.866 to -1.115) | | | |
| Cycle 3 Day 15 | -20.13 (-38.253 to -1.136) | | | |
| Cycle 3 Day 28 | -6.10 (-21.697 to 17.000) | | | |
| Study Completion/Early Termination | -11.01 (-28.906 to 6.667) | | | |

Notes:

[16] - Pharmacodynamic samples were collected at timepoints through the study where possible.

Statistical analyses

No statistical analyses for this end point

Secondary: Evaluation of AEs Stratified by FcγRIIa Polymorphism

| | |
|--|--|
| End point title | Evaluation of AEs Stratified by FcγRIIa Polymorphism |
| End point description: | |
| Incidence of AEs as stratified by FcγRIIa polymorphism subgroups | |
| End point type | Secondary |
| End point timeframe: | |
| From first dose until 30 days after last dose of MOR00208, up to 8.5 years | |

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 74 | | | |
| Units: adverse events | | | | |
| Genotype HH | 210 | | | |
| Genotype HR | 188 | | | |
| Genotype RR | 61 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Evaluation of AEs Stratified by FcγRIIIa Polymorphism

| | |
|-----------------|---|
| End point title | Evaluation of AEs Stratified by FcγRIIIa Polymorphism |
|-----------------|---|

End point description:

Incidence of AEs as stratified by FcγRIIIa polymorphism subgroups

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

End point timeframe:

From first dose until 30 days after last dose of MOR00208, up to 8.5 years

| End point values | MOR00208 | | | |
|-----------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 74 | | | |
| Units: adverse events | | | | |
| Genotype FF | 110 | | | |
| Genotype FV | 149 | | | |
| Genotype VV | 200 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Evaluation of ORR Stratified by FcγRIIa Polymorphism

| | |
|-----------------|--|
| End point title | Evaluation of ORR Stratified by FcγRIIa Polymorphism |
|-----------------|--|

End point description:

The analysis of the primary endpoint (ORR) will additionally be stratified by FcγRIIa polymorphism subgroups

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

End point timeframe:

From first dose until Follow-up Visit 12, up to 4.5 years

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: patients | | | | |
| Genotype HH | 6 | | | |
| Genotype HR | 8 | | | |
| Genotype RR | 3 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Evaluation of ORR Stratified by FcγRIIIa Polymorphism

| | |
|---|---|
| End point title | Evaluation of ORR Stratified by FcγRIIIa Polymorphism |
| End point description: The analysis of the primary endpoint (ORR) will additionally be stratified by FcγRIIIa polymorphism subgroups | |
| End point type | Secondary |
| End point timeframe: From first dose until Follow-up Visit 12, up to 4.5 years | |

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 34 | | | |
| Units: patients | | | | |
| Genotype FF | 10 | | | |
| Genotype FV | 5 | | | |
| Genotype VV | 2 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Area Under the Concentration Curve From Dose Time Zero to Infinity (AUC[0-inf]) of MOR00208

| | |
|---|---|
| End point title | PK Parameter: Area Under the Concentration Curve From Dose Time Zero to Infinity (AUC[0-inf]) of MOR00208 |
| End point description: Area under the concentration curve. The time curve from time zero (0) to infinity (inf), where infinity is computed from $AUC_{0-t} + [C_t/\lambda_Z]$. C_t is calculated from the concentration at the last sampling time at which the sample is above LLQ. | |
| End point type | Secondary |
| End point timeframe: Estimated from final dose (samples collected on the last day of Cycle 3 [C3D28; each cycle is 28 days long], and Follow-up Visits 1 [C3D28 + 4 weeks], 2 [C3D28 + 10 weeks], and 3 [C3D28 + 16 weeks]) | |

| | | | | |
|--------------------------------------|--------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 91 ^[17] | | | |
| Units: h*µg/mL | | | | |
| arithmetic mean (standard deviation) | 0 (± 0) | | | |

Notes:

[17] - The parameter could not be accurately estimated for the PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Total Body Clearance (CL) of MOR00208

| | |
|------------------------|--|
| End point title | PK Parameter: Total Body Clearance (CL) of MOR00208 |
| End point description: | Total body clearance calculated for single or multiple doses: dose(s)/AUC(0-inf) |
| End point type | Secondary |
| End point timeframe: | Estimated from final dose (samples collected on the last day of Cycle 3 [C3D28; each cycle is 28 days long], and Follow-up Visits 1 [C3D28 + 4 weeks], 2 [C3D28 + 10 weeks], and 3 [C3D28 + 16 weeks]) |

| | | | | |
|--------------------------------------|--------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 91 ^[18] | | | |
| Units: L/h | | | | |
| arithmetic mean (standard deviation) | 0 (± 0) | | | |

Notes:

[18] - The parameter could not be accurately estimated for the PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: PK Parameter: Apparent Volume of Distribution (Vz) of MOR00208

| | |
|------------------------|--|
| End point title | PK Parameter: Apparent Volume of Distribution (Vz) of MOR00208 |
| End point description: | Apparent volume of distribution during the terminal phase, calculated from dose/(AUC(0-inf)*λz) |
| End point type | Secondary |
| End point timeframe: | Estimated from final dose (samples collected on the last day of Cycle 3 [C3D28; each cycle is 28 days long], and Follow-up Visits 1 [C3D28 + 4 weeks], 2 [C3D28 + 10 weeks], and 3 [C3D28 + 16 weeks]) |

| | | | | |
|--------------------------------------|--------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 91 ^[19] | | | |
| Units: L | | | | |
| arithmetic mean (standard deviation) | 0 (\pm 0) | | | |

Notes:

[19] - The parameter could not be accurately estimated for the PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Evaluation of AEs Stratified by Baseline CD19 Expression on Malignant Lymphoma Cells

| | |
|------------------------|---|
| End point title | Evaluation of AEs Stratified by Baseline CD19 Expression on Malignant Lymphoma Cells |
| End point description: | Incidence of AEs as stratified by presence of CD19 on malignant lymphoma cells detected by tumor biopsy/aspirate during Screening |
| End point type | Secondary |
| End point timeframe: | From first dose until 30 days after last dose of MOR00208, up to 8.5 years |

| | | | | |
|-----------------------------|-------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0 ^[20] | | | |
| Units: adverse events | | | | |

Notes:

[20] - CD19 expression could not be measured in sufficient cases for such an analysis to be meaningful.

Statistical analyses

No statistical analyses for this end point

Secondary: Evaluation of ORR Stratified by Baseline CD19 Expression on Malignant Lymphoma Cells

| | |
|------------------------|---|
| End point title | Evaluation of ORR Stratified by Baseline CD19 Expression on Malignant Lymphoma Cells |
| End point description: | The analysis of the primary endpoint (ORR) will additionally be stratified by presence of CD19 on malignant lymphoma cells detected by tumor biopsy/aspirate during Screening |
| End point type | Secondary |
| End point timeframe: | From first dose until Follow-up Visit 12, up to 4.5 years |

| | | | | |
|-----------------------------|-------------------|--|--|--|
| End point values | MOR00208 | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0 ^[21] | | | |
| Units: patients | | | | |

Notes:

[21] - CD19 expression could not be measured in sufficient cases for such an analysis to be meaningful.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from informed consent until 30 days after last dose of MOR00208, up to 8.5 years

Adverse event reporting additional description:

AEs were detected when volunteered by the patient during or between study visits or through physical examination, laboratory tests, or other assessments. All SAEs are reported, including non-treatment-emergent events. For non-serious AEs, only treatment-emergent events are reported.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 24.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | MOR00208 |
|-----------------------|----------|

Reporting group description:

All patients who received at least one dose of study drug.

| Serious adverse events | MOR00208 | | |
|---|------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 30 / 92 (32.61%) | | |
| number of deaths (all causes) | 9 | | |
| number of deaths resulting from adverse events | 9 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bone cancer | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Fracture | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infusion related reaction | | | |

| | | | |
|--|------------------|--|--|
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Cardiac failure | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| General disorders and administration site conditions | | | |
| Disease progression | | | |
| subjects affected / exposed | 11 / 92 (11.96%) | | |
| occurrences causally related to treatment / all | 0 / 12 | | |
| deaths causally related to treatment / all | 0 / 8 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 2 / 92 (2.17%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Vision blurred | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Colitis | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Respiratory failure | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Hepatobiliary disorders | | | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Pneumonia | | | |
| subjects affected / exposed | 3 / 92 (3.26%) | | |
| occurrences causally related to treatment / all | 0 / 5 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Genital herpes zoster | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Herpes zoster | | | |
| subjects affected / exposed | 2 / 92 (2.17%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infected bite | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Device related infection | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumococcal infection | | | |
| subjects affected / exposed | 1 / 92 (1.09%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| | | | |
|---|------------------|--|--|
| Non-serious adverse events | MOR00208 | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 77 / 92 (83.70%) | | |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 12 / 92 (13.04%) | | |
| occurrences (all) | 15 | | |
| Nervous system disorders | | | |

| | | | |
|---|------------------------|--|--|
| Dizziness subjects affected / exposed occurrences (all) | 9 / 92 (9.78%) 11 | | |
| Headache subjects affected / exposed occurrences (all) | 10 / 92 (10.87%) 15 | | |
| Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all) | 6 / 92 (6.52%) 9 | | |
| Neutropenia subjects affected / exposed occurrences (all) | 9 / 92 (9.78%) 12 | | |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 5 / 92 (5.43%) 14 | | |
| General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all) | 7 / 92 (7.61%) 9 | | |
| Oedema peripheral subjects affected / exposed occurrences (all) | 8 / 92 (8.70%) 9 | | |
| Fatigue subjects affected / exposed occurrences (all) | 8 / 92 (8.70%) 12 | | |
| Pyrexia subjects affected / exposed occurrences (all) | 5 / 92 (5.43%) 8 | | |
| Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) | 8 / 92 (8.70%) 9 | | |
| Constipation subjects affected / exposed occurrences (all) | 6 / 92 (6.52%) 7 | | |

| | | | |
|--|---|--|--|
| Nausea subjects affected / exposed occurrences (all) | 9 / 92 (9.78%) 11 | | |
| Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) | 7 / 92 (7.61%) 9 8 / 92 (8.70%) 14 | | |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 7 / 92 (7.61%) 8 | | |
| Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) | 7 / 92 (7.61%) 7 | | |
| Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all) Bronchitis subjects affected / exposed occurrences (all) | 11 / 92 (11.96%) 14 6 / 92 (6.52%) 8 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|---|
| 07 January 2013 | 1. A clinical deficiency/information request from FDA dated 05 October 2012. 2. A clinical deficiency/information request from FDA dated 11 October 2012. 3. Minor inconsistencies identified and organizational changes made since release of the original protocol, none of which constitute a change in the conduct or scientific value of the study. |
| 02 October 2013 | 1. Organizational issues that came up during the initiation of the first study sites. 2. Minor inconsistencies identified and organizational changes made since the release of the original protocol, none of which constituted a change in the conduct or scientific value of the study. |
| 15 April 2014 | 1. New recommendations for the screening of hepatitis B for anti-CD20 antibodies were published. 2. Minor inconsistencies identified and organizational changes were made since the release of the previous amendment, none of which constitute a change in the conduct or scientific value of the study. |
| 19 September 2017 | 1. Change of address of sponsor and CRO. 2. Addition of optional prolongation of maintenance treatment for patients beyond Follow-up Visit 12 until progression. 3. Change of sponsor signatories and change of key personnel at sponsor and CRO. 4. Change of data collection as a result of this amendment. 5. Minor editorial changes for clarification of content and removal of inconsistencies. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported