



## Clinical trial results:

### A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Magrolimab versus Placebo in Combination with Venetoclax and Azacitidine in Newly Diagnosed, Previously Untreated Patients with Acute Myeloid Leukemia Who Are Ineligible for Intensive Chemotherapy

#### Summary

|                          |                                  |
|--------------------------|----------------------------------|
| EudraCT number           | 2021-003434-36                   |
| Trial protocol           | CZ DE HU BE FR AT PL NL IT ES NO |
| Global end of trial date | 11 April 2024                    |

#### Results information

|                                |  |
|--------------------------------|--|
| Result version number          | v2 (current)   |
| This version publication date  | 19 April 2025  |
| First version publication date | 19 March 2025  |
| Version creation reason        | <ul style="list-style-type: none"><li>New data added to full data set</li></ul> To update endpoint data as per NIH review. |

#### Trial information

##### Trial identification

|                       |                |
|-----------------------|----------------|
| Sponsor protocol code | GS-US-590-6154 |
|-----------------------|----------------|

##### Additional study identifiers

|                                    |  |
|------------------------------------|--|
| ISRCTN number                      | -  |
| ClinicalTrials.gov id (NCT number) | NCT05079230  |
| WHO universal trial number (UTN)   | -  |
| Other trial identifiers            | Israel Clinical Research Site: MOH_2022-08-15_011983 |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Gilead Sciences  |
| Sponsor organisation address | 333 Lakeside Drive, Foster City, CA, United States, 94404                                  |
| Public contact               | Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com |
| Scientific contact           | Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.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                       | 11 April 2024 |
| Is this the analysis of the primary completion data? | Yes           |
| Primary completion date                              | 11 April 2024 |
| Global end of trial reached?                         | Yes           |
| Global end of trial date                             | 11 April 2024 |
| Was the trial ended prematurely?                     | Yes           |

Notes:

## General information about the trial

Main objective of the trial:

The goal of this clinical study was to compare the study drugs, magrolimab + venetoclax + azacitidine, versus placebo + venetoclax + azacitidine in participants with untreated acute myeloid leukemia (AML) who were not able to have chemotherapy.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements. This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

|   |              |
|---|--------------|
| Actual start date of recruitment                          | 07 July 2022 |
| Long term follow-up planned                               | No           |
| Independent data monitoring committee (IDMC) involvement? | Yes          |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                   |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | United Kingdom: 6 |
| Country: Number of subjects enrolled | United States: 93 |
| Country: Number of subjects enrolled | Austria: 5        |
| Country: Number of subjects enrolled | Belgium: 17       |
| Country: Number of subjects enrolled | Czechia: 26       |
| Country: Number of subjects enrolled | France: 40        |
| Country: Number of subjects enrolled | Germany: 22       |
| Country: Number of subjects enrolled | Hungary: 4        |
| Country: Number of subjects enrolled | Italy: 10         |
| Country: Number of subjects enrolled | Netherlands: 21   |
| Country: Number of subjects enrolled | Norway: 4         |
| Country: Number of subjects enrolled | Poland: 6         |
| Country: Number of subjects enrolled | Spain: 52         |

|                                      |                        |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Switzerland: 2         |
| Country: Number of subjects enrolled | Hong Kong: 9           |
| Country: Number of subjects enrolled | Taiwan: 22             |
| Country: Number of subjects enrolled | Australia: 18          |
| Country: Number of subjects enrolled | Canada: 1              |
| Country: Number of subjects enrolled | Israel: 8              |
| Country: Number of subjects enrolled | Korea, Republic of: 12 |
| Worldwide total number of subjects   | 378                    |
| EEA total number of subjects         | 207                    |

Notes:

| <b>Subjects enrolled per age group</b>    |     |
|---|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 0   |
| Children (2-11 years)                     | 0   |
| Adolescents (12-17 years)                 | 0   |
| Adults (18-64 years)                      | 30  |
| From 65 to 84 years                       | 324 |
| 85 years and over                         | 24  |

## Subject disposition

### Recruitment

Recruitment details:

502 participants were screened.

### Pre-assignment

Screening details:

Participants were enrolled at study sites in Asia, Europe, North America and Australia.

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall Study (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Randomised - controlled        |
| Blinding used                | Double blind                   |
| Roles blinded                | Subject, Investigator          |

### Arms

|                              |                                       |
|------------------------------|---------------------------------------|
| Are arms mutually exclusive? | Yes                                   |
| <b>Arm title</b>             | Magrolimab + Venetoclax + Azacitidine |

Arm description:

Participants received magrolimab 1 mg/kg priming dose intravenously (IV) on Days 1 and 4; 15 mg/kg on Day 8; and 30 mg/kg on Days 11, 15, and then every week for 5 doses, and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3, and daily thereafter; azacitidine 75 mg/m<sup>2</sup> subcutaneously (SC) or IV on Days 1-7 or Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days.

|  |                        |
|--|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | Magrolimab             |
| Investigational medicinal product code |                        |
| Other name                             | GS-4721                |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Intravenous use        |

Dosage and administration details:

Administered intravenously (IV)

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Azacitidine                       |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Solution for injection            |
| Routes of administration               | Intravenous use, Subcutaneous use |

Dosage and administration details:

Administered according to region-specific drug labeling, either subcutaneously (SC) or intravenously (IV)

|  |                    |
|--|--------------------|
| Investigational medicinal product name | Venetoclax         |
| Investigational medicinal product code |                    |
| Other name                             | VENCLEXTA          |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

Tablets administered orally

|                  |  |
|------------------|--|
| <b>Arm title</b> | Magrolimab Matching Placebo + Venetoclax + Azacitidine |
|------------------|--|

Arm description:

Participants received magrolimab matching placebo IV on Days 1, 4, 8, 11, and 15, then every week for 5 doses and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3 and daily thereafter; azacitidine 75 mg/m<sup>2</sup> SC or IV on Days 1-7 or

Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days.

|  |                             |
|--|-----------------------------|
| Arm type                               | Experimental                |
| Investigational medicinal product name | Magrolimab Matching Placebo |
| Investigational medicinal product code |                             |
| Other name                             |                             |
| Pharmaceutical forms                   | Solution for injection      |
| Routes of administration               | Intravenous use             |

Dosage and administration details:

Administered intravenously (IV)

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Azacitidine                       |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Solution for injection            |
| Routes of administration               | Intravenous use, Subcutaneous use |

Dosage and administration details:

Administered according to region-specific drug labeling, either subcutaneously (SC) or intravenously (IV)

|  |                    |
|--|--------------------|
| Investigational medicinal product name | Venetoclax         |
| Investigational medicinal product code |                    |
| Other name                             | VENCLEXTA          |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

Tablets administered orally

| Number of subjects in period 1 | Magrolimab +<br>Venetoclax +<br>Azacitidine | Magrolimab<br>Matching Placebo +<br>Venetoclax +<br>Azacitidine |
|--------------------------------|---|---|
|                                |   |   |
| Started                        | 189   | 189   |
| Completed                      | 0   | 0   |
| Not completed                  | 189   | 189   |
| Death                          | 72  | 66  |
| Study Terminated by Sponsor    | 101   | 102   |
| Withdrew consent               | 16  | 18  |
| Lost to follow-up              | -   | 3   |

## Baseline characteristics

### Reporting groups

|  |  |
|--|--|
| Reporting group title  | Magrolimab + Venetoclax + Azacitidine                  |
| Reporting group description:   |  |
| Participants received magrolimab 1 mg/kg priming dose intravenously (IV) on Days 1 and 4; 15 mg/kg on Day 8; and 30 mg/kg on Days 11, 15, and then every week for 5 doses, and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3, and daily thereafter; azacitidine 75 mg/m <sup>2</sup> subcutaneously (SC) or IV on Days 1-7 or Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days. |  |
| Reporting group title  | Magrolimab Matching Placebo + Venetoclax + Azacitidine |
| Reporting group description:   |  |
| Participants received magrolimab matching placebo IV on Days 1, 4, 8, 11, and 15, then every week for 5 doses and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3 and daily thereafter; azacitidine 75 mg/m <sup>2</sup> SC or IV on Days 1-7 or Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days.  |  |

| Reporting group values      | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine | Total |
|-----------------------------|---------------------------------------|--|-------|
| Number of subjects          | 189                                   | 189  | 378   |
| Age categorical             |                                       |  |       |
| Units: Subjects             |                                       |  |       |
| < 75 Years                  | 93                                    | 91   | 184   |
| >= 75 Years                 | 96                                    | 98   | 194   |
| Age continuous              |                                       |  |       |
| Units: years                |                                       |  |       |
| arithmetic mean             | 74                                    | 74   |       |
| standard deviation          | ± 7.0                                 | ± 8.0  | -     |
| Gender categorical          |                                       |  |       |
| Units: Subjects             |                                       |  |       |
| Female                      | 73                                    | 83   | 156   |
| Male                        | 116                                   | 106  | 222   |
| Race                        |                                       |  |       |
| Units: Subjects             |                                       |  |       |
| White                       | 130                                   | 130  | 260   |
| Not Collected               | 26                                    | 30   | 56    |
| Asian                       | 26                                    | 25   | 51    |
| Other or More Than One Race | 4                                     | 2  | 6     |
| Black or African American   | 3                                     | 2  | 5     |
| Ethnicity (NIH/OMB)         |                                       |  |       |
| Units: Subjects             |                                       |  |       |
| Hispanic or Latino          | 18                                    | 12   | 30    |
| Not Hispanic or Latino      | 149                                   | 149  | 298   |
| Unknown or Not Reported     | 22                                    | 28   | 50    |

## End points

### End points reporting groups

|  |  |
|--|--|
| Reporting group title  | Magrolimab + Venetoclax + Azacitidine                  |
| Reporting group description:<br>Participants received magrolimab 1 mg/kg priming dose intravenously (IV) on Days 1 and 4; 15 mg/kg on Day 8; and 30 mg/kg on Days 11, 15, and then every week for 5 doses, and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3, and daily thereafter; azacitidine 75 mg/m <sup>2</sup> subcutaneously (SC) or IV on Days 1-7 or Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days. |  |
| Reporting group title  | Magrolimab Matching Placebo + Venetoclax + Azacitidine |
| Reporting group description:<br>Participants received magrolimab matching placebo IV on Days 1, 4, 8, 11, and 15, then every week for 5 doses and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3 and daily thereafter; azacitidine 75 mg/m <sup>2</sup> SC or IV on Days 1-7 or Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days.  |  |

### Primary: Overall Survival (OS)

|   |                       |
|---|-----------------------|
| End point title   | Overall Survival (OS) |
| End point description:<br>OS was measured from the date of randomization to the date of death from any cause. Participants were censored at last known alive date. Kaplan-Meier (KM) estimates were used in outcome measure analysis. Analysis Population Description: Participants in the Intent-to-Treat Analysis Set were analyzed. The Intent-to-Treat Analysis Set included all randomized participants according to the treatment arm to which the participants were randomized, unless otherwise specified. 9999: Upper limit of confidence interval (CI) was not estimable due to low number of participants with events. |                       |
| End point type  | Primary               |
| End point timeframe:<br>Up to 1.6 years   |                       |

| End point values                 | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|----------------------------------|---------------------------------------|--|--|--|
| Subject group type               | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed      | 189                                   | 189  |  |  |
| Units: months                    |                                       |  |  |  |
| median (confidence interval 95%) | 10.7 (8.7 to 14.9)                    | 14.1 (9.7 to 9999)                                     |  |  |

### Statistical analyses

|                            |  |
|----------------------------|--|
| Statistical analysis title | Experimental Group vs Control Group  |
| Comparison groups          | Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine |

|   |                          |
|---|--------------------------|
| Number of subjects included in analysis | 378                      |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | = 0.3276 <sup>[1]</sup>  |
| Method                                  | stratified log-rank test |
| Parameter estimate                      | Hazard ratio (HR)        |
| Point estimate                          | 1.178                    |
| Confidence interval                     |                          |
| level                                   | 95 %                     |
| sides                                   | 2-sided                  |
| lower limit                             | 0.848                    |
| upper limit                             | 1.637                    |

Notes:

[1] - The 2-sided P-value was based on stratified log-rank test, stratified by stratification factors at randomization. Stratified hazard ratio (HR) and its 95% CI were calculated using the stratified cox proportional hazards model.

## Secondary: Rate of Complete Remission (CR) + Complete Remission With Partial Hematologic Recovery (CRh)

|                 |  |
|-----------------|--|
| End point title | Rate of Complete Remission (CR) + Complete Remission With Partial Hematologic Recovery (CRh) |
|-----------------|--|

End point description:

The CR + CRh rate was defined as the percentage of participants who achieved a CR (including CR without minimal residual disease (CRM RD-) and CR with positive or unknown MRD (CRM RD+/unk)) or CRh as defined by CR with partial platelet and absolute neutrophil count recovery within 6 cycles of treatment while on study prior to initiation of any new anti-acute myeloid leukemia (AML) therapy or stem cell transplant (SCT). CRM RD- and CRM RD+/unk: neutrophils  $>1.0 \times 10^9/L$ , platelets  $>100 \times 10^9/L$ ,  $<5\%$  bone marrow blasts, no circulating blasts or extramedullary disease (confirmed by flow cytometry  $<0.1\%$  sensitivity for CRM RD-) within the response assessment window of 1.6 years. Percentages were rounded-off. Clopper-Pearson method were used in outcome measure analysis. Each cycle was of 28 days. Analysis Population Description: Participants in the Intent-to-Treat analysis set were analyzed.

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

End point timeframe:

Up to 1.6 years

| End point values                  | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type                | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed       | 189                                   | 189  |  |  |
| Units: percentage of participants |                                       |  |  |  |
| number (confidence interval 95%)  | 47.6 (40.3 to 55.0)                   | 53.4 (46.1 to 60.7)                                    |  |  |

## Statistical analyses

|                            |  |
|----------------------------|--|
| Statistical analysis title | Experimental Group vs Control Group  |
| Comparison groups          | Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine |



|   |                                  |
|---|----------------------------------|
| Number of subjects included in analysis | 378                              |
| Analysis specification                  | Pre-specified                    |
| Analysis type                           | superiority                      |
| P-value                                 | = 0.3616 <sup>[2]</sup>          |
| Method                                  | Stratum-adjusted Mantel-Haenszel |
| Parameter estimate                      | Stratified Odds Ratio            |
| Point estimate                          | 0.826                            |
| Confidence interval                     |                                  |
| level                                   | 95 %                             |
| sides                                   | 2-sided                          |
| lower limit                             | 0.545                            |
| upper limit                             | 1.251                            |

Notes:

[2] - Stratified odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for stratification factors.

## Secondary: Rate of Complete Remission (CR)

|                 |                                 |
|-----------------|---------------------------------|
| End point title | Rate of Complete Remission (CR) |
|-----------------|---------------------------------|

End point description:

CR was defined as the percentage of the participants who achieved CR (including CRMRD- and CRMRD+/unk) within 6 cycles of treatment as determined by the investigator while on study prior to initiation of any new anti-acute myeloid leukemia (AML) therapy or stem cell transplant (SCT) within the response assessment window of 1.6 years. Definitions for CRMRD- and CRMRD+/unk were mentioned in outcome measure #2. Percentages were rounded-off. Clopper-Pearson method were used in outcome measure analysis. Each cycle was of 28 days. Analysis Population Description: Participants in the Intent-To-Treat Analysis Set were analyzed.

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

End point timeframe:

Up to 1.6 years

| End point values                  | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type                | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed       | 189                                   | 189  |  |  |
| Units: percentage of participants |                                       |  |  |  |
| number (confidence interval 95%)  | 41.3 (34.2 to 48.6)                   | 46.0 (38.8 to 53.4)                                    |  |  |

## Statistical analyses

|                            |  |
|----------------------------|--|
| Statistical analysis title | Experimental Group vs Control Group  |
| Comparison groups          | Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine |

|   |                                  |
|---|----------------------------------|
| Number of subjects included in analysis | 378                              |
| Analysis specification                  | Pre-specified                    |
| Analysis type                           | superiority                      |
| P-value                                 | = 0.4679 <sup>[3]</sup>          |
| Method                                  | Stratum-adjusted Mantel-Haenszel |
| Parameter estimate                      | Stratified Odds Ratio            |
| Point estimate                          | 0.856                            |
| Confidence interval                     |                                  |
| level                                   | 95 %                             |
| sides                                   | 2-sided                          |
| lower limit                             | 0.56                             |
| upper limit                             | 1.307                            |

Notes:

[3] - Stratified odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for stratification factors.

## Secondary: Event-Free Survival (EFS)

|   |                           |
|---|---------------------------|
| End point title   | Event-Free Survival (EFS) |
| End point description:  |                           |
| EFS was defined as time from the date of randomization to the earliest date of the documented relapse from CR, treatment failure (defined as failure to achieve CR within 6 cycles of treatment), or death from any cause within the response window. CR is defined in outcome measure #2. KM estimates were used in outcome measure analysis. Analysis Population Description: Participants in the Intent-To-Treat Analysis Set were analyzed. |                           |
| End point type  | Secondary                 |
| End point timeframe:  |                           |
| Up to 1.6 years   |                           |

| End point values                 | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|----------------------------------|---------------------------------------|--|--|--|
| Subject group type               | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed      | 189                                   | 189  |  |  |
| Units: months                    |                                       |  |  |  |
| median (confidence interval 95%) | 0.0 (0.0 to 5.4)                      | 1.7 (0.0 to 4.5)                                       |  |  |

## Statistical analyses

|                            |  |
|----------------------------|--|
| Statistical analysis title | Experimental Group vs Control Group  |
| Comparison groups          | Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine |

|   |                         |
|---|-------------------------|
| Number of subjects included in analysis | 378                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           | superiority             |
| P-value                                 | = 0.7903 <sup>[4]</sup> |
| Method                                  | Stratified Log Rank     |
| Parameter estimate                      | Stratified Hazard Ratio |
| Point estimate                          | 0.946                   |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 0.73                    |
| upper limit                             | 1.225                   |

Notes:

[4] - The 2-sided P-value was based on stratified log-rank test, stratified by stratification factors at randomization.

### Secondary: Duration of CR + CRh in Participants who achieved Complete Remission (CR) or Complete Remission With Partial Hematologic Recovery (CRh)

|                 |   |
|-----------------|---|
| End point title | Duration of CR + CRh in Participants who achieved Complete Remission (CR) or Complete Remission With Partial Hematologic Recovery (CRh) |
|-----------------|---|

End point description:

The duration of CR + CRh was measured from the time the assessment criteria were first met for CR (including CRMRD- and CRMRD+/unk) or CRh within 6 cycles of treatment until the first date of AML relapse or death (including assessments post SCT). Those who were not observed to have relapsed disease or death while on study were censored at the date of their last response assessment with no evidence of relapse on or prior to the data cut off date within the response assessment window of 1.6 years. Participants started taking new anti-AML therapies (excluding post-SCT maintenance therapy) before relapse, duration of CR + CRh were censored at the last response assessment before the initiation of the new anti-AML therapies. CR and CRh are defined in Outcome Measure #2. Each cycle was of 28 days. Participants in the Intent-To-Treat Analysis Set who achieved CR + CRh within 6 cycles were analyzed. 9999: Upper limit of CI was not estimable due to low number of participants with events.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Up to 1.6 years      |           |

| End point values                 | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|----------------------------------|---------------------------------------|--|--|--|
| Subject group type               | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed      | 90                                    | 101  |  |  |
| Units: months                    |                                       |  |  |  |
| median (confidence interval 95%) | 9.4 (5.9 to 9999)                     | 9.2 (5.8 to 9999)                                      |  |  |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Duration of Complete Remission (DCR) in Participants who achieved Complete Remission (CR)

|  |   |
|--|---|
| End point title  | Duration of Complete Remission (DCR) in Participants who achieved Complete Remission (CR) |
| End point description:<br>The DCR measured from the time the assessment criteria were first met for CR (including CRMRD- and CRMRD+/unk) within 6 cycles of treatment until the first date of AML relapse or death (including assessments post SCT). Those who were not observed to have relapsed disease or death while on study were censored at the date of their last response assessment with no evidence of relapse on or prior to the data cutoff date within the response assessment window of 1.6 years. Participants started taking new anti-AML therapies (excluding post-SCT maintenance therapy) before relapse, DCR were censored at the last response assessment before the initiation of the new anti-AML therapies. KM estimates were used in outcome measure analysis. CRMRD- and CRMRD+/unk are defined in outcome measure #2. Each cycle was of 28 days. Participants in the ITT Analysis Set who achieved CR within 6 cycle were analyzed. 9999: Upper limit of CI was not estimable due to low number of participants with events. |   |
| End point type   | Secondary   |
| End point timeframe:<br>Up to 1.6 years  |   |

| End point values                 | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|----------------------------------|---------------------------------------|--|--|--|
| Subject group type               | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed      | 78                                    | 87   |  |  |
| Units: months                    |                                       |  |  |  |
| median (confidence interval 95%) | 9.4 (6.3 to 9999)                     | 8.1 (5.7 to 9999)                                      |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Rate of CR/CRh Without Minimal Residual Disease (CR/CRhMRD-)

|   |  |
|---|--|
| End point title   | Rate of CR/CRh Without Minimal Residual Disease (CR/CRhMRD-) |
| End point description:<br>The CR/CRhMRD- rate was the percentage of participants who achieved a CRMRD- or CRhMRD- within 6 cycles of treatment while on study prior to initiation of any new anti-AML therapy or SCT within the response assessment window of 1.6 years. Each cycle was of 28 days. KM estimates were used for outcome measure analysis. CRhMRD- : neutrophils > $0.5 \times 10^9/L$ ; platelets > $50 \times 10^9/L$ ; bone marrow blasts < 5%; MRD negative (determined using multiparameter flow cytometry with a sensitivity of < 0.1%). Absence of circulating blasts and blasts with Auer rods; absence of extramedullary disease. CRMRD is defined in outcome measure #2. Percentages were rounded off. Analysis Population Description: Participants in the Intent-To-Treat Analysis Set were analyzed. |  |
| End point type  | Secondary  |
| End point timeframe:<br>Up to 1.6 years   |  |

| End point values                  | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type                | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed       | 189                                   | 189  |  |  |
| Units: percentage of participants |                                       |  |  |  |
| number (confidence interval 95%)  | 24.3 (18.4 to 31.1)                   | 22.2 (16.5 to 28.8)                                    |  |  |

## Statistical analyses

| Statistical analysis title              | Experimental Group vs Control Group  |
|---|--|
| Comparison groups                       | Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine |
| Number of subjects included in analysis | 378  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.4873 <sup>[5]</sup>  |
| Method                                  | Stratum-adjusted Mantel Haenszel   |
| Parameter estimate                      | Stratified Odds Ratio  |
| Point estimate                          | 1.189  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.727  |
| upper limit                             | 1.945  |

Notes:

[5] - Stratified odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for stratification factors.

## Secondary: Rate of CR Without Minimal Residual Disease (CRM RD-)

| End point title        | Rate of CR Without Minimal Residual Disease (CRM RD-)   |
|------------------------|---|
| End point description: | The CRM RD- rate was the percentage of participants who achieved a CRM RD- within 6 cycles of treatment SCT within the response assessment window of 1.6 years. Percentages were rounded-off. Clopper-Pearson method were used in outcome measure analysis. CRM RD- is defined in outcome measure #2. Each cycle was of 28 days. Analysis Population Description: Participants in the Intent-To-Treat Analysis Set were analyzed. |
| End point type         | Secondary   |
| End point timeframe:   | Up to 1.6 years   |

| End point values                  | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type                | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed       | 189                                   | 189  |  |  |
| Units: percentage of participants |                                       |  |  |  |
| number (confidence interval 95%)  | 21.7 (16.0 to 28.3)                   | 20.1 (14.6 to 26.5)                                    |  |  |

## Statistical analyses

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Experimental Group vs Control Group  |
| Comparison groups                       | Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine |
| Number of subjects included in analysis | 378  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.5842 <sup>[6]</sup>  |
| Method                                  | Stratum-adjusted Mantel Haenszel   |
| Parameter estimate                      | Stratified Odds Ratio  |
| Point estimate                          | 1.154  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.69   |
| upper limit                             | 1.932  |

Notes:

[6] - Stratified odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for stratification factors.

## Secondary: Red blood cell (RBC) Transfusion Independence Conversion Rate

|   |   |
|---|---|
| End point title   | Red blood cell (RBC) Transfusion Independence Conversion Rate |
| End point description:  |   |
| The RBC transfusion independence conversion rate was the percentage of participants who had a 56-day or longer period with no RBC or whole blood transfusions at any time between the date of the first dose of study treatment and discontinuation of study treatment among all participants who were RBC transfusion dependent at baseline. Percentages were rounded-off. Clopper-Pearson method were used in outcome measure analysis. |   |
| End point type  | Secondary   |
| End point timeframe:  |   |
| Up to 1.6 years   |   |

| End point values                  | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type                | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed       | 151                                   | 151  |  |  |
| Units: percentage of participants |                                       |  |  |  |
| number (confidence interval 95%)  | 51.7 (43.4 to 59.9)                   | 58.3 (50.0 to 66.2)                                    |  |  |

## Statistical analyses

| Statistical analysis title              | Experimental Group vs Control Group  |
|---|--|
| Comparison groups                       | Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine |
| Number of subjects included in analysis | 302  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.3003 <sup>[7]</sup>  |
| Method                                  | Cochran-Mantel-Haenszel  |
| Parameter estimate                      | Stratified Odds Ratio  |
| Point estimate                          | 0.783  |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.492  |
| upper limit                             | 1.245  |

Notes:

[7] - The 2-sided P-value was based on Cochran-Mantel-Haenszel (CMH) method stratified by the stratification factors at randomization (age, genetic risk group, and geographic region).

## Secondary: Time to First Deterioration (TTD) on the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) Global Health Status/Quality of Life (GHS/QoL) Scale

|                 |  |
|-----------------|--|
| End point title | Time to First Deterioration (TTD) on the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) Global Health Status/Quality of Life (GHS/QoL) Scale |
|-----------------|--|

End point description:

The TTD on the EORTC QLQ-C30 GHS/QoL scale was defined as time from the date of randomization to the time a participant experienced at least 1 threshold value deterioration from baseline or death, whichever was earlier. Questionnaire includes 30 questions resulting in 5 functional scales (physical functioning, role functioning, emotional functioning, cognitive functioning, social functioning), 1 GHS/QoL scale, 3 symptom scales (fatigue, nausea and vomiting, pain), and 6 single items (dyspnea, insomnia, loss of appetite, constipation, diarrhea, financial difficulties). After linear transformation, all scales and single item measures range in score from 0-100. Higher score on GHS/QoL scale meant better GHS/QoL. KM estimates were used in outcome measure analysis. Participants in the Intent-To-Treat Analysis Set were analyzed.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Up to 1.6 years      |           |

| <b>End point values</b>          | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|----------------------------------|---------------------------------------|--|--|--|
| Subject group type               | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed      | 189                                   | 189  |  |  |
| Units: months                    |                                       |  |  |  |
| median (confidence interval 95%) | 4.7 (2.3 to 6.3)                      | 5.1 (2.8 to 6.9)                                       |  |  |

## Statistical analyses

| <b>Statistical analysis title</b>       | Experimental Group vs Control Group  |
|---|--|
| Comparison groups                       | Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine |
| Number of subjects included in analysis | 378  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.5796 <sup>[8]</sup>  |
| Method                                  | Stratified Log Rank  |
| Parameter estimate                      | Stratified Hazard Ratio  |
| Point estimate                          | 1.09   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.799  |
| upper limit                             | 1.487  |

Notes:

[8] - The 2-sided P-value was based on stratified log-rank test, stratified by stratification factors at randomization.

## Secondary: Platelet Transfusion Independence Conversion Rate

| <b>End point title</b>  | Platelet Transfusion Independence Conversion Rate |
|---|---|
| End point description:  |   |
| <p>The platelet transfusion independence conversion rate was the percentage of participants who had a 56-day or longer period with no platelet transfusions at any time between the date of the first dose of study treatment and discontinuation of study treatment among all participants who were platelet transfusion dependent at baseline. Percentages were rounded-off. Clopper-Pearson method were used in outcome measure analysis.</p> <p>Analysis Population Description: Participants in the Intent-To-Treat Analysis Set with Platelet transfusion dependence at Baseline were analyzed.</p> |   |
| <b>End point type</b>   | Secondary   |
| End point timeframe:  |   |
| Up to 1.6 years   |   |



| End point values                  | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type                | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed       | 74                                    | 74   |  |  |
| Units: percentage of participants |                                       |  |  |  |
| number (confidence interval 95%)  | 48.6 (36.9 to 60.6)                   | 47.3 (35.6 to 59.3)                                    |  |  |

## Statistical analyses

| Statistical analysis title              | Experimental Group vs Control Group  |
|---|--|
| Comparison groups                       | Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine |
| Number of subjects included in analysis | 148  |
| Analysis specification                  | Pre-specified  |
| Analysis type                           | superiority  |
| P-value                                 | = 0.579 <sup>[9]</sup>   |
| Method                                  | Cochran-Mantel-Haenszel  |
| Parameter estimate                      | Stratified Odds Ratio  |
| Point estimate                          | 1.21   |
| Confidence interval                     |  |
| level                                   | 95 %   |
| sides                                   | 2-sided  |
| lower limit                             | 0.62   |
| upper limit                             | 2.36   |

Notes:

[9] - The 2-sided P-value was based on Cochran-Mantel-Haenszel (CMH) method stratified by the stratification factors at randomization (age, genetic risk group, and geographic region).

## Secondary: Time to First Deterioration (TTD) on the EORTC QLQ-C30 Physical Functioning Scale

|                        |  |
|------------------------|--|
| End point title        | Time to First Deterioration (TTD) on the EORTC QLQ-C30 Physical Functioning Scale  |
| End point description: | The TTD on the EORTC QLQ-C30 physical functioning scale was defined as time from the date of randomization to the time a participant experienced at least 1 threshold value deterioration from baseline or death, whichever is earlier. Physical functioning scale is one of the five functional scales of the EORTC QLQ C30 questionnaire. After linear transformation, scale range in score from 0-100. A higher score on functional scales means better functioning and better quality of life. KM estimates were used in outcome measure analysis. Participants in the Intent-To-Treat Analysis Set were analyzed. |
| End point type         | Secondary  |
| End point timeframe:   | Up to 1.6 years  |

| End point values                 | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|----------------------------------|---------------------------------------|--|--|--|
| Subject group type               | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed      | 189                                   | 189  |  |  |
| Units: months                    |                                       |  |  |  |
| number (confidence interval 95%) | 3.0 (2.1 to 4.4)                      | 3.9 (2.8 to 6.9)                                       |  |  |

## Statistical analyses

| Statistical analysis title   | Time to First Deterioration (TTD) on the EORTC QLQ   |
|--|--|
| Statistical analysis description:<br>-C30 Physical Functioning Scale |  |
| Comparison groups  | Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine |
| Number of subjects included in analysis                              | 378  |
| Analysis specification   | Pre-specified  |
| Analysis type  | superiority  |
| P-value  | = 0.1026 <sup>[10]</sup>   |
| Method   | Stratified Log Rank  |
| Parameter estimate   | Stratified Hazard Ratio  |
| Point estimate   | 1.271  |
| Confidence interval  |  |
| level  | 95 %   |
| sides  | 2-sided  |
| lower limit  | 0.948  |
| upper limit  | 1.704  |

Notes:

[10] - PLACEHOLDER20

## Secondary: Percentage of Participants Experiencing Treatment-Emergent Adverse Events (TEAEs)

| End point title  | Percentage of Participants Experiencing Treatment-Emergent Adverse Events (TEAEs) |
|--|---|
| End point description:<br>An AE was defined as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of an investigational product or other protocol-imposed intervention, regardless of attribution. TEAEs were defined as any AEs with an onset date on or after the study drug start date and no later than 70 days after the study drug last dose date or the day before initiation of new anti-AML therapy including stem cell transplantation, whichever is earlier. Percentages were rounded-off. Analysis Population Description: The Safety Analysis Set included all participants who received at least 1 dose of any study treatment, with treatment assignments designated according to the actual treatment received. |   |
| End point type   | Secondary   |
| End point timeframe:<br>First dose date up to 1.4 years plus 70 days   |   |

| End point values                  | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type                | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed       | 189                                   | 184  |  |  |
| Units: percentage of participants |                                       |  |  |  |
| number (not applicable)           | 99.5                                  | 100  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Experiencing Grade 3 or Higher Treatment-Emergent Laboratory Abnormalities

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Experiencing Grade 3 or Higher Treatment-Emergent Laboratory Abnormalities |
|-----------------|---|

End point description:

Treatment-emergent laboratory abnormalities were defined as values that increased by at least 1 toxicity grade from baseline at any postbaseline time point, up to and including the date of the last dose of study drug plus 70 days or the day before the initiation of new anti-AML therapy including SCT, whichever came first, and were summarized by treatment group. Severity grades were defined by the CTCAE Version 5.0. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Percentages were rounded-off. Participants in the Safety Analysis Set were analyzed.

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

End point timeframe:

First dose date up to 1.4 years, plus 70 days

| End point values                  | Magrolimab + Venetoclax + Azacitidine | Magrolimab Matching Placebo + Venetoclax + Azacitidine |  |  |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type                | Reporting group                       | Reporting group  |  |  |
| Number of subjects analysed       | 189                                   | 184  |  |  |
| Units: percentage of participants |                                       |  |  |  |
| number (not applicable)           | 99.5                                  | 100  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Serum Concentration of Magrolimab over time

|                 |   |
|-----------------|---|
| End point title | Serum Concentration of Magrolimab over time <sup>[11]</sup> |
|-----------------|---|

End point description:

The Pharmacokinetic (PK) Analysis Set included all randomized participants who took at least one dose of magrolimab and have at least 1 measurable (non - below the limit of quantitation (BLQ) numeric

values) post-treatment serum concentration of magrolimab with data available for analysis.

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

End point timeframe:

Predose on Day 1, Day 8, Day 15, Day 29; Predose on Day 57 and 1 hour post-dose; Predose on Day 113, Day 169, Day 253, and Day 337.

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical comparison was planned or performed.

| End point values                     | Magrolimab + Venetoclax + Azacitidine |  |  |  |
|--------------------------------------|---------------------------------------|--|--|--|
| Subject group type                   | Reporting group                       |  |  |  |
| Number of subjects analysed          | 156                                   |  |  |  |
| Units: µg/mL                         |                                       |  |  |  |
| arithmetic mean (standard deviation) |                                       |  |  |  |
| D 1 Predose N=156                    | 0 (± 0)                               |  |  |  |
| D 8 Predose N=135                    | 0 (± 0)                               |  |  |  |
| D 15 Predose N=143                   | 291 (± 123)                           |  |  |  |
| D 29 Predose N=129                   | 385 (± 206)                           |  |  |  |
| D 57 Predose N=111                   | 503 (± 230)                           |  |  |  |
| D 57, 1 h Postdose N=103             | 1060 (± 289)                          |  |  |  |
| D 113 Predose N=91                   | 281 (± 140)                           |  |  |  |
| D 169 Predose N=62                   | 274 (± 120)                           |  |  |  |
| D 253 Predose N=28                   | 322 (± 151)                           |  |  |  |
| D 337 Predose N=16                   | 298 (± 72.9)                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants With Anti-Magrolimab Antibodies

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants With Anti-Magrolimab Antibodies <sup>[12]</sup> |
|-----------------|--|

End point description:

Percentages were rounded-off. Analysis Population Description: The participants in the Immunogenicity Analysis Set with available data were analyzed. The Immunogenicity Analysis Set included all randomized participants who received at least one dose of magrolimab and had at least one evaluable anti-magrolimab antibody test result.

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

End point timeframe:

Up to 1.6 years

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical comparison was planned or performed.

|                                   |   |  |  |  |
|-----------------------------------|---|--|--|--|
| <b>End point values</b>           | Magrolimab +<br>Venetoclax +<br>Azacitidine |  |  |  |
| Subject group type                | Reporting group                             |  |  |  |
| Number of subjects analysed       | 166   |  |  |  |
| Units: percentage of participants |   |  |  |  |
| number (not applicable)           |   |  |  |  |
| ADA Incidence                     | 2.4   |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Maximum Levels of Serum Anti-Magrolimab Antibodies

|                 |  |
|-----------------|--|
| End point title | Maximum Levels of Serum Anti-Magrolimab Antibodies <sup>[13]</sup> |
|-----------------|--|

End point description:

Analysis Population Description: Data is reported for participants in the Immunogenicity Analysis Set with quantifiable measurement for ADA for magrolimab.

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

End point timeframe:

Up to 1.6 years

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical comparison was planned or performed.

|                                      |   |  |  |  |
|--------------------------------------|---|--|--|--|
| <b>End point values</b>              | Magrolimab +<br>Venetoclax +<br>Azacitidine |  |  |  |
| Subject group type                   | Reporting group                             |  |  |  |
| Number of subjects analysed          | 4   |  |  |  |
| Units: Titer                         |   |  |  |  |
| arithmetic mean (standard deviation) | 40 (± 67.33)                                |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: Up to 1.6 years; Adverse events: 1.4 years plus 70 days

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

### Dictionary used

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

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

### Reporting groups

|                       |                                       |
|-----------------------|---------------------------------------|
| Reporting group title | Magrolimab + Venetoclax + Azacitidine |
|-----------------------|---------------------------------------|

Reporting group description:

Patients who received Magrolimab + Venetoclax + Azacitidine

|                       |  |
|-----------------------|--|
| Reporting group title | Magrolimab Matching Placebo + Venetoclax + Azacitidine |
|-----------------------|--|

Reporting group description:

Patients who received magrolimab matching placebo + venetoclax + azacitidine

| <b>Serious adverse events</b>                     | Magrolimab +<br>Venetoclax +<br>Azacitidine | Magrolimab<br>Matching Placebo +<br>Venetoclax +<br>Azacitidine |  |
|---|---|---|--|
| Total subjects affected by serious adverse events |   |   |  |
| subjects affected / exposed                       | 138 / 189 (73.02%)                          | 134 / 184 (72.83%)  |  |
| number of deaths (all causes)                     | 84  | 70  |  |
| number of deaths resulting from adverse events    | 0   | 0   |  |
| Vascular disorders                                |   |   |  |
| Hypotension                                       |   |   |  |
| subjects affected / exposed                       | 1 / 189 (0.53%)                             | 2 / 184 (1.09%)   |  |
| occurrences causally related to treatment / all   | 0 / 1                                       | 1 / 4   |  |
| deaths causally related to treatment / all        | 0 / 0                                       | 0 / 0   |  |
| Embolism venous                                   |   |   |  |
| subjects affected / exposed                       | 0 / 189 (0.00%)                             | 1 / 184 (0.54%)   |  |
| occurrences causally related to treatment / all   | 0 / 0                                       | 0 / 1   |  |
| deaths causally related to treatment / all        | 0 / 0                                       | 0 / 0   |  |
| Orthostatic hypotension                           |   |   |  |
| subjects affected / exposed                       | 1 / 189 (0.53%)                             | 1 / 184 (0.54%)   |  |
| occurrences causally related to treatment / all   | 1 / 1                                       | 1 / 1   |  |
| deaths causally related to treatment / all        | 0 / 0                                       | 0 / 0   |  |
| Aortitis  |   |   |  |

|  |                 |                 |  |
|--|-----------------|-----------------|--|
| subjects affected / exposed                          | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0           |  |
| Superficial vein thrombosis                          |                 |                 |  |
| subjects affected / exposed                          | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all      | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0           |  |
| Haematoma  |                 |                 |  |
| subjects affected / exposed                          | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0           |  |
| Haemorrhage  |                 |                 |  |
| subjects affected / exposed                          | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0           |  |
| General disorders and administration site conditions |                 |                 |  |
| Malaise  |                 |                 |  |
| subjects affected / exposed                          | 2 / 189 (1.06%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all      | 1 / 2           | 1 / 1           |  |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0           |  |
| Fatigue  |                 |                 |  |
| subjects affected / exposed                          | 2 / 189 (1.06%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all      | 2 / 2           | 0 / 1           |  |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0           |  |
| General physical health ~ deterioration              |                 |                 |  |
| subjects affected / exposed                          | 2 / 189 (1.06%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all      | 2 / 3           | 2 / 2           |  |
| deaths causally related to treatment / all           | 0 / 1           | 0 / 0           |  |
| Pyrexia  |                 |                 |  |
| subjects affected / exposed                          | 9 / 189 (4.76%) | 4 / 184 (2.17%) |  |
| occurrences causally related to treatment / all      | 4 / 9           | 0 / 4           |  |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0           |  |
| Pain   |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Asthenia  |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Infusion site extravasation                     |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hypothermia                                     |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Inflammation                                    |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Multiple organ dysfunction syndrome             |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 1 / 1           | 0 / 0           |  |
| Respiratory, thoracic and mediastinal disorders |                 |                 |  |
| Hypoxia   |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Lung disorder                                   |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Respiratory failure                             |                 |                 |  |



|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 6 / 189 (3.17%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 6           | 0 / 0           |  |
| deaths causally related to treatment / all      | 1 / 4           | 0 / 0           |  |
| Pneumothorax                                    |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Acute respiratory failure                       |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Pulmonary oedema                                |                 |                 |  |
| subjects affected / exposed                     | 3 / 189 (1.59%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 3           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Dyspnoea  |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pulmonary embolism                              |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pleural effusion                                |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pneumonitis                                     |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pulmonary haemorrhage                           |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Respiratory distress                            |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pulmonary toxicity                              |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Epistaxis                                       |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Acute pulmonary oedema                          |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Psychiatric disorders                           |                 |                 |  |
| Confusional state                               |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Delirium  |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Investigations                                  |                 |                 |  |
| Aspartate aminotransferase increased            |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 2 / 2           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |

|  |                 |                 |  |
|--|-----------------|-----------------|--|
| Alanine aminotransferase increased<br>subjects affected / exposed  | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to<br>treatment / all                 | 1 / 1           | 0 / 0           |  |
| deaths causally related to<br>treatment / all                      | 0 / 0           | 0 / 0           |  |
| C-reactive protein increased<br>subjects affected / exposed        | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to<br>treatment / all                 | 0 / 1           | 1 / 1           |  |
| deaths causally related to<br>treatment / all                      | 0 / 0           | 0 / 0           |  |
| Neutrophil count decreased<br>subjects affected / exposed          | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to<br>treatment / all                 | 0 / 0           | 1 / 1           |  |
| deaths causally related to<br>treatment / all                      | 0 / 0           | 0 / 0           |  |
| General physical condition abnormal<br>subjects affected / exposed | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to<br>treatment / all                 | 0 / 2           | 0 / 1           |  |
| deaths causally related to<br>treatment / all                      | 0 / 0           | 0 / 0           |  |
| Blood bilirubin increased<br>subjects affected / exposed           | 3 / 189 (1.59%) | 0 / 184 (0.00%) |  |
| occurrences causally related to<br>treatment / all                 | 2 / 3           | 0 / 0           |  |
| deaths causally related to<br>treatment / all                      | 0 / 0           | 0 / 0           |  |
| Blood creatinine increased<br>subjects affected / exposed          | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to<br>treatment / all                 | 0 / 0           | 1 / 1           |  |
| deaths causally related to<br>treatment / all                      | 0 / 0           | 0 / 0           |  |
| White blood cell count decreased<br>subjects affected / exposed    | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to<br>treatment / all                 | 1 / 1           | 0 / 0           |  |
| deaths causally related to<br>treatment / all                      | 0 / 0           | 0 / 0           |  |
| Troponin I increased<br>subjects affected / exposed                | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to<br>treatment / all                 | 1 / 1           | 0 / 0           |  |
| deaths causally related to<br>treatment / all                      | 0 / 0           | 0 / 0           |  |
| Haemoglobin decreased  |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hepatic enzyme increased                        |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Platelet count decreased                        |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Injury, poisoning and procedural complications  |                 |                 |  |
| Fall  |                 |                 |  |
| subjects affected / exposed                     | 6 / 189 (3.17%) | 3 / 184 (1.63%) |  |
| occurrences causally related to treatment / all | 1 / 6           | 0 / 3           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Refractoriness to platelet ~ transfusion        |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Spinal compression fracture                     |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Medication error                                |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Infusion related reaction                       |                 |                 |  |
| subjects affected / exposed                     | 7 / 189 (3.70%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 8 / 8           | 2 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Wrist fracture                                  |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Lumbar vertebral fracture                       |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Femur fracture                                  |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Craniocerebral injury                           |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| Hip fracture                                    |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Subdural haematoma                              |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| Spinal fracture                                 |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 3           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Post procedural haemorrhage                     |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Cardiac disorders                               |                 |                 |  |
| Sinus bradycardia                               |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Atrial flutter                                  |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pericardial effusion                            |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Cardiac arrest                                  |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| Cardiogenic shock                               |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Angina pectoris                                 |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Coronary artery disease                         |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Cardiac tamponade                               |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 2 / 2           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Sinus tachycardia                               |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Atrial fibrillation                             |                 |                 |  |
| subjects affected / exposed                     | 4 / 189 (2.12%) | 4 / 184 (2.17%) |  |
| occurrences causally related to treatment / all | 0 / 4           | 0 / 4           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Cardiac failure                                 |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 4 / 184 (2.17%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 1 / 6           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| Acute myocardial infarction                     |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 2           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Nervous system disorders                        |                 |                 |  |
| Cerebral haemorrhage                            |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| Encephalopathy                                  |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Presyncope                                      |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Cerebrovascular accident                        |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Cerebral ischaemia                              |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Transient ischaemic attack                      |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Seizure   |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Altered state of consciousness                  |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Syncope   |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Cerebrovascular disorder                        |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Metabolic encephalopathy                        |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Headache  |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Cerebral microembolism                          |                 |                 |  |



|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Extrapyramidal disorder                         |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Tremor  |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Polyneuropathy chronic                          |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Haemorrhage intracranial                        |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| Blood and lymphatic system disorders            |                 |                 |  |
| Neutropenia                                     |                 |                 |  |
| subjects affected / exposed                     | 8 / 189 (4.23%) | 8 / 184 (4.35%) |  |
| occurrences causally related to treatment / all | 12 / 13         | 8 / 10          |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Bone marrow failure                             |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Agranulocytosis                                 |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 2 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Febrile neutropenia                             |                 |                 |  |

|   |                   |                   |  |
|---|-------------------|-------------------|--|
| subjects affected / exposed                     | 44 / 189 (23.28%) | 47 / 184 (25.54%) |  |
| occurrences causally related to treatment / all | 38 / 59           | 39 / 62           |  |
| deaths causally related to treatment / all      | 2 / 2             | 1 / 2             |  |
| Haemolysis                                      |                   |                   |  |
| subjects affected / exposed                     | 2 / 189 (1.06%)   | 0 / 184 (0.00%)   |  |
| occurrences causally related to treatment / all | 2 / 2             | 0 / 0             |  |
| deaths causally related to treatment / all      | 0 / 0             | 0 / 0             |  |
| Thrombocytopenia                                |                   |                   |  |
| subjects affected / exposed                     | 0 / 189 (0.00%)   | 1 / 184 (0.54%)   |  |
| occurrences causally related to treatment / all | 0 / 0             | 0 / 1             |  |
| deaths causally related to treatment / all      | 0 / 0             | 0 / 0             |  |
| Febrile bone marrow aplasia                     |                   |                   |  |
| subjects affected / exposed                     | 2 / 189 (1.06%)   | 2 / 184 (1.09%)   |  |
| occurrences causally related to treatment / all | 1 / 2             | 2 / 2             |  |
| deaths causally related to treatment / all      | 0 / 0             | 0 / 0             |  |
| Pancytopenia                                    |                   |                   |  |
| subjects affected / exposed                     | 1 / 189 (0.53%)   | 2 / 184 (1.09%)   |  |
| occurrences causally related to treatment / all | 0 / 1             | 2 / 3             |  |
| deaths causally related to treatment / all      | 0 / 0             | 0 / 0             |  |
| Splenic infarction                              |                   |                   |  |
| subjects affected / exposed                     | 0 / 189 (0.00%)   | 1 / 184 (0.54%)   |  |
| occurrences causally related to treatment / all | 0 / 0             | 0 / 1             |  |
| deaths causally related to treatment / all      | 0 / 0             | 0 / 0             |  |
| Lymphadenopathy                                 |                   |                   |  |
| subjects affected / exposed                     | 1 / 189 (0.53%)   | 0 / 184 (0.00%)   |  |
| occurrences causally related to treatment / all | 1 / 1             | 0 / 0             |  |
| deaths causally related to treatment / all      | 0 / 0             | 0 / 0             |  |
| Anaemia   |                   |                   |  |
| subjects affected / exposed                     | 5 / 189 (2.65%)   | 2 / 184 (1.09%)   |  |
| occurrences causally related to treatment / all | 3 / 5             | 1 / 2             |  |
| deaths causally related to treatment / all      | 0 / 0             | 0 / 0             |  |
| Ear and labyrinth disorders                     |                   |                   |  |
| Ear pain  |                   |                   |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Gastrointestinal disorders                      |                 |                 |  |
| Enterocolitis                                   |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Large intestine perforation                     |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Mouth haemorrhage                               |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Abdominal pain                                  |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Intestinal obstruction                          |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 2           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Colitis   |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 1 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Diarrhoea                                       |                 |                 |  |
| subjects affected / exposed                     | 4 / 189 (2.12%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 4           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Vomiting  |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 1 / 189 (0.53%) | 5 / 184 (2.72%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 2 / 5           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Lower gastrointestinal haemorrhage              |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Abdominal pain upper                            |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Enteritis                                       |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Diverticulum                                    |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Gastrointestinal haemorrhage                    |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Gastrointestinal inflammation                   |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Ileus   |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Haemorrhoids                                    |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Gastric haemorrhage                             |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Stomatitis                                      |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hepatobiliary disorders                         |                 |                 |  |
| Cholecystitis                                   |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Bile duct stone                                 |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hepatic hypoperfusion                           |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Skin and subcutaneous tissue disorders          |                 |                 |  |
| Rash maculo-papular                             |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Skin ulcer                                      |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Renal and urinary disorders                     |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| Renal failure                                   |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 3 / 184 (1.63%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 3 / 4           |  |
| deaths causally related to treatment / all      | 0 / 0           | 1 / 1           |  |
| Chronic kidney disease                          |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Acute kidney injury                             |                 |                 |  |
| subjects affected / exposed                     | 5 / 189 (2.65%) | 5 / 184 (2.72%) |  |
| occurrences causally related to treatment / all | 2 / 5           | 1 / 5           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Renal impairment                                |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| Haematuria                                      |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Renal tubular necrosis                          |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Musculoskeletal and connective tissue disorders |                 |                 |  |
| Back pain                                       |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Muscle haemorrhage                              |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |

|   |                  |                  |  |
|---|------------------|------------------|--|
| Arthritis                                       |                  |                  |  |
| subjects affected / exposed                     | 0 / 189 (0.00%)  | 1 / 184 (0.54%)  |  |
| occurrences causally related to treatment / all | 0 / 0            | 1 / 1            |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0            |  |
| Bursitis  |                  |                  |  |
| subjects affected / exposed                     | 2 / 189 (1.06%)  | 0 / 184 (0.00%)  |  |
| occurrences causally related to treatment / all | 2 / 2            | 0 / 0            |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0            |  |
| Arthralgia                                      |                  |                  |  |
| subjects affected / exposed                     | 0 / 189 (0.00%)  | 1 / 184 (0.54%)  |  |
| occurrences causally related to treatment / all | 0 / 0            | 0 / 1            |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0            |  |
| Muscular weakness                               |                  |                  |  |
| subjects affected / exposed                     | 1 / 189 (0.53%)  | 0 / 184 (0.00%)  |  |
| occurrences causally related to treatment / all | 0 / 1            | 0 / 0            |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0            |  |
| Neck pain                                       |                  |                  |  |
| subjects affected / exposed                     | 0 / 189 (0.00%)  | 1 / 184 (0.54%)  |  |
| occurrences causally related to treatment / all | 0 / 0            | 0 / 1            |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0            |  |
| Infections and infestations                     |                  |                  |  |
| Septic shock                                    |                  |                  |  |
| subjects affected / exposed                     | 5 / 189 (2.65%)  | 7 / 184 (3.80%)  |  |
| occurrences causally related to treatment / all | 1 / 5            | 1 / 7            |  |
| deaths causally related to treatment / all      | 0 / 2            | 0 / 3            |  |
| Pneumonia                                       |                  |                  |  |
| subjects affected / exposed                     | 17 / 189 (8.99%) | 15 / 184 (8.15%) |  |
| occurrences causally related to treatment / all | 7 / 19           | 2 / 16           |  |
| deaths causally related to treatment / all      | 2 / 7            | 0 / 4            |  |
| Covid-19  |                  |                  |  |
| subjects affected / exposed                     | 7 / 189 (3.70%)  | 6 / 184 (3.26%)  |  |
| occurrences causally related to treatment / all | 1 / 7            | 0 / 7            |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0            |  |
| Infection                                       |                  |                  |  |

|   |                  |                 |  |
|---|------------------|-----------------|--|
| subjects affected / exposed                     | 7 / 189 (3.70%)  | 3 / 184 (1.63%) |  |
| occurrences causally related to treatment / all | 4 / 7            | 1 / 3           |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0           |  |
| Sepsis  |                  |                 |  |
| subjects affected / exposed                     | 17 / 189 (8.99%) | 8 / 184 (4.35%) |  |
| occurrences causally related to treatment / all | 10 / 21          | 5 / 8           |  |
| deaths causally related to treatment / all      | 4 / 7            | 2 / 2           |  |
| Device related infection                        |                  |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%)  | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1            | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0           |  |
| Bronchopulmonary aspergillosis                  |                  |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%)  | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 3            | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0           |  |
| Respiratory tract infection                     |                  |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%)  | 3 / 184 (1.63%) |  |
| occurrences causally related to treatment / all | 0 / 0            | 1 / 3           |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0           |  |
| Escherichia bacteraemia                         |                  |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%)  | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 0 / 1            | 2 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0           |  |
| Anorectal infection                             |                  |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%)  | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1            | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0           |  |
| Bacteraemia                                     |                  |                 |  |
| subjects affected / exposed                     | 3 / 189 (1.59%)  | 3 / 184 (1.63%) |  |
| occurrences causally related to treatment / all | 3 / 3            | 1 / 3           |  |
| deaths causally related to treatment / all      | 0 / 0            | 0 / 0           |  |
| Cellulitis                                      |                  |                 |  |



|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 2 / 189 (1.06%) | 3 / 184 (1.63%) |  |
| occurrences causally related to treatment / all | 2 / 2           | 1 / 3           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Influenza                                       |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Urinary tract infection                         |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 3 / 184 (1.63%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 1 / 4           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Diverticulitis                                  |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 3 / 184 (1.63%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 5           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Erysipelas                                      |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Staphylococcal infection                        |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Coronavirus infection                           |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Covid-19 pneumonia                              |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Staphylococcal sepsis                           |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Sinusitis                                       |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pulmonary sepsis                                |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 1           |  |
| Pseudomonal sepsis                              |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 2 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Bacterial infection                             |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Neutropenic sepsis                              |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Catheter site cellulitis                        |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Arthritis infective                             |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Bacillus bacteraemia                            |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Device related sepsis                           |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Haematological infection                        |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Enterobacter infection                          |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Vascular device infection                       |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Abdominal sepsis                                |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Abscess of salivary gland                       |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Bacterial sepsis                                |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Meningitis                                      |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Liver abscess                                   |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Escherichia sepsis                              |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Infusion site cellulitis                        |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Oral infection                                  |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Osteomyelitis                                   |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Gastroenteritis adenovirus                      |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Klebsiella sepsis                               |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Escherichia pyelonephritis                      |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Infectious pleural effusion                     |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Renal abscess                                   |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pseudomonal bacteraemia                         |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Paronychia                                      |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pneumonia bacterial                             |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Peritonitis                                     |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| Periorbital cellulitis                          |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 1           |  |
| Otosalpingitis                                  |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Diverticulitis intestinal perforated            |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pneumonia klebsiella                            |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pneumonia fungal                                |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Staphylococcal bacteraemia                      |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pneumonia respiratory syncytial ~ viral         |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Streptococcal sepsis                            |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Stenotrophomonas sepsis                         |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           |  |
| Upper respiratory tract infection               |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Metabolism and nutrition disorders              |                 |                 |  |
| Hypokalaemia                                    |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 2 / 184 (1.09%) |  |
| occurrences causally related to treatment / all | 1 / 1           | 1 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Decreased appetite                              |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hypervolaemia                                   |                 |                 |  |
| subjects affected / exposed                     | 2 / 189 (1.06%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 4           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Gout  |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hyperglycaemia                                  |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Tumour lysis syndrome                           |                 |                 |  |
| subjects affected / exposed                     | 0 / 189 (0.00%) | 1 / 184 (0.54%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Hyperkalaemia                                   |                 |                 |  |
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Dehydration                                     |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 1 / 189 (0.53%) | 0 / 184 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |

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

| <b>Non-serious adverse events</b>                     | Magrolimab +<br>Venetoclax +<br>Azacitidine | Magrolimab<br>Matching Placebo +<br>Venetoclax +<br>Azacitidine |  |
|---|---|---|--|
| Total subjects affected by non-serious adverse events |   |   |  |
| subjects affected / exposed                           | 180 / 189 (95.24%)                          | 179 / 184 (97.28%)  |  |
| Vascular disorders                                    |   |   |  |
| Hypotension   |   |   |  |
| subjects affected / exposed                           | 19 / 189 (10.05%)                           | 19 / 184 (10.33%)   |  |
| occurrences (all)                                     | 25  | 30  |  |
| Hypertension  |   |   |  |
| subjects affected / exposed                           | 14 / 189 (7.41%)                            | 16 / 184 (8.70%)  |  |
| occurrences (all)                                     | 25  | 22  |  |
| General disorders and administration site conditions  |   |   |  |
| Asthenia  |   |   |  |
| subjects affected / exposed                           | 22 / 189 (11.64%)                           | 16 / 184 (8.70%)  |  |
| occurrences (all)                                     | 34  | 22  |  |
| Pyrexia   |   |   |  |
| subjects affected / exposed                           | 58 / 189 (30.69%)                           | 51 / 184 (27.72%)   |  |
| occurrences (all)                                     | 85  | 72  |  |
| Oedema peripheral                                     |   |   |  |
| subjects affected / exposed                           | 27 / 189 (14.29%)                           | 39 / 184 (21.20%)   |  |
| occurrences (all)                                     | 32  | 45  |  |
| Fatigue   |   |   |  |
| subjects affected / exposed                           | 34 / 189 (17.99%)                           | 36 / 184 (19.57%)   |  |
| occurrences (all)                                     | 37  | 44  |  |
| Injection site reaction                               |   |   |  |
| subjects affected / exposed                           | 7 / 189 (3.70%)                             | 14 / 184 (7.61%)  |  |
| occurrences (all)                                     | 7   | 14  |  |
| Oedema  |   |   |  |



|  |                         |                         |  |
|--|-------------------------|-------------------------|--|
| subjects affected / exposed<br>occurrences (all)                       | 10 / 189 (5.29%)<br>11  | 1 / 184 (0.54%)<br>1    |  |
| Chills<br>subjects affected / exposed<br>occurrences (all)             | 14 / 189 (7.41%)<br>18  | 11 / 184 (5.98%)<br>18  |  |
| Respiratory, thoracic and mediastinal disorders                        |                         |                         |  |
| Dyspnoea<br>subjects affected / exposed<br>occurrences (all)           | 26 / 189 (13.76%)<br>29 | 19 / 184 (10.33%)<br>22 |  |
| Epistaxis<br>subjects affected / exposed<br>occurrences (all)          | 15 / 189 (7.94%)<br>17  | 16 / 184 (8.70%)<br>17  |  |
| Pleural effusion<br>subjects affected / exposed<br>occurrences (all)   | 11 / 189 (5.82%)<br>11  | 9 / 184 (4.89%)<br>11   |  |
| Rhinorrhoea<br>subjects affected / exposed<br>occurrences (all)        | 5 / 189 (2.65%)<br>7    | 14 / 184 (7.61%)<br>19  |  |
| Hypoxia<br>subjects affected / exposed<br>occurrences (all)            | 6 / 189 (3.17%)<br>6    | 11 / 184 (5.98%)<br>12  |  |
| Cough<br>subjects affected / exposed<br>occurrences (all)              | 28 / 189 (14.81%)<br>30 | 20 / 184 (10.87%)<br>22 |  |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all) | 5 / 189 (2.65%)<br>5    | 15 / 184 (8.15%)<br>16  |  |
| Psychiatric disorders  |                         |                         |  |
| Insomnia<br>subjects affected / exposed<br>occurrences (all)           | 20 / 189 (10.58%)<br>20 | 12 / 184 (6.52%)<br>14  |  |
| Anxiety<br>subjects affected / exposed<br>occurrences (all)            | 3 / 189 (1.59%)<br>3    | 10 / 184 (5.43%)<br>10  |  |
| Delirium   |                         |                         |  |

|  |                          |                          |  |
|--|--------------------------|--------------------------|--|
| subjects affected / exposed<br>occurrences (all)   | 3 / 189 (1.59%)<br>3     | 10 / 184 (5.43%)<br>11   |  |
| Investigations   |                          |                          |  |
| Blood bilirubin increased<br>subjects affected / exposed<br>occurrences (all)            | 34 / 189 (17.99%)<br>46  | 14 / 184 (7.61%)<br>14   |  |
| Neutrophil count decreased<br>subjects affected / exposed<br>occurrences (all)           | 51 / 189 (26.98%)<br>170 | 38 / 184 (20.65%)<br>126 |  |
| Platelet count decreased<br>subjects affected / exposed<br>occurrences (all)             | 40 / 189 (21.16%)<br>130 | 45 / 184 (24.46%)<br>116 |  |
| White blood cell count decreased<br>subjects affected / exposed<br>occurrences (all)     | 19 / 189 (10.05%)<br>39  | 21 / 184 (11.41%)<br>40  |  |
| Weight decreased<br>subjects affected / exposed<br>occurrences (all)                     | 20 / 189 (10.58%)<br>26  | 13 / 184 (7.07%)<br>13   |  |
| Aspartate aminotransferase increased<br>subjects affected / exposed<br>occurrences (all) | 17 / 189 (8.99%)<br>21   | 11 / 184 (5.98%)<br>12   |  |
| Blood creatinine increased<br>subjects affected / exposed<br>occurrences (all)           | 12 / 189 (6.35%)<br>21   | 14 / 184 (7.61%)<br>18   |  |
| Blood alkaline phosphatase increased<br>subjects affected / exposed<br>occurrences (all) | 14 / 189 (7.41%)<br>16   | 8 / 184 (4.35%)<br>8     |  |
| Alanine aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)   | 15 / 189 (7.94%)<br>18   | 4 / 184 (2.17%)<br>7     |  |
| Injury, poisoning and procedural complications   |                          |                          |  |
| Infusion related reaction<br>subjects affected / exposed<br>occurrences (all)            | 28 / 189 (14.81%)<br>39  | 14 / 184 (7.61%)<br>15   |  |
| Fall   |                          |                          |  |

|   |                          |                          |  |
|---|--------------------------|--------------------------|--|
| subjects affected / exposed<br>occurrences (all)  | 20 / 189 (10.58%)<br>23  | 16 / 184 (8.70%)<br>23   |  |
| Contusion<br>subjects affected / exposed<br>occurrences (all)   | 12 / 189 (6.35%)<br>12   | 8 / 184 (4.35%)<br>13    |  |
| Cardiac disorders<br>Atrial fibrillation<br>subjects affected / exposed<br>occurrences (all)                    | 18 / 189 (9.52%)<br>20   | 9 / 184 (4.89%)<br>11    |  |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)                        | 22 / 189 (11.64%)<br>32  | 24 / 184 (13.04%)<br>34  |  |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)   | 14 / 189 (7.41%)<br>19   | 25 / 184 (13.59%)<br>31  |  |
| Blood and lymphatic system disorders<br>Febrile neutropenia<br>subjects affected / exposed<br>occurrences (all) | 38 / 189 (20.11%)<br>48  | 31 / 184 (16.85%)<br>38  |  |
| Thrombocytopenia<br>subjects affected / exposed<br>occurrences (all)  | 39 / 189 (20.63%)<br>76  | 47 / 184 (25.54%)<br>85  |  |
| Anaemia<br>subjects affected / exposed<br>occurrences (all)   | 92 / 189 (48.68%)<br>198 | 63 / 184 (34.24%)<br>141 |  |
| Neutropenia<br>subjects affected / exposed<br>occurrences (all)   | 67 / 189 (35.45%)<br>239 | 76 / 184 (41.30%)<br>232 |  |
| Gastrointestinal disorders<br>Vomiting<br>subjects affected / exposed<br>occurrences (all)                      | 30 / 189 (15.87%)<br>39  | 39 / 184 (21.20%)<br>53  |  |
| Stomatitis<br>subjects affected / exposed<br>occurrences (all)  | 12 / 189 (6.35%)<br>12   | 20 / 184 (10.87%)<br>20  |  |
| Dyspepsia   |                          |                          |  |

|   |                   |                   |  |
|---|-------------------|-------------------|--|
| subjects affected / exposed                     | 7 / 189 (3.70%)   | 10 / 184 (5.43%)  |  |
| occurrences (all)                               | 7                 | 12                |  |
| Abdominal pain                                  |                   |                   |  |
| subjects affected / exposed                     | 18 / 189 (9.52%)  | 20 / 184 (10.87%) |  |
| occurrences (all)                               | 22                | 27                |  |
| Diarrhoea                                       |                   |                   |  |
| subjects affected / exposed                     | 76 / 189 (40.21%) | 67 / 184 (36.41%) |  |
| occurrences (all)                               | 110               | 92                |  |
| Nausea  |                   |                   |  |
| subjects affected / exposed                     | 66 / 189 (34.92%) | 60 / 184 (32.61%) |  |
| occurrences (all)                               | 86                | 86                |  |
| Haemorrhoids                                    |                   |                   |  |
| subjects affected / exposed                     | 19 / 189 (10.05%) | 15 / 184 (8.15%)  |  |
| occurrences (all)                               | 19                | 17                |  |
| Constipation                                    |                   |                   |  |
| subjects affected / exposed                     | 72 / 189 (38.10%) | 76 / 184 (41.30%) |  |
| occurrences (all)                               | 90                | 101               |  |
| Hepatobiliary disorders                         |                   |                   |  |
| Hyperbilirubinaemia                             |                   |                   |  |
| subjects affected / exposed                     | 10 / 189 (5.29%)  | 3 / 184 (1.63%)   |  |
| occurrences (all)                               | 10                | 3                 |  |
| Skin and subcutaneous tissue disorders          |                   |                   |  |
| Pruritus  |                   |                   |  |
| subjects affected / exposed                     | 17 / 189 (8.99%)  | 17 / 184 (9.24%)  |  |
| occurrences (all)                               | 20                | 17                |  |
| Rash  |                   |                   |  |
| subjects affected / exposed                     | 17 / 189 (8.99%)  | 12 / 184 (6.52%)  |  |
| occurrences (all)                               | 21                | 15                |  |
| Rash maculo-papular                             |                   |                   |  |
| subjects affected / exposed                     | 11 / 189 (5.82%)  | 14 / 184 (7.61%)  |  |
| occurrences (all)                               | 15                | 17                |  |
| Renal and urinary disorders                     |                   |                   |  |
| Acute kidney injury                             |                   |                   |  |
| subjects affected / exposed                     | 15 / 189 (7.94%)  | 5 / 184 (2.72%)   |  |
| occurrences (all)                               | 15                | 6                 |  |
| Musculoskeletal and connective tissue disorders |                   |                   |  |

|                                    |                   |                   |  |
|------------------------------------|-------------------|-------------------|--|
| Arthralgia                         |                   |                   |  |
| subjects affected / exposed        | 22 / 189 (11.64%) | 22 / 184 (11.96%) |  |
| occurrences (all)                  | 27                | 25                |  |
| Back pain                          |                   |                   |  |
| subjects affected / exposed        | 20 / 189 (10.58%) | 18 / 184 (9.78%)  |  |
| occurrences (all)                  | 22                | 20                |  |
| Pain in extremity                  |                   |                   |  |
| subjects affected / exposed        | 12 / 189 (6.35%)  | 17 / 184 (9.24%)  |  |
| occurrences (all)                  | 13                | 23                |  |
| Muscular weakness                  |                   |                   |  |
| subjects affected / exposed        | 9 / 189 (4.76%)   | 13 / 184 (7.07%)  |  |
| occurrences (all)                  | 9                 | 17                |  |
| Infections and infestations        |                   |                   |  |
| Covid-19                           |                   |                   |  |
| subjects affected / exposed        | 18 / 189 (9.52%)  | 22 / 184 (11.96%) |  |
| occurrences (all)                  | 18                | 24                |  |
| Pneumonia                          |                   |                   |  |
| subjects affected / exposed        | 15 / 189 (7.94%)  | 14 / 184 (7.61%)  |  |
| occurrences (all)                  | 19                | 14                |  |
| Urinary tract infection            |                   |                   |  |
| subjects affected / exposed        | 6 / 189 (3.17%)   | 11 / 184 (5.98%)  |  |
| occurrences (all)                  | 10                | 13                |  |
| Bacteraemia                        |                   |                   |  |
| subjects affected / exposed        | 5 / 189 (2.65%)   | 10 / 184 (5.43%)  |  |
| occurrences (all)                  | 5                 | 10                |  |
| Metabolism and nutrition disorders |                   |                   |  |
| Hypokalaemia                       |                   |                   |  |
| subjects affected / exposed        | 49 / 189 (25.93%) | 54 / 184 (29.35%) |  |
| occurrences (all)                  | 99                | 101               |  |
| Hypophosphataemia                  |                   |                   |  |
| subjects affected / exposed        | 26 / 189 (13.76%) | 27 / 184 (14.67%) |  |
| occurrences (all)                  | 37                | 39                |  |
| Hypomagnesaemia                    |                   |                   |  |
| subjects affected / exposed        | 23 / 189 (12.17%) | 10 / 184 (5.43%)  |  |
| occurrences (all)                  | 40                | 13                |  |
| Hypocalcaemia                      |                   |                   |  |

|                             |                   |                   |  |
|-----------------------------|-------------------|-------------------|--|
| subjects affected / exposed | 15 / 189 (7.94%)  | 14 / 184 (7.61%)  |  |
| occurrences (all)           | 21                | 19                |  |
| Hyperglycaemia              |                   |                   |  |
| subjects affected / exposed | 10 / 189 (5.29%)  | 15 / 184 (8.15%)  |  |
| occurrences (all)           | 10                | 17                |  |
| Hyponatraemia               |                   |                   |  |
| subjects affected / exposed | 9 / 189 (4.76%)   | 11 / 184 (5.98%)  |  |
| occurrences (all)           | 12                | 17                |  |
| Hypoalbuminaemia            |                   |                   |  |
| subjects affected / exposed | 6 / 189 (3.17%)   | 12 / 184 (6.52%)  |  |
| occurrences (all)           | 7                 | 18                |  |
| Decreased appetite          |                   |                   |  |
| subjects affected / exposed | 40 / 189 (21.16%) | 29 / 184 (15.76%) |  |
| occurrences (all)           | 44                | 39                |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date              | Amendment   |
|-------------------|---|
| 08 September 2021 | Herein was a summary of the major changes made to the original protocol dated 30 June 2021 and reflected in Amendment 1 dated 08 September 2021. The protocol had been amended primarily to: incorporate changes based on feedback from the United States (US) Food and Drug Administration (FDA) and incorporate changes based on feedback from the Medicines and Healthcare products Regulatory Agency (MHRA). To highlight the cumulative differences between the original protocol and Amendment 1 of the protocol, changes/additions were in bold italicized font and deletions were depicted with strikethrough text. |
| 01 November 2021  | Herein was a summary of the major changes made to Amendment 1 dated 08 September 2021 and reflected in Amendment 2 dated 01 November 2021. The protocol had been amended primarily to: incorporate changes based on feedback from the Voluntary Harmonization Procedure (VHP). To highlight the cumulative differences between Amendment 1 and Amendment 2 of the protocol, changes/additions were in bold italicized font and deletions were depicted with strikethrough text.   |
| 29 November 2021  | The major update(s) to the protocol and related rationale were as follows:<br>A Per-Protocol Analysis Set for the primary and key secondary efficacy endpoints had been added.<br>Details on how the randomization list would be generated had been provided.   |
| 30 March 2022     | The primary reason for this amendment was to provide additional guidance for anemia management in response to the Dear Investigator Letter dated 17 January 2022. The protocol had been updated with the following additional requirements for monitoring hemoglobin:<br>A minimum hemoglobin threshold prior to the first 2 doses of magrolimab/placebo during treatment initiation.<br>Post-magrolimab/placebo treatment hemoglobin monitoring after the first 2 doses of magrolimab/placebo, during treatment initiation.  |
| 27 July 2022      | The primary reason for this amendment was to update the contraception requirements for female patients to align with the revised contraception recommendations in the azacitidine prescribing information dated June 2022.  |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported