



## Clinical trial results:

**A randomized, double-blind, placebo-controlled, multicenter study of ensovibep (MP0420) in ambulatory adult patients with symptomatic COVID-19**

### Summary

|                          |                 |
|--------------------------|-----------------|
| EudraCT number           | 2021-000890-10  |
| Trial protocol           | HU NL           |
| Global end of trial date | 27 January 2022 |

### Results information

|                                |  |
|--------------------------------|--|
| Result version number          | v2 (current)   |
| This version publication date  | 18 January 2023  |
| First version publication date | 18 December 2022   |
| Version creation reason        | <ul style="list-style-type: none"><li>• Correction of full data set</li><li>Timeframe correction for PK endpoints.</li></ul> |

### Trial information

#### Trial identification

|                       |              |
|-----------------------|--------------|
| Sponsor protocol code | MP0420-CP302 |
|-----------------------|--------------|

#### Additional study identifiers

|                                    |  |
|------------------------------------|--|
| ISRCTN number                      | -  |
| ClinicalTrials.gov id (NCT number) | NCT04828161                                  |
| WHO universal trial number (UTN)   | -  |
| Other trial identifiers            | CSKO136A12201J: Novartis protocol identifier |

Notes:

### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Molecular Partners AG  |
| Sponsor organisation address | Wagistrasse 14, Schlieren, Switzerland, 8952   |
| Public contact               | Clinical Disclosure Office, Novartis Pharma AG, +41 613241111, Novartis.email@Novartis.com |
| Scientific contact           | Clinical Disclosure Office, Novartis Pharma AG, +41 613241111, Novartis.email@Novartis.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                       | 27 January 2022 |
| Is this the analysis of the primary completion data? | No              |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 27 January 2022 |
| Was the trial ended prematurely?                     | No              |

Notes:

## General information about the trial

Main objective of the trial:

Part A: To assess the effect of ensovibep, compared to placebo, in reducing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral load from Baseline through Day 8.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

|   |             |
|---|-------------|
| Actual start date of recruitment                          | 10 May 2021 |
| 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 | Hungary: 3         |
| Country: Number of subjects enrolled | India: 49          |
| Country: Number of subjects enrolled | Netherlands: 19    |
| Country: Number of subjects enrolled | South Africa: 87   |
| Country: Number of subjects enrolled | United States: 242 |
| Worldwide total number of subjects   | 400                |
| EEA total number of subjects         | 22                 |

Notes:

### Subjects enrolled per age group

|   |   |
|---|---|
| In utero                                  | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days)                      | 0 |
| Infants and toddlers (28 days-23 months)  | 0 |
| Children (2-11 years)                     | 0 |
| Adolescents (12-17 years)                 | 0 |

|                      |     |
|----------------------|-----|
| Adults (18-64 years) | 388 |
| From 65 to 84 years  | 12  |
| 85 years and over    | 0   |

## Subject disposition

### Recruitment

Recruitment details:

This study consisted of 2 parts, Part A and Part B. The Part A was Phase II proof of efficacy study conducted in ambulatory adult participants with symptomatic coronavirus disease 2019 (COVID-19). The Part B was to be Phase III confirmatory study. Only Part A analysis is reported as Part B of the study was not initiated.

### Pre-assignment

Screening details:

Part A of the study consisted of a screening period (up to 3 days) followed by study treatment on Day 1. Participants were randomized in 1:1:1:1 ratio, stratified by risk for COVID-19 disease progression, to receive 1 of 4 study treatments (Ensovibep 600 mg or 225 mg or 75 mg or Placebo). A total of 400 participants were treated in the study.

### Period 1

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

Blinding implementation details:

Two patients randomized to ensovibep 225 mg didn't receive treatment they were randomized to: 1 patient received no active drug as infusion was not prepared correctly; 1 patient received lower dose (<75 mg) as infusion was interrupted. For Safety set, these 2 were reported in placebo and ensovibep 75 mg arms, respectively.

### Arms

|                              |                  |
|------------------------------|------------------|
| Are arms mutually exclusive? | Yes              |
| <b>Arm title</b>             | Ensovibep 600 mg |

Arm description:

Participants received single intravenous (IV) infusion of ensovibep 600 milligram (mg) on Day 1.

|  |                       |
|--|-----------------------|
| Arm type                               | Experimental          |
| Investigational medicinal product name | Ensovibep             |
| Investigational medicinal product code | MP0420, SKO136        |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Intravenous use       |

Dosage and administration details:

Single IV infusion of ensovibep 600 mg was administered for over 60 minutes on Day 1.

|                  |                  |
|------------------|------------------|
| <b>Arm title</b> | Ensovibep 225 mg |
|------------------|------------------|

Arm description:

Participants received single IV infusion of ensovibep 225 mg on Day 1.

|  |                       |
|--|-----------------------|
| Arm type                               | Experimental          |
| Investigational medicinal product name | Ensovibep             |
| Investigational medicinal product code | MP0420, SKO136        |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Intravenous use       |

Dosage and administration details:

Single IV infusion of ensovibep 225 mg was administered for over 60 minutes on Day 1.

|                  |                 |
|------------------|-----------------|
| <b>Arm title</b> | Ensovibep 75 mg |
|------------------|-----------------|

Arm description:

Participants received single IV infusion of ensovibep 75 mg on Day 1.

|  |                       |
|--|-----------------------|
| Arm type                               | Experimental          |
| Investigational medicinal product name | Ensovibep             |
| Investigational medicinal product code | MP0420, SKO136        |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Intravenous use       |

Dosage and administration details:

Single IV infusion of ensovibep 75 mg was administered for over 60 minutes on Day 1.

|                  |         |
|------------------|---------|
| <b>Arm title</b> | Placebo |
|------------------|---------|

Arm description:

Participants received single IV infusion of placebo matching with ensovibep on Day 1.

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

Dosage and administration details:

Single IV infusion of placebo matching with ensovibep was administered for over 60 minutes on Day 1.

| <b>Number of subjects in period 1</b> | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |
|---------------------------------------|------------------|------------------|-----------------|
| Started                               | 100              | 100              | 101             |
| Completed                             | 97               | 95               | 96              |
| Not completed                         | 3                | 5                | 5               |
| Consent withdrawn by subject          | -                | 1                | 2               |
| Death                                 | -                | -                | -               |
| Unspecified                           | 2                | -                | 1               |
| Lost to follow-up                     | 1                | 4                | 2               |

| <b>Number of subjects in period 1</b> | Placebo |
|---------------------------------------|---------|
| Started                               | 99      |
| Completed                             | 94      |
| Not completed                         | 5       |
| Consent withdrawn by subject          | 1       |
| Death                                 | 2       |
| Unspecified                           | -       |
| Lost to follow-up                     | 2       |

## Baseline characteristics

### Reporting groups

|  |                  |
|--|------------------|
| Reporting group title  | Ensovibep 600 mg |
| Reporting group description:   |                  |
| Participants received single intravenous (IV) infusion of ensovibep 600 milligram (mg) on Day 1. |                  |
| Reporting group title  | Ensovibep 225 mg |
| Reporting group description:   |                  |
| Participants received single IV infusion of ensovibep 225 mg on Day 1.                           |                  |
| Reporting group title  | Ensovibep 75 mg  |
| Reporting group description:   |                  |
| Participants received single IV infusion of ensovibep 75 mg on Day 1.                            |                  |
| Reporting group title  | Placebo          |
| Reporting group description:   |                  |
| Participants received single IV infusion of placebo matching with ensovibep on Day 1.            |                  |

| Reporting group values             | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |
|------------------------------------|------------------|------------------|-----------------|
| Number of subjects                 | 100              | 100              | 101             |
| Age categorical<br>Units: Subjects |                  |                  |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 40.6<br>± 11.50 | 40.2<br>± 12.90 | 41.5<br>± 12.84 |
| Gender categorical<br>Units: Subjects                                   |                 |                 |                 |
| Female  | 47              | 54              | 60              |
| Male  | 53              | 46              | 41              |
| Race and Ethnicity<br>Units: Subjects                                   |                 |                 |                 |
| White   | 59              | 63              | 62              |
| Asian   | 14              | 14              | 13              |
| Black or African American   | 16              | 11              | 14              |
| Multiple  | 5               | 4               | 6               |
| Not reported  | 1               | 4               | 3               |
| Native Hawaiian or Other Pacific Islander                               | 1               | 1               | 2               |
| American Indian or Alaska Native  | 3               | 0               | 1               |
| Unknown   | 1               | 3               | 0               |

| Reporting group values             | Placebo | Total |  |
|------------------------------------|---------|-------|--|
| Number of subjects                 | 99      | 400   |  |
| Age categorical<br>Units: Subjects |         |       |  |

|   |                 |     |  |
|---|-----------------|-----|--|
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 42.3<br>± 13.75 | -   |  |
| Gender categorical<br>Units: Subjects                                   |                 |     |  |
| Female  | 57              | 218 |  |
| Male  | 42              | 182 |  |
| Race and Ethnicity<br>Units: Subjects                                   |                 |     |  |
| White   | 63              | 247 |  |
| Asian   | 16              | 57  |  |
| Black or African American   | 11              | 52  |  |
| Multiple  | 8               | 23  |  |
| Not reported  | 1               | 9   |  |
| Native Hawaiian or Other Pacific<br>Islander                            | 0               | 4   |  |
| American Indian or Alaska Native  | 0               | 4   |  |
| Unknown   | 0               | 4   |  |

## End points

### End points reporting groups

|  |                                 |
|--|---------------------------------|
| Reporting group title  | Ensovibep 600 mg                |
| Reporting group description:<br>Participants received single intravenous (IV) infusion of ensovibep 600 milligram (mg) on Day 1. |                                 |
| Reporting group title  | Ensovibep 225 mg                |
| Reporting group description:<br>Participants received single IV infusion of ensovibep 225 mg on Day 1.                           |                                 |
| Reporting group title  | Ensovibep 75 mg                 |
| Reporting group description:<br>Participants received single IV infusion of ensovibep 75 mg on Day 1.                            |                                 |
| Reporting group title  | Placebo                         |
| Reporting group description:<br>Participants received single IV infusion of placebo matching with ensovibep on Day 1.            |                                 |
| Subject analysis set title   | Phase 3/Part B: Ensovibep 75 mg |
| Subject analysis set type  | Full analysis                   |
| Subject analysis set description:<br>Phase 3/Part B: ensovibep active treatment. Part B was not initiated.                       |                                 |
| Subject analysis set title   | Phase 3/Part B: Placebo         |
| Subject analysis set type  | Full analysis                   |
| Subject analysis set description:<br>Phase 3/Part B: Placebo. Part B was not initiated.  |                                 |

### Primary: Part A: Time-Weighted Change From Baseline in Log10 SARSCoV- 2 Viral Load Through Day 8

|   |   |
|---|---|
| End point title   | Part A: Time-Weighted Change From Baseline in Log10 SARSCoV- 2 Viral Load Through Day 8 |
| End point description:<br>The SARS-CoV-2 viral load was measured by means of a nasopharyngeal swab, followed by quantitative reverse transcription-polymerase chain reaction assay at a central laboratory. The multiple comparison procedure-modeling methodology was used. Time-weighted change from baseline was used as viral loads were measured at multiple time points. The full analysis set (FAS) included all participants in the randomized set for whom IV infusion of study treatment was administered. Only participants included in the analysis are reported. |   |
| End point type  | Primary   |
| End point timeframe:<br>Baseline (Day 1) and Days 3, 5 and 8  |   |

| End point values                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg | Placebo         |
|-------------------------------------|------------------|------------------|-----------------|-----------------|
| Subject group type                  | Reporting group  | Reporting group  | Reporting group | Reporting group |
| Number of subjects analysed         | 89               | 97               | 97              | 87              |
| Units: log10 copies/milliliter (mL) |                  |                  |                 |                 |
| least squares mean (standard error) | -1.99 (± 0.097)  | -1.73 (± 0.093)  | -1.81 (± 0.093) | -1.40 (± 0.098) |

## Statistical analyses

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Treatment difference in SARSCoV- 2 Viral Load - 1 |
| Comparison groups                       | Ensovibep 600 mg v Placebo                        |
| Number of subjects included in analysis | 176   |
| Analysis specification                  | Pre-specified                                     |
| Analysis type                           | superiority                                       |
| P-value                                 | < 0.001   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | Least square (LS) mean difference                 |
| Point estimate                          | -0.59   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.86   |
| upper limit                             | -0.32   |
| Variability estimate                    | Standard error of the mean                        |
| Dispersion value                        | 0.138   |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Treatment difference in SARSCoV- 2 Viral Load - 2 |
| Comparison groups                       | Ensovibep 225 mg v Placebo                        |
| Number of subjects included in analysis | 184   |
| Analysis specification                  | Pre-specified                                     |
| Analysis type                           | superiority                                       |
| P-value                                 | = 0.014   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | LS mean difference                                |
| Point estimate                          | -0.33   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.6  |
| upper limit                             | -0.07   |
| Variability estimate                    | Standard error of the mean                        |
| Dispersion value                        | 0.135   |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Treatment difference in SARSCoV- 2 Viral Load - 3 |
| Comparison groups                       | Ensovibep 75 mg v Placebo                         |
| Number of subjects included in analysis | 184   |
| Analysis specification                  | Pre-specified                                     |
| Analysis type                           | superiority                                       |
| P-value                                 | = 0.002   |
| Method                                  | ANCOVA  |
| Parameter estimate                      | LS mean difference                                |
| Point estimate                          | -0.42   |

|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 95 %                       |
| sides                | 2-sided                    |
| lower limit          | -0.68                      |
| upper limit          | -0.15                      |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 0.135                      |

### Primary: Part B: Percentage of Participants With Hospitalizations and/or Emergency Room (ER) Visits Related to COVID-19 or Death From Any Cause

|                 |   |
|-----------------|---|
| End point title | Part B: Percentage of Participants With Hospitalizations and/or Emergency Room (ER) Visits Related to COVID-19 or Death From Any Cause <sup>[1]</sup> |
|-----------------|---|

End point description:

Percentage of participants experiencing hospitalizations [ $\geq$  24 hour (h) of acute care] and/or ER visits related to COVID-19 or death from any cause up to Day 29. The Part B of the study was not initiated based on regulatory feedback indicating that with evolving treatment options, a placebo controlled design was no longer considered to be appropriate.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to Day 29

Notes:

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

Justification: The Part B of the study was not initiated based on regulatory feedback indicating that with evolving treatment options, a placebo controlled design was no longer considered to be appropriate.

| End point values                  | Phase 3/Part B: Ensovibep 75 mg | Phase 3/Part B: Placebo |  |  |
|-----------------------------------|---------------------------------|-------------------------|--|--|
| Subject group type                | Subject analysis set            | Subject analysis set    |  |  |
| Number of subjects analysed       | 0 <sup>[2]</sup>                | 0 <sup>[3]</sup>        |  |  |
| Units: percentage of participants |                                 |                         |  |  |
| number (not applicable)           |                                 |                         |  |  |

Notes:

[2] - Part B was not initiated.

[3] - Part B was not initiated.

### Statistical analyses

No statistical analyses for this end point

### Secondary: Part A: Percentage of Participants With Hospitalizations and/or ER Visits Related to COVID-19 or Death From Any Cause

|                 |   |
|-----------------|---|
| End point title | Part A: Percentage of Participants With Hospitalizations and/or ER Visits Related to COVID-19 or Death From Any Cause |
|-----------------|---|

End point description:

Percentage of participants experiencing hospitalizations ( $\geq$  24 h of acute care) and/or ER visits related to COVID-19 or death from any cause up to Day 29 were presented along with relative risk to placebo. The FAS included all participants in the randomized set for whom IV infusion of study treatment was administered.

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

End point timeframe:

Up to Day 29

| End point values                              | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg | Placebo         |
|---|------------------|------------------|-----------------|-----------------|
| Subject group type                            | Reporting group  | Reporting group  | Reporting group | Reporting group |
| Number of subjects analysed                   | 100              | 100              | 101             | 99              |
| Units: percentage of participants             |                  |                  |                 |                 |
| number (not applicable)                       |                  |                  |                 |                 |
| Any event                                     | 1.0              | 3.0              | 0.0             | 6.1             |
| Hospitalizations ( $\geq 24$ h of acute care) | 0.0              | 2.0              | 0.0             | 5.1             |
| ER visits related to COVID-19                 | 1.0              | 1.0              | 0.0             | 5.1             |
| Death from any cause                          | 0.0              | 0.0              | 0.0             | 2.0             |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Part A: Time to Sustained Clinical Recovery

|  |   |
|--|---|
| End point title  | Part A: Time to Sustained Clinical Recovery |
| End point description:   |   |
| Sustained clinical recovery was defined as follows;  |   |
| 1. All symptoms from the modified Food and Drug Administration (FDA) COVID-19 questionnaire scored as moderate or severe at baseline were subsequently scored as mild or absent, and |   |
| 2. All symptoms from the modified FDA COVID-19 questionnaire scored as mild or absent at baseline were subsequently scored as absent, with no subsequent worsening, up to Day 29.    |   |
| The FAS included all participants in the randomized set for whom IV infusion of study treatment was administered. Only participants included in the analysis are reported.           |   |
| End point type   | Secondary                                   |
| End point timeframe:   |   |
| Up to Day 29   |   |

| End point values                 | Ensovibep 600 mg    | Ensovibep 225 mg    | Ensovibep 75 mg     | Placebo             |
|----------------------------------|---------------------|---------------------|---------------------|---------------------|
| Subject group type               | Reporting group     | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed      | 63                  | 66                  | 74                  | 70                  |
| Units: days                      |                     |                     |                     |                     |
| median (confidence interval 95%) | 23.0 (14.0 to 29.0) | 15.0 (13.0 to 21.0) | 14.0 (11.0 to 28.0) | 29.0 (21.0 to 32.0) |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Part A: Observed Maximum Serum Concentration (C<sub>max</sub>) of Total and Free Ensovibep

|                 |  |
|-----------------|--|
| End point title | Part A: Observed Maximum Serum Concentration (Cmax) of Total and Free Ensovibep <sup>[4]</sup> |
|-----------------|--|

End point description:

Blood samples were collected to determine the Cmax of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The Pharmacokinetic (PK) analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

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

End point timeframe:

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Days 3, 8, 15, 29, 61 and 91

Notes:

[4] - 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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 94               | 92               | 95              |  |
| Units: microgram (mcg) per mL                       |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=94, 90, 93)                      | 187 (± 25.3)     | 70.4 (± 27.5)    | 25.1 (± 38.4)   |  |
| Free Ensovibep (n=94, 92, 95)                       | 210 (± 26.3)     | 78.1 (± 31.5)    | 29.3 (± 46.4)   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Part A: Area Under the Concentration-Time Curve From Time Zero to the Time of the Last Quantifiable Concentration (AUClast) of Total and Free Ensovibep

|                 |  |
|-----------------|--|
| End point title | Part A: Area Under the Concentration-Time Curve From Time Zero to the Time of the Last Quantifiable Concentration (AUClast) of Total and Free Ensovibep <sup>[5]</sup> |
|-----------------|--|

End point description:

Blood samples were collected to determine the AUClast of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The PK analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

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

End point timeframe:

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Days 3, 8, 15, 29, 61 and 91

Notes:

[5] - 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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 94               | 91               | 95              |  |
| Units: h*mcg/mL                                     |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=94, 88, 95)                      | 63300 (± 87.6)   | 21100 (± 122.0)  | 7950 (± 67.1)   |  |
| Free Ensovibep (n=94, 91, 95)                       | 68200 (± 84.4)   | 22500 (± 126.9)  | 8380 (± 67.9)   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Part A: Area Under the Concentration-Time Curve From Time Zero to 48 Hours (AUC 0-48h) of Total and Free Ensovibep

|                 |   |
|-----------------|---|
| End point title | Part A: Area Under the Concentration-Time Curve From Time Zero to 48 Hours (AUC 0-48h) of Total and Free Ensovibep <sup>[6]</sup> |
|-----------------|---|

End point description:

Blood samples were collected to determine the AUC 0-48h of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The PK analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

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

End point timeframe:

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Day 3

Notes:

[6] - 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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 95               | 90               | 95              |  |
| Units: h*mcg/mL                                     |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=93, 89, 95)                      | 7520 (± 35.3)    | 2830 (± 35.7)    | 999 (± 34.4)    |  |
| Free Ensovibep (n=95, 90, 95)                       | 8290 (± 32.1)    | 2800 (± 156.2)   | 1120 (± 36.7)   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Part A: Area Under the Concentration-Time Curve From Time Zero to 168 Hours (AUC 0-168h) of Total and Free Ensovibep

|                 |   |
|-----------------|---|
| End point title | Part A: Area Under the Concentration-Time Curve From Time Zero to 168 Hours (AUC 0-168h) of Total and Free Ensovibep <sup>[7]</sup> |
|-----------------|---|

End point description:

Blood samples were collected to determine the AUC 0-168h of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The PK analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

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

End point timeframe:

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Days 3 and 8

Notes:

[7] - 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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 95               | 89               | 95              |  |
| Units: h*mcg/mL                                     |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=93, 89, 94)                      | 23000 (± 23.7)   | 8570 (± 33.1)    | 3020 (± 31.4)   |  |
| Free Ensovibep (n= 95, 89, 95)                      | 25200 (± 23.2)   | 8940 (± 73.2)    | 3390 (± 35.3)   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Part A: Area Under the Concentration-Time Curve From Time Zero to 336 Hours (AUC 0-336h) of Total and Free Ensovibep

|                 |   |
|-----------------|---|
| End point title | Part A: Area Under the Concentration-Time Curve From Time Zero to 336 Hours (AUC 0-336h) of Total and Free Ensovibep <sup>[8]</sup> |
|-----------------|---|

End point description:

Blood samples were collected to determine the AUC 0-336h of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The PK analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

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

End point timeframe:

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Days 3, 8 and 15

Notes:

[8] - 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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 95               | 88               | 94              |  |
| Units: h*mcg/mL                                     |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=93, 87, 93)                      | 38200 (± 23.2)   | 13800 (± 37.6)   | 5040 (± 31.9)   |  |
| Free Ensovibep (n=95, 88, 94)                       | 41800 (± 23.5)   | 15300 (± 41.6)   | 5620 (± 39.1)   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Part A: Area Under the Concentration-Time Curve From Time Zero to Infinity (AUCinfinity) of Total and Free Ensovibep

|                 |   |
|-----------------|---|
| End point title | Part A: Area Under the Concentration-Time Curve From Time Zero to Infinity (AUCinfinity) of Total and Free Ensovibep <sup>[9]</sup> |
|-----------------|---|

End point description:

Blood samples were collected to determine the AUCinfinity of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The PK analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

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

End point timeframe:

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Days 3, 8, 15, 29, 61 and 91

Notes:

[9] - 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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 87               | 82               | 82              |  |
| Units: h*mcg/mL                                     |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=87, 77, 82)                      | 75400 (± 33.5)   | 27600 (± 36.3)   | 9930 (± 41.0)   |  |
| Free Ensovibep (n=87, 82, 80)                       | 80100 (± 40.6)   | 29400 (± 34.8)   | 9540 (± 45.8)   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Part A: Time to Reach the Maximum Concentration (Tmax) of Total and Free Ensovibep

|                 |  |
|-----------------|--|
| End point title | Part A: Time to Reach the Maximum Concentration (Tmax) of Total and Free Ensovibep <sup>[10]</sup> |
|-----------------|--|

**End point description:**

Blood samples were collected to determine the Tmax of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The PK analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

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

**End point timeframe:**

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Days 3, 8, 15, 29, 61 and 91

**Notes:**

[10] - 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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 95               | 92               | 95              |  |
| Units: hour   |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=95, 90, 92)                      | 0.935 (± 457.5)  | 1.30 (± 693.5)   | 1.05 (± 573.6)  |  |
| Free Ensovibep (n=95, 92, 95)                       | 1.01 (± 473.8)   | 1.09 (± 516.6)   | 1.24 (± 810.1)  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Part A: Apparent Total Body Clearance (CL) of Total and Free Ensovibep**

|                 |  |
|-----------------|--|
| End point title | Part A: Apparent Total Body Clearance (CL) of Total and Free Ensovibep <sup>[11]</sup> |
|-----------------|--|

**End point description:**

Blood samples were collected to determine the CL of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The PK analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

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

**End point timeframe:**

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Days 3, 8, 15, 29, 61 and 91

**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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 84               | 80               | 74              |  |
| Units: mL/h   |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=77, 78, 74)                      | 8.07 (± 35.4)    | 8.11 (± 36.1)    | 7.48 (± 42.1)   |  |
| Free Ensovibep (n=84, 80, 74)                       | 7.55 (± 37.3)    | 7.64 (± 35.3)    | 7.78 (± 43.0)   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Part A: Terminal Elimination Rate Constant (Lambda z) of Total and Free Ensovibep

|                 |   |
|-----------------|---|
| End point title | Part A: Terminal Elimination Rate Constant (Lambda z) of Total and Free Ensovibep <sup>[12]</sup> |
|-----------------|---|

End point description:

Blood samples were collected to determine the lambda z of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The PK analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

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

End point timeframe:

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Days 3, 8, 15, 29, 61 and 91

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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 84               | 79               | 74              |  |
| Units: per hour                                     |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=83, 70, 72)                      | 0.003 (± 52.1)   | 0.002 (± 50.6)   | 0.002 (± 39.5)  |  |
| Free Ensovibep (n=84, 79, 74)                       | 0.003 (± 69.6)   | 0.003 (± 48.3)   | 0.003 (± 61.2)  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Part A: Terminal Elimination Half-Life (T1/2) of Total and Free Ensovibep

|                 |   |
|-----------------|---|
| End point title | Part A: Terminal Elimination Half-Life (T1/2) of Total and Free |
|-----------------|---|

## End point description:

Blood samples were collected to determine the T1/2 of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The PK analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

## End point type

Secondary

## End point timeframe:

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Days 3, 8, 15, 29, 61 and 91

## 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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 90               | 83               | 83              |  |
| Units: hour   |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=89, 81, 83)                      | 274 (± 54.0)     | 290 (± 53.8)     | 309 (± 39.8)    |  |
| Free Ensovibep (n=90, 83, 81)                       | 262 (± 67.7)     | 234 (± 48.3)     | 215 (± 60.6)    |  |

## Statistical analyses

No statistical analyses for this end point

**Secondary: Part A: Apparent Volume of Distribution (V<sub>z</sub>) of Total and Free Ensovibep**

## End point title

Part A: Apparent Volume of Distribution (V<sub>z</sub>) of Total and Free Ensovibep<sup>[14]</sup>

## End point description:

Blood samples were collected to determine the V<sub>z</sub> of free ensovibep (ensovibep not bound to target) and total ensovibep (sum of ensovibep not bound to and bound to target) concentrations in serum. The PK analysis set included all participants with at least 1 available valid (that is, not flagged for exclusion) PK concentration measurement, who received any study treatment and with no protocol deviations that impacted PK data. Here, 'n' is number of participants analyzed for each parameter.

## End point type

Secondary

## End point timeframe:

Data was summarized from pre-dose and at 15 minutes and 90 minutes after end of study drug infusion on Day 1, and at Days 3, 8, 15, 29, 61 and 91

## Notes:

[14] - 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: Only participants who received study treatment were analyzed for this endpoint.

| End point values                                    | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |  |
|---|------------------|------------------|-----------------|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group |  |
| Number of subjects analysed                         | 84               | 80               | 74              |  |
| Units: mL   |                  |                  |                 |  |
| geometric mean (geometric coefficient of variation) |                  |                  |                 |  |
| Total Ensovibep (n=77, 78, 74)                      | 3230 (± 35.0)    | 3310 (± 37.5)    | 3330 (± 38.7)   |  |
| Free Ensovibep (n=84, 80, 74)                       | 2760 (± 46.1)    | 2590 (± 36.4)    | 2470 (± 45.6)   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Part B: Change From Baseline in Log10 SARS-CoV-2 Viral Load Through Day 8

|                 |   |
|-----------------|---|
| End point title | Part B: Change From Baseline in Log10 SARS-CoV-2 Viral Load Through Day 8 |
|-----------------|---|

End point description:

The SARS-CoV-2 viral load was measured by means of a nasopharyngeal swab, followed by quantitative reverse transcription-polymerase chain reaction assay at a central laboratory. The multiple comparison procedure-modeling methodology was used. The Part B of the study was not initiated based on regulatory feedback indicating that with evolving treatment options, a placebo controlled design was no longer considered to be appropriate.

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

End point timeframe:

Baseline (Day 1) and Days 3, 5 and 8

| End point values                    | Phase 3/Part B: Ensovibep 75 mg | Phase 3/Part B: Placebo |  |  |
|-------------------------------------|---------------------------------|-------------------------|--|--|
| Subject group type                  | Subject analysis set            | Subject analysis set    |  |  |
| Number of subjects analysed         | 0 <sup>[15]</sup>               | 0 <sup>[16]</sup>       |  |  |
| Units: log10 values                 |                                 |                         |  |  |
| least squares mean (standard error) | ()                              | ()                      |  |  |

Notes:

[15] - Part B was not initiated.

[16] - Part B was not initiated.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Part B: Time to Sustained Clinical Recovery

|                 |   |
|-----------------|---|
| End point title | Part B: Time to Sustained Clinical Recovery |
|-----------------|---|

End point description:

Sustained clinical recovery was defined as follows;

1. All symptoms from the modified FDA COVID-19 questionnaire scored as moderate or severe at baseline were subsequently scored as mild or absent, and
2. All symptoms from the modified FDA COVID-19 questionnaire scored as mild or absent at baseline

were subsequently scored as absent, with no subsequent worsening, up to Day 29.  
The Part B of the study was not initiated based on regulatory feedback indicating that with evolving treatment options, a placebo controlled design was no longer considered to be appropriate.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Up to Day 29         |           |

| End point values                 | Phase 3/Part B: Ensovibep 75 mg | Phase 3/Part B: Placebo |  |  |
|----------------------------------|---------------------------------|-------------------------|--|--|
| Subject group type               | Subject analysis set            | Subject analysis set    |  |  |
| Number of subjects analysed      | 0 <sup>[17]</sup>               | 0 <sup>[18]</sup>       |  |  |
| Units: days                      |                                 |                         |  |  |
| median (confidence interval 95%) | ( to )                          | ( to )                  |  |  |

Notes:

[17] - Part B was not initiated.

[18] - Part B was not initiated.

### Statistical analyses

No statistical analyses for this end point

### Secondary: Part B: Percentage of Participants With Treatment-Emergent Anti-Drug Antibody (ADA) Response to Ensovibep

|                 |   |
|-----------------|---|
| End point title | Part B: Percentage of Participants With Treatment-Emergent Anti-Drug Antibody (ADA) Response to Ensovibep |
|-----------------|---|

End point description:

Treatment-emergent ADA was defined as any participant with a

1. 2-fold (1 dilution) increase in titer than the minimum required dilution if no ADAs were detected at baseline (treatment-induced ADA); or,
2. 4-fold (2 dilutions) increase in titer compared with baseline if ADAs were detected at baseline (treatment-boosted ADA).

The Part B of the study was not initiated based on regulatory feedback indicating that with evolving treatment options, a placebo controlled design was no longer considered to be appropriate.

|  |           |
|--|-----------|
| End point type   | Secondary |
| End point timeframe:   |           |
| Pre-dose on Day 1 and Days 15, 29, 61 and 91 postdose of Ensovibep |           |

| End point values                  | Phase 3/Part B: Ensovibep 75 mg | Phase 3/Part B: Placebo |  |  |
|-----------------------------------|---------------------------------|-------------------------|--|--|
| Subject group type                | Subject analysis set            | Subject analysis set    |  |  |
| Number of subjects analysed       | 0 <sup>[19]</sup>               | 0 <sup>[20]</sup>       |  |  |
| Units: percentage of participants |                                 |                         |  |  |
| number (not applicable)           |                                 |                         |  |  |

Notes:

[19] - Part B was not initiated.

[20] - Part B was not initiated.

### Statistical analyses



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events were reported from first dose of study treatment (Day 1) until end of study treatment, up to a maximum duration of 98 days.

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 24.1 |
|--------------------|------|

### Reporting groups

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Ensovibep 600 mg |
|-----------------------|------------------|

Reporting group description:

Participants received single IV infusion of ensovibep 600 mg on Day 1.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Ensovibep 225 mg |
|-----------------------|------------------|

Reporting group description:

Participants received single IV infusion of ensovibep 225 mg on Day 1.

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | Ensovibep 75 mg |
|-----------------------|-----------------|

Reporting group description:

Participants received single IV infusion of ensovibep 75 mg on Day 1.

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | Ensovibep Total |
|-----------------------|-----------------|

Reporting group description:

Participants received single IV infusion of ensovibep on Day 1.

|                       |         |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Participants received single IV infusion of placebo matching with ensovibep on Day 1.

| Serious adverse events                            | Ensovibep 600 mg | Ensovibep 225 mg | Ensovibep 75 mg |
|---|------------------|------------------|-----------------|
| Total subjects affected by serious adverse events |                  |                  |                 |
| subjects affected / exposed                       | 0 / 100 (0.00%)  | 2 / 98 (2.04%)   | 1 / 102 (0.98%) |
| number of deaths (all causes)                     | 0                | 0                | 0               |
| number of deaths resulting from adverse events    | 0                | 0                | 0               |
| Cardiac disorders                                 |                  |                  |                 |
| Angina pectoris                                   |                  |                  |                 |
| subjects affected / exposed                       | 0 / 100 (0.00%)  | 0 / 98 (0.00%)   | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all   | 0 / 0            | 0 / 0            | 0 / 0           |
| deaths causally related to treatment / all        | 0 / 0            | 0 / 0            | 0 / 0           |
| Cor pulmonale                                     |                  |                  |                 |

|  |                 |                |                 |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed                            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0           | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all             | 0 / 0           | 0 / 0          | 0 / 0           |
| <b>Gastrointestinal disorders</b>                      |                 |                |                 |
| Hiatus hernia  |                 |                |                 |
| subjects affected / exposed                            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0           | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all             | 0 / 0           | 0 / 0          | 0 / 0           |
| Pancreatitis acute                                     |                 |                |                 |
| subjects affected / exposed                            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0           | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all             | 0 / 0           | 0 / 0          | 0 / 0           |
| <b>Respiratory, thoracic and mediastinal disorders</b> |                 |                |                 |
| Acute respiratory failure                              |                 |                |                 |
| subjects affected / exposed                            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0           | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all             | 0 / 0           | 0 / 0          | 0 / 0           |
| Paranasal sinus inflammation                           |                 |                |                 |
| subjects affected / exposed                            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences causally related to treatment / all        | 0 / 0           | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all             | 0 / 0           | 0 / 0          | 0 / 0           |
| Pulmonary embolism                                     |                 |                |                 |
| subjects affected / exposed                            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0           | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all             | 0 / 0           | 0 / 0          | 0 / 0           |
| <b>Renal and urinary disorders</b>                     |                 |                |                 |
| Acute kidney injury                                    |                 |                |                 |
| subjects affected / exposed                            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0           | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all             | 0 / 0           | 0 / 0          | 0 / 0           |
| <b>Infections and infestations</b>                     |                 |                |                 |
| COVID-19   |                 |                |                 |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0           |
| COVID-19 pneumonia                              |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0           |
| Sepsis  |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0           |
| Septic shock                                    |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0           |

| <b>Serious adverse events</b>                     | Ensovibep Total | Placebo         |  |
|---|-----------------|-----------------|--|
| Total subjects affected by serious adverse events |                 |                 |  |
| subjects affected / exposed                       | 3 / 300 (1.00%) | 9 / 100 (9.00%) |  |
| number of deaths (all causes)                     | 0               | 2               |  |
| number of deaths resulting from adverse events    | 0               | 0               |  |
| Cardiac disorders                                 |                 |                 |  |
| Angina pectoris                                   |                 |                 |  |
| subjects affected / exposed                       | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences causally related to treatment / all   | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all        | 0 / 0           | 0 / 0           |  |
| Cor pulmonale                                     |                 |                 |  |
| subjects affected / exposed                       | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences causally related to treatment / all   | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all        | 0 / 0           | 0 / 0           |  |
| Gastrointestinal disorders                        |                 |                 |  |
| Hiatus hernia                                     |                 |                 |  |
| subjects affected / exposed                       | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences causally related to treatment / all   | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all        | 0 / 0           | 0 / 0           |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| Pancreatitis acute                              |                 |                 |  |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Respiratory, thoracic and mediastinal disorders |                 |                 |  |
| Acute respiratory failure                       |                 |                 |  |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Paranasal sinus inflammation                    |                 |                 |  |
| subjects affected / exposed                     | 1 / 300 (0.33%) | 0 / 100 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Pulmonary embolism                              |                 |                 |  |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Renal and urinary disorders                     |                 |                 |  |
| Acute kidney injury                             |                 |                 |  |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Infections and infestations                     |                 |                 |  |
| COVID-19  |                 |                 |  |
| subjects affected / exposed                     | 1 / 300 (0.33%) | 0 / 100 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| COVID-19 pneumonia                              |                 |                 |  |
| subjects affected / exposed                     | 1 / 300 (0.33%) | 4 / 100 (4.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 4           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 2           |  |
| Sepsis  |                 |                 |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Septic shock                                    |                 |                 |  |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 2 / 100 (2.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 2           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |

Frequency threshold for reporting non-serious adverse events: 0 %

| <b>Non-serious adverse events</b>                     | Ensovibep 600 mg  | Ensovibep 225 mg | Ensovibep 75 mg   |
|---|-------------------|------------------|-------------------|
| Total subjects affected by non-serious adverse events |                   |                  |                   |
| subjects affected / exposed                           | 51 / 100 (51.00%) | 40 / 98 (40.82%) | 40 / 102 (39.22%) |
| Vascular disorders                                    |                   |                  |                   |
| Hypertension  |                   |                  |                   |
| subjects affected / exposed                           | 1 / 100 (1.00%)   | 2 / 98 (2.04%)   | 2 / 102 (1.96%)   |
| occurrences (all)                                     | 1                 | 2                | 2                 |
| Phlebitis superficial                                 |                   |                  |                   |
| subjects affected / exposed                           | 1 / 100 (1.00%)   | 0 / 98 (0.00%)   | 0 / 102 (0.00%)   |
| occurrences (all)                                     | 1                 | 0                | 0                 |
| General disorders and administration site conditions  |                   |                  |                   |
| Adverse drug reaction                                 |                   |                  |                   |
| subjects affected / exposed                           | 1 / 100 (1.00%)   | 0 / 98 (0.00%)   | 0 / 102 (0.00%)   |
| occurrences (all)                                     | 1                 | 0                | 0                 |
| Asthenia  |                   |                  |                   |
| subjects affected / exposed                           | 0 / 100 (0.00%)   | 0 / 98 (0.00%)   | 0 / 102 (0.00%)   |
| occurrences (all)                                     | 0                 | 0                | 0                 |
| Fatigue   |                   |                  |                   |
| subjects affected / exposed                           | 2 / 100 (2.00%)   | 0 / 98 (0.00%)   | 1 / 102 (0.98%)   |
| occurrences (all)                                     | 2                 | 0                | 1                 |
| Infusion site haematoma                               |                   |                  |                   |
| subjects affected / exposed                           | 0 / 100 (0.00%)   | 0 / 98 (0.00%)   | 0 / 102 (0.00%)   |
| occurrences (all)                                     | 0                 | 0                | 0                 |
| Infusion site swelling                                |                   |                  |                   |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 0               | 0              | 1               |
| Non-cardiac chest pain                          |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 2 / 98 (2.04%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 0               | 2              | 1               |
| Swelling face                                   |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 0               | 0              | 1               |
| Pyrexia   |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 0               | 0              | 0               |
| Pain  |                 |                |                 |
| subjects affected / exposed                     | 1 / 100 (1.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 1               | 1              | 0               |
| Vessel puncture site haematoma                  |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 0               | 1              | 1               |
| Immune system disorders                         |                 |                |                 |
| Allergy to chemicals                            |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 0               | 0              | 1               |
| Reproductive system and breast disorders        |                 |                |                 |
| Menstruation irregular                          |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 0               | 0              | 1               |
| Heavy menstrual bleeding                        |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 0               | 0              | 0               |
| Dysmenorrhoea                                   |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 0               | 0              | 1               |
| Respiratory, thoracic and mediastinal disorders |                 |                |                 |
| Asthma  |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 0               | 1              | 0               |
| Chronic obstructive pulmonary                   |                 |                |                 |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| disease   |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 0               | 0              | 0               |
| Haemoptysis                                     |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 0               | 1              | 0               |
| Cough   |                 |                |                 |
| subjects affected / exposed                     | 1 / 100 (1.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 1               | 0              | 0               |
| Oropharyngeal pain                              |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 0               | 0              | 0               |
| Rhinitis allergic                               |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 0               | 0              | 1               |
| Throat irritation                               |                 |                |                 |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 0               | 0              | 0               |
| Psychiatric disorders                           |                 |                |                 |
| Anxiety   |                 |                |                 |
| subjects affected / exposed                     | 2 / 100 (2.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 2               | 0              | 1               |
| Depression                                      |                 |                |                 |
| subjects affected / exposed                     | 1 / 100 (1.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 1               | 0              | 0               |
| Insomnia  |                 |                |                 |
| subjects affected / exposed                     | 1 / 100 (1.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                               | 1               | 0              | 0               |
| Investigations                                  |                 |                |                 |
| Activated partial thromboplastin time prolonged |                 |                |                 |
| subjects affected / exposed                     | 3 / 100 (3.00%) | 1 / 98 (1.02%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 3               | 1              | 1               |
| Alanine aminotransferase increased              |                 |                |                 |
| subjects affected / exposed                     | 7 / 100 (7.00%) | 3 / 98 (3.06%) | 1 / 102 (0.98%) |
| occurrences (all)                               | 7               | 3              | 1               |
| Aspartate aminotransferase increased            |                 |                |                 |

|  |                 |                |                 |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed            | 6 / 100 (6.00%) | 3 / 98 (3.06%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 6               | 3              | 1               |
| Amylase increased                      |                 |                |                 |
| subjects affected / exposed            | 4 / 100 (4.00%) | 1 / 98 (1.02%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 4               | 1              | 1               |
| Blood alkaline phosphatase increased   |                 |                |                 |
| subjects affected / exposed            | 1 / 100 (1.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)                      | 1               | 1              | 0               |
| Blood bilirubin increased              |                 |                |                 |
| subjects affected / exposed            | 3 / 100 (3.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 3               | 0              | 1               |
| Blood creatine phosphokinase increased |                 |                |                 |
| subjects affected / exposed            | 3 / 100 (3.00%) | 1 / 98 (1.02%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 3               | 1              | 1               |
| Blood creatinine increased             |                 |                |                 |
| subjects affected / exposed            | 6 / 100 (6.00%) | 4 / 98 (4.08%) | 3 / 102 (2.94%) |
| occurrences (all)                      | 7               | 4              | 3               |
| Blood glucose increased                |                 |                |                 |
| subjects affected / exposed            | 1 / 100 (1.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 1               | 0              | 1               |
| Blood pressure increased               |                 |                |                 |
| subjects affected / exposed            | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 0               | 1              | 1               |
| Blood lactate dehydrogenase increased  |                 |                |                 |
| subjects affected / exposed            | 1 / 100 (1.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                      | 1               | 0              | 0               |
| Blood phosphorus decreased             |                 |                |                 |
| subjects affected / exposed            | 2 / 100 (2.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                      | 2               | 0              | 0               |
| Blood sodium increased                 |                 |                |                 |
| subjects affected / exposed            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 0               | 0              | 1               |
| Blood uric acid increased              |                 |                |                 |

|  |                 |                |                 |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed              | 0 / 100 (0.00%) | 3 / 98 (3.06%) | 1 / 102 (0.98%) |
| occurrences (all)                        | 0               | 3              | 1               |
| Blood sodium decreased                   |                 |                |                 |
| subjects affected / exposed              | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)                        | 0               | 1              | 0               |
| Fibrin D dimer increased                 |                 |                |                 |
| subjects affected / exposed              | 5 / 100 (5.00%) | 2 / 98 (2.04%) | 4 / 102 (3.92%) |
| occurrences (all)                        | 5               | 3              | 4               |
| Gamma-glutamyltransferase increased      |                 |                |                 |
| subjects affected / exposed              | 3 / 100 (3.00%) | 1 / 98 (1.02%) | 3 / 102 (2.94%) |
| occurrences (all)                        | 3               | 1              | 3               |
| C-reactive protein increased             |                 |                |                 |
| subjects affected / exposed              | 1 / 100 (1.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                        | 1               | 0              | 1               |
| Haematocrit decreased                    |                 |                |                 |
| subjects affected / exposed              | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)                        | 0               | 1              | 0               |
| Hepatic enzyme increased                 |                 |                |                 |
| subjects affected / exposed              | 2 / 100 (2.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                        | 2               | 0              | 0               |
| Haemoglobin decreased                    |                 |                |                 |
| subjects affected / exposed              | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)                        | 0               | 1              | 0               |
| Lipase increased                         |                 |                |                 |
| subjects affected / exposed              | 6 / 100 (6.00%) | 0 / 98 (0.00%) | 3 / 102 (2.94%) |
| occurrences (all)                        | 6               | 0              | 3               |
| International normalised ratio increased |                 |                |                 |
| subjects affected / exposed              | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                        | 0               | 0              | 0               |
| Liver function test increased            |                 |                |                 |
| subjects affected / exposed              | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                        | 0               | 0              | 0               |
| Monocyte count increased                 |                 |                |                 |

|  |                      |                     |                      |
|--|----------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)                                     | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Pancreatic enzymes increased<br>subjects affected / exposed<br>occurrences (all)     | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Monocyte count decreased<br>subjects affected / exposed<br>occurrences (all)         | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Serum ferritin decreased<br>subjects affected / exposed<br>occurrences (all)         | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Prothrombin time prolonged<br>subjects affected / exposed<br>occurrences (all)       | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Platelet count increased<br>subjects affected / exposed<br>occurrences (all)         | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| White blood cell count increased<br>subjects affected / exposed<br>occurrences (all) | 1 / 100 (1.00%)<br>1 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Injury, poisoning and procedural complications                                       |                      |                     |                      |
| Bone contusion<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Fall<br>subjects affected / exposed<br>occurrences (all)                             | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Post procedural complication<br>subjects affected / exposed<br>occurrences (all)     | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Infusion related reaction<br>subjects affected / exposed<br>occurrences (all)        | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Ligament sprain  |                      |                     |                      |

|   |                      |                     |                      |
|---|----------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)  | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Procedural pain<br>subjects affected / exposed<br>occurrences (all)                                 | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Skin abrasion<br>subjects affected / exposed<br>occurrences (all)                                   | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Nervous system disorders<br>Dizziness<br>subjects affected / exposed<br>occurrences (all)           | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Headache<br>subjects affected / exposed<br>occurrences (all)  | 2 / 100 (2.00%)<br>4 | 2 / 98 (2.04%)<br>2 | 4 / 102 (3.92%)<br>4 |
| Neuropathy peripheral<br>subjects affected / exposed<br>occurrences (all)                           | 1 / 100 (1.00%)<br>1 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Blood and lymphatic system disorders<br>Anaemia<br>subjects affected / exposed<br>occurrences (all) | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 3 / 102 (2.94%)<br>3 |
| Eosinophilia<br>subjects affected / exposed<br>occurrences (all)                                    | 1 / 100 (1.00%)<br>1 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Haemorrhagic diathesis<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Iron deficiency anaemia<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Leukopenia<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Lymphadenopathy   |                      |                     |                      |

|  |                      |                     |                      |
|--|----------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)   | 2 / 100 (2.00%)<br>2 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Lymphocytosis<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Neutropenia<br>subjects affected / exposed<br>occurrences (all)                                  | 3 / 100 (3.00%)<br>3 | 1 / 98 (1.02%)<br>1 | 4 / 102 (3.92%)<br>4 |
| Eye disorders<br>Abnormal sensation in eye<br>subjects affected / exposed<br>occurrences (all)   | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Uveitis<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Disorder of globe<br>subjects affected / exposed<br>occurrences (all)                            | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Vision blurred<br>subjects affected / exposed<br>occurrences (all)                               | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Gastrointestinal disorders<br>Abdominal pain<br>subjects affected / exposed<br>occurrences (all) | 1 / 100 (1.00%)<br>1 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Constipation<br>subjects affected / exposed<br>occurrences (all)                                 | 1 / 100 (1.00%)<br>1 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Aphthous ulcer<br>subjects affected / exposed<br>occurrences (all)                               | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Diarrhoea  |                      |                     |                      |

|  |                 |                |                 |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed            | 1 / 100 (1.00%) | 1 / 98 (1.02%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 1               | 1              | 1               |
| Haemorrhoids                           |                 |                |                 |
| subjects affected / exposed            | 1 / 100 (1.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                      | 1               | 0              | 0               |
| Dyspepsia                              |                 |                |                 |
| subjects affected / exposed            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                      | 0               | 0              | 0               |
| Nausea                                 |                 |                |                 |
| subjects affected / exposed            | 3 / 100 (3.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)                      | 3               | 1              | 0               |
| Pancreatitis                           |                 |                |                 |
| subjects affected / exposed            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 0               | 0              | 1               |
| Vomiting                               |                 |                |                 |
| subjects affected / exposed            | 3 / 100 (3.00%) | 2 / 98 (2.04%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 3               | 2              | 1               |
| Hepatobiliary disorders                |                 |                |                 |
| Nonalcoholic fatty liver disease       |                 |                |                 |
| subjects affected / exposed            | 1 / 100 (1.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                      | 1               | 0              | 0               |
| Skin and subcutaneous tissue disorders |                 |                |                 |
| Dermatitis contact                     |                 |                |                 |
| subjects affected / exposed            | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)                      | 0               | 1              | 0               |
| Eczema                                 |                 |                |                 |
| subjects affected / exposed            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                      | 0               | 0              | 0               |
| Petechiae                              |                 |                |                 |
| subjects affected / exposed            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 0               | 0              | 1               |
| Rash papular                           |                 |                |                 |
| subjects affected / exposed            | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                      | 0               | 0              | 1               |
| Rash                                   |                 |                |                 |

|   |                      |                     |                      |
|---|----------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)                        | 3 / 100 (3.00%)<br>3 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Rash maculo-papular<br>subjects affected / exposed<br>occurrences (all) | 1 / 100 (1.00%)<br>1 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Renal and urinary disorders   |                      |                     |                      |
| Dysuria<br>subjects affected / exposed<br>occurrences (all)             | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Hydronephrosis<br>subjects affected / exposed<br>occurrences (all)      | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Ureterolithiasis<br>subjects affected / exposed<br>occurrences (all)    | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Renal pain<br>subjects affected / exposed<br>occurrences (all)          | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Musculoskeletal and connective tissue disorders                         |                      |                     |                      |
| Arthralgia<br>subjects affected / exposed<br>occurrences (all)          | 1 / 100 (1.00%)<br>1 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Myalgia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Back pain<br>subjects affected / exposed<br>occurrences (all)           | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Arthritis<br>subjects affected / exposed<br>occurrences (all)           | 1 / 100 (1.00%)<br>1 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Pain in extremity<br>subjects affected / exposed<br>occurrences (all)   | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Myositis  |                      |                     |                      |

|  |                      |                     |                      |
|--|----------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Infections and infestations                      |                      |                     |                      |
| COVID-19   |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 6 / 100 (6.00%)<br>6 | 2 / 98 (2.04%)<br>2 | 1 / 102 (0.98%)<br>1 |
| COVID-19 pneumonia                               |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 2 / 100 (2.00%)<br>2 | 2 / 98 (2.04%)<br>2 | 0 / 102 (0.00%)<br>0 |
| Bronchitis                                       |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Cystitis   |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Eye infection bacterial                          |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Gastroenteritis                                  |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 1 / 100 (1.00%)<br>1 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Nasopharyngitis                                  |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 5 / 100 (5.00%)<br>5 | 1 / 98 (1.02%)<br>1 | 3 / 102 (2.94%)<br>4 |
| Genital infection fungal                         |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 0 / 100 (0.00%)<br>0 | 1 / 98 (1.02%)<br>1 | 0 / 102 (0.00%)<br>0 |
| Otitis media                                     |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 1 / 100 (1.00%)<br>1 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |
| Pancreatitis viral                               |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 1 / 102 (0.98%)<br>1 |
| Oral candidiasis                                 |                      |                     |                      |
| subjects affected / exposed<br>occurrences (all) | 0 / 100 (0.00%)<br>0 | 0 / 98 (0.00%)<br>0 | 0 / 102 (0.00%)<br>0 |

|                                    |                 |                |                 |
|------------------------------------|-----------------|----------------|-----------------|
| Pyelonephritis                     |                 |                |                 |
| subjects affected / exposed        | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                  | 0               | 0              | 0               |
| Pneumonia                          |                 |                |                 |
| subjects affected / exposed        | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                  | 0               | 0              | 1               |
| Pharyngitis bacterial              |                 |                |                 |
| subjects affected / exposed        | 1 / 100 (1.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                  | 1               | 0              | 0               |
| Sinusitis                          |                 |                |                 |
| subjects affected / exposed        | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                  | 0               | 0              | 0               |
| Upper respiratory tract infection  |                 |                |                 |
| subjects affected / exposed        | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 1 / 102 (0.98%) |
| occurrences (all)                  | 0               | 1              | 1               |
| Sinusitis bacterial                |                 |                |                 |
| subjects affected / exposed        | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                  | 0               | 0              | 1               |
| Urinary tract infection            |                 |                |                 |
| subjects affected / exposed        | 1 / 100 (1.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)                  | 1               | 0              | 1               |
| Metabolism and nutrition disorders |                 |                |                 |
| Dehydration                        |                 |                |                 |
| subjects affected / exposed        | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                  | 0               | 0              | 0               |
| Diabetes mellitus                  |                 |                |                 |
| subjects affected / exposed        | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                  | 0               | 0              | 0               |
| Hyperamylasaemia                   |                 |                |                 |
| subjects affected / exposed        | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)                  | 0               | 0              | 0               |
| Hyperglycaemia                     |                 |                |                 |
| subjects affected / exposed        | 1 / 100 (1.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)                  | 1               | 1              | 0               |
| Hyperkalaemia                      |                 |                |                 |

|                             |                 |                |                 |
|-----------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all)           | 0               | 0              | 1               |
| Hyperlipidaemia             |                 |                |                 |
| subjects affected / exposed | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)           | 0               | 1              | 0               |
| Hypernatraemia              |                 |                |                 |
| subjects affected / exposed | 0 / 100 (0.00%) | 3 / 98 (3.06%) | 0 / 102 (0.00%) |
| occurrences (all)           | 0               | 3              | 0               |
| Hyperlipasaemia             |                 |                |                 |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 98 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all)           | 0               | 0              | 0               |
| Type 2 diabetes mellitus    |                 |                |                 |
| subjects affected / exposed | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)           | 0               | 1              | 0               |
| Hypokalaemia                |                 |                |                 |
| subjects affected / exposed | 0 / 100 (0.00%) | 1 / 98 (1.02%) | 0 / 102 (0.00%) |
| occurrences (all)           | 0               | 1              | 0               |

| <b>Non-serious adverse events</b>                     | Ensovibep Total    | Placebo           |  |
|---|--------------------|-------------------|--|
| Total subjects affected by non-serious adverse events |                    |                   |  |
| subjects affected / exposed                           | 131 / 300 (43.67%) | 53 / 100 (53.00%) |  |
| Vascular disorders                                    |                    |                   |  |
| Hypertension  |                    |                   |  |
| subjects affected / exposed                           | 5 / 300 (1.67%)    | 0 / 100 (0.00%)   |  |
| occurrences (all)                                     | 5                  | 0                 |  |
| Phlebitis superficial                                 |                    |                   |  |
| subjects affected / exposed                           | 1 / 300 (0.33%)    | 0 / 100 (0.00%)   |  |
| occurrences (all)                                     | 1                  | 0                 |  |
| General disorders and administration site conditions  |                    |                   |  |
| Adverse drug reaction                                 |                    |                   |  |
| subjects affected / exposed                           | 1 / 300 (0.33%)    | 0 / 100 (0.00%)   |  |
| occurrences (all)                                     | 1                  | 0                 |  |
| Asthenia  |                    |                   |  |
| subjects affected / exposed                           | 0 / 300 (0.00%)    | 1 / 100 (1.00%)   |  |
| occurrences (all)                                     | 0                  | 1                 |  |
| Fatigue   |                    |                   |  |

|  |                      |                      |  |
|--|----------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all)   | 3 / 300 (1.00%)<br>3 | 1 / 100 (1.00%)<br>1 |  |
| Infusion site haematoma<br>subjects affected / exposed<br>occurrences (all)  | 0 / 300 (0.00%)<br>0 | 2 / 100 (2.00%)<br>2 |  |
| Infusion site swelling<br>subjects affected / exposed<br>occurrences (all)   | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Non-cardiac chest pain<br>subjects affected / exposed<br>occurrences (all)   | 3 / 300 (1.00%)<br>3 | 0 / 100 (0.00%)<br>0 |  |
| Swelling face<br>subjects affected / exposed<br>occurrences (all)  | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)  | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Pain<br>subjects affected / exposed<br>occurrences (all)   | 2 / 300 (0.67%)<br>2 | 0 / 100 (0.00%)<br>0 |  |
| Vessel puncture site haematoma<br>subjects affected / exposed<br>occurrences (all)                                     | 2 / 300 (0.67%)<br>2 | 0 / 100 (0.00%)<br>0 |  |
| Immune system disorders<br>Allergy to chemicals<br>subjects affected / exposed<br>occurrences (all)                    | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Reproductive system and breast disorders<br>Menstruation irregular<br>subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Heavy menstrual bleeding<br>subjects affected / exposed<br>occurrences (all)   | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Dysmenorrhoea  |                      |                      |  |

|  |                      |                      |  |
|--|----------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Respiratory, thoracic and mediastinal disorders  |                      |                      |  |
| Asthma   |                      |                      |  |
| subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Chronic obstructive pulmonary disease            |                      |                      |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Haemoptysis                                      |                      |                      |  |
| subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Cough  |                      |                      |  |
| subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Oropharyngeal pain                               |                      |                      |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Rhinitis allergic                                |                      |                      |  |
| subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Throat irritation                                |                      |                      |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Psychiatric disorders                            |                      |                      |  |
| Anxiety  |                      |                      |  |
| subjects affected / exposed<br>occurrences (all) | 3 / 300 (1.00%)<br>3 | 0 / 100 (0.00%)<br>0 |  |
| Depression                                       |                      |                      |  |
| subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Insomnia   |                      |                      |  |
| subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Investigations                                   |                      |                      |  |

|   |                  |                 |
|---|------------------|-----------------|
| Activated partial thromboplastin time prolonged |                  |                 |
| subjects affected / exposed                     | 5 / 300 (1.67%)  | 1 / 100 (1.00%) |
| occurrences (all)                               | 5                | 1               |
| Alanine aminotransferase increased              |                  |                 |
| subjects affected / exposed                     | 11 / 300 (3.67%) | 2 / 100 (2.00%) |
| occurrences (all)                               | 11               | 2               |
| Aspartate aminotransferase increased            |                  |                 |
| subjects affected / exposed                     | 10 / 300 (3.33%) | 2 / 100 (2.00%) |
| occurrences (all)                               | 10               | 2               |
| Amylase increased                               |                  |                 |
| subjects affected / exposed                     | 6 / 300 (2.00%)  | 2 / 100 (2.00%) |
| occurrences (all)                               | 6                | 2               |
| Blood alkaline phosphatase increased            |                  |                 |
| subjects affected / exposed                     | 2 / 300 (0.67%)  | 0 / 100 (0.00%) |
| occurrences (all)                               | 2                | 0               |
| Blood bilirubin increased                       |                  |                 |
| subjects affected / exposed                     | 4 / 300 (1.33%)  | 0 / 100 (0.00%) |
| occurrences (all)                               | 4                | 0               |
| Blood creatine phosphokinase increased          |                  |                 |
| subjects affected / exposed                     | 5 / 300 (1.67%)  | 1 / 100 (1.00%) |
| occurrences (all)                               | 5                | 1               |
| Blood creatinine increased                      |                  |                 |
| subjects affected / exposed                     | 13 / 300 (4.33%) | 6 / 100 (6.00%) |
| occurrences (all)                               | 14               | 6               |
| Blood glucose increased                         |                  |                 |
| subjects affected / exposed                     | 2 / 300 (0.67%)  | 1 / 100 (1.00%) |
| occurrences (all)                               | 2                | 1               |
| Blood pressure increased                        |                  |                 |
| subjects affected / exposed                     | 2 / 300 (0.67%)  | 1 / 100 (1.00%) |
| occurrences (all)                               | 2                | 1               |
| Blood lactate dehydrogenase increased           |                  |                 |
| subjects affected / exposed                     | 1 / 300 (0.33%)  | 0 / 100 (0.00%) |
| occurrences (all)                               | 1                | 0               |
| Blood phosphorus decreased                      |                  |                 |

|  |                  |                 |
|--|------------------|-----------------|
| subjects affected / exposed              | 2 / 300 (0.67%)  | 1 / 100 (1.00%) |
| occurrences (all)                        | 2                | 1               |
| Blood sodium increased                   |                  |                 |
| subjects affected / exposed              | 1 / 300 (0.33%)  | 0 / 100 (0.00%) |
| occurrences (all)                        | 1                | 0               |
| Blood uric acid increased                |                  |                 |
| subjects affected / exposed              | 4 / 300 (1.33%)  | 1 / 100 (1.00%) |
| occurrences (all)                        | 4                | 1               |
| Blood sodium decreased                   |                  |                 |
| subjects affected / exposed              | 1 / 300 (0.33%)  | 1 / 100 (1.00%) |
| occurrences (all)                        | 1                | 1               |
| Fibrin D dimer increased                 |                  |                 |
| subjects affected / exposed              | 11 / 300 (3.67%) | 3 / 100 (3.00%) |
| occurrences (all)                        | 12               | 3               |
| Gamma-glutamyltransferase increased      |                  |                 |
| subjects affected / exposed              | 7 / 300 (2.33%)  | 1 / 100 (1.00%) |
| occurrences (all)                        | 7                | 1               |
| C-reactive protein increased             |                  |                 |
| subjects affected / exposed              | 2 / 300 (0.67%)  | 0 / 100 (0.00%) |
| occurrences (all)                        | 2                | 0               |
| Haematocrit decreased                    |                  |                 |
| subjects affected / exposed              | 1 / 300 (0.33%)  | 1 / 100 (1.00%) |
| occurrences (all)                        | 1                | 1               |
| Hepatic enzyme increased                 |                  |                 |
| subjects affected / exposed              | 2 / 300 (0.67%)  | 2 / 100 (2.00%) |
| occurrences (all)                        | 2                | 2               |
| Haemoglobin decreased                    |                  |                 |
| subjects affected / exposed              | 1 / 300 (0.33%)  | 1 / 100 (1.00%) |
| occurrences (all)                        | 1                | 1               |
| Lipase increased                         |                  |                 |
| subjects affected / exposed              | 9 / 300 (3.00%)  | 1 / 100 (1.00%) |
| occurrences (all)                        | 9                | 1               |
| International normalised ratio increased |                  |                 |

|  |                      |                      |  |
|--|----------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all)                                     | 0 / 300 (0.00%)<br>0 | 2 / 100 (2.00%)<br>2 |  |
| Liver function test increased<br>subjects affected / exposed<br>occurrences (all)    | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Monocyte count increased<br>subjects affected / exposed<br>occurrences (all)         | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Pancreatic enzymes increased<br>subjects affected / exposed<br>occurrences (all)     | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Monocyte count decreased<br>subjects affected / exposed<br>occurrences (all)         | 1 / 300 (0.33%)<br>1 | 1 / 100 (1.00%)<br>1 |  |
| Serum ferritin decreased<br>subjects affected / exposed<br>occurrences (all)         | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Prothrombin time prolonged<br>subjects affected / exposed<br>occurrences (all)       | 0 / 300 (0.00%)<br>0 | 3 / 100 (3.00%)<br>3 |  |
| Platelet count increased<br>subjects affected / exposed<br>occurrences (all)         | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| White blood cell count increased<br>subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Injury, poisoning and procedural complications                                       |                      |                      |  |
| Bone contusion<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Fall<br>subjects affected / exposed<br>occurrences (all)                             | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Post procedural complication   |                      |                      |  |

|                                      |                 |                 |  |
|--------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed          | 1 / 300 (0.33%) | 0 / 100 (0.00%) |  |
| occurrences (all)                    | 1               | 0               |  |
| Infusion related reaction            |                 |                 |  |
| subjects affected / exposed          | 1 / 300 (0.33%) | 0 / 100 (0.00%) |  |
| occurrences (all)                    | 1               | 0               |  |
| Ligament sprain                      |                 |                 |  |
| subjects affected / exposed          | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences (all)                    | 0               | 1               |  |
| Procedural pain                      |                 |                 |  |
| subjects affected / exposed          | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences (all)                    | 0               | 1               |  |
| Skin abrasion                        |                 |                 |  |
| subjects affected / exposed          | 1 / 300 (0.33%) | 0 / 100 (0.00%) |  |
| occurrences (all)                    | 1               | 0               |  |
| Nervous system disorders             |                 |                 |  |
| Dizziness                            |                 |                 |  |
| subjects affected / exposed          | 1 / 300 (0.33%) | 1 / 100 (1.00%) |  |
| occurrences (all)                    | 1               | 1               |  |
| Headache                             |                 |                 |  |
| subjects affected / exposed          | 8 / 300 (2.67%) | 1 / 100 (1.00%) |  |
| occurrences (all)                    | 10              | 1               |  |
| Neuropathy peripheral                |                 |                 |  |
| subjects affected / exposed          | 1 / 300 (0.33%) | 0 / 100 (0.00%) |  |
| occurrences (all)                    | 1               | 0               |  |
| Blood and lymphatic system disorders |                 |                 |  |
| Anaemia                              |                 |                 |  |
| subjects affected / exposed          | 3 / 300 (1.00%) | 0 / 100 (0.00%) |  |
| occurrences (all)                    | 3               | 0               |  |
| Eosinophilia                         |                 |                 |  |
| subjects affected / exposed          | 1 / 300 (0.33%) | 1 / 100 (1.00%) |  |
| occurrences (all)                    | 1               | 1               |  |
| Haemorrhagic diathesis               |                 |                 |  |
| subjects affected / exposed          | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences (all)                    | 0               | 1               |  |
| Iron deficiency anaemia              |                 |                 |  |

|   |                      |                      |  |
|---|----------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all)                              | 1 / 300 (0.33%)<br>1 | 1 / 100 (1.00%)<br>1 |  |
| Leukopenia<br>subjects affected / exposed<br>occurrences (all)                | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Lymphadenopathy<br>subjects affected / exposed<br>occurrences (all)           | 2 / 300 (0.67%)<br>2 | 0 / 100 (0.00%)<br>0 |  |
| Lymphocytosis<br>subjects affected / exposed<br>occurrences (all)             | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Neutropenia<br>subjects affected / exposed<br>occurrences (all)               | 8 / 300 (2.67%)<br>8 | 1 / 100 (1.00%)<br>1 |  |
| Eye disorders   |                      |                      |  |
| Abnormal sensation in eye<br>subjects affected / exposed<br>occurrences (all) | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Uveitis<br>subjects affected / exposed<br>occurrences (all)                   | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Disorder of globe<br>subjects affected / exposed<br>occurrences (all)         | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Vision blurred<br>subjects affected / exposed<br>occurrences (all)            | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Gastrointestinal disorders  |                      |                      |  |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)            | 2 / 300 (0.67%)<br>2 | 0 / 100 (0.00%)<br>0 |  |
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)      | 0 / 300 (0.00%)<br>0 | 2 / 100 (2.00%)<br>2 |  |
| Constipation  |                      |                      |  |

|  |                      |                      |  |
|--|----------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all)   | 2 / 300 (0.67%)<br>2 | 0 / 100 (0.00%)<br>0 |  |
| Aphthous ulcer<br>subjects affected / exposed<br>occurrences (all)   | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)  | 3 / 300 (1.00%)<br>3 | 1 / 100 (1.00%)<br>1 |  |
| Haemorrhoids<br>subjects affected / exposed<br>occurrences (all)   | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Dyspepsia<br>subjects affected / exposed<br>occurrences (all)  | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Nausea<br>subjects affected / exposed<br>occurrences (all)   | 4 / 300 (1.33%)<br>4 | 2 / 100 (2.00%)<br>2 |  |
| Pancreatitis<br>subjects affected / exposed<br>occurrences (all)   | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)   | 6 / 300 (2.00%)<br>6 | 1 / 100 (1.00%)<br>1 |  |
| Hepatobiliary disorders<br>Nonalcoholic fatty liver disease<br>subjects affected / exposed<br>occurrences (all)  | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Skin and subcutaneous tissue disorders<br>Dermatitis contact<br>subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 2 / 100 (2.00%)<br>2 |  |
| Eczema<br>subjects affected / exposed<br>occurrences (all)   | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Petechiae  |                      |                      |  |

|   |                      |                      |  |
|---|----------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all)  | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Rash papular<br>subjects affected / exposed<br>occurrences (all)  | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Rash<br>subjects affected / exposed<br>occurrences (all)  | 4 / 300 (1.33%)<br>4 | 0 / 100 (0.00%)<br>0 |  |
| Rash maculo-papular<br>subjects affected / exposed<br>occurrences (all)   | 1 / 300 (0.33%)<br>1 | 1 / 100 (1.00%)<br>1 |  |
| Renal and urinary disorders<br>Dysuria<br>subjects affected / exposed<br>occurrences (all)                        | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Hydronephrosis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Ureterolithiasis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 300 (0.00%)<br>0 | 1 / 100 (1.00%)<br>1 |  |
| Renal pain<br>subjects affected / exposed<br>occurrences (all)  | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Myalgia<br>subjects affected / exposed<br>occurrences (all)   | 1 / 300 (0.33%)<br>1 | 0 / 100 (0.00%)<br>0 |  |
| Back pain<br>subjects affected / exposed<br>occurrences (all)   | 1 / 300 (0.33%)<br>1 | 1 / 100 (1.00%)<br>1 |  |
| Arthritis   |                      |                      |  |

|  |                       |                      |  |
|--|-----------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all)                             | 1 / 300 (0.33%)<br>1  | 0 / 100 (0.00%)<br>0 |  |
| Pain in extremity<br>subjects affected / exposed<br>occurrences (all)        | 1 / 300 (0.33%)<br>1  | 0 / 100 (0.00%)<br>0 |  |
| Myositis<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 300 (0.33%)<br>1  | 0 / 100 (0.00%)<br>0 |  |
| Infections and infestations  |                       |                      |  |
| COVID-19<br>subjects affected / exposed<br>occurrences (all)                 | 9 / 300 (3.00%)<br>9  | 4 / 100 (4.00%)<br>4 |  |
| COVID-19 pneumonia<br>subjects affected / exposed<br>occurrences (all)       | 4 / 300 (1.33%)<br>4  | 1 / 100 (1.00%)<br>1 |  |
| Bronchitis<br>subjects affected / exposed<br>occurrences (all)               | 1 / 300 (0.33%)<br>1  | 1 / 100 (1.00%)<br>1 |  |
| Cystitis<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 300 (0.00%)<br>0  | 1 / 100 (1.00%)<br>1 |  |
| Eye infection bacterial<br>subjects affected / exposed<br>occurrences (all)  | 1 / 300 (0.33%)<br>1  | 0 / 100 (0.00%)<br>0 |  |
| Gastroenteritis<br>subjects affected / exposed<br>occurrences (all)          | 1 / 300 (0.33%)<br>1  | 0 / 100 (0.00%)<br>0 |  |
| Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)          | 9 / 300 (3.00%)<br>10 | 5 / 100 (5.00%)<br>5 |  |
| Genital infection fungal<br>subjects affected / exposed<br>occurrences (all) | 1 / 300 (0.33%)<br>1  | 0 / 100 (0.00%)<br>0 |  |
| Otitis media<br>subjects affected / exposed<br>occurrences (all)             | 1 / 300 (0.33%)<br>1  | 0 / 100 (0.00%)<br>0 |  |

|                                    |                 |                 |  |
|------------------------------------|-----------------|-----------------|--|
| Pancreatitis viral                 |                 |                 |  |
| subjects affected / exposed        | 1 / 300 (0.33%) | 0 / 100 (0.00%) |  |
| occurrences (all)                  | 1               | 0               |  |
| Oral candidiasis                   |                 |                 |  |
| subjects affected / exposed        | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences (all)                  | 0               | 1               |  |
| Pyelonephritis                     |                 |                 |  |
| subjects affected / exposed        | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences (all)                  | 0               | 1               |  |
| Pneumonia                          |                 |                 |  |
| subjects affected / exposed        | 1 / 300 (0.33%) | 0 / 100 (0.00%) |  |
| occurrences (all)                  | 1               | 0               |  |
| Pharyngitis bacterial              |                 |                 |  |
| subjects affected / exposed        | 1 / 300 (0.33%) | 0 / 100 (0.00%) |  |
| occurrences (all)                  | 1               | 0               |  |
| Sinusitis                          |                 |                 |  |
| subjects affected / exposed        | 0 / 300 (0.00%) | 2 / 100 (2.00%) |  |
| occurrences (all)                  | 0               | 2               |  |
| Upper respiratory tract infection  |                 |                 |  |
| subjects affected / exposed        | 2 / 300 (0.67%) | 1 / 100 (1.00%) |  |
| occurrences (all)                  | 2               | 1               |  |
| Sinusitis bacterial                |                 |                 |  |
| subjects affected / exposed        | 1 / 300 (0.33%) | 0 / 100 (0.00%) |  |
| occurrences (all)                  | 1               | 0               |  |
| Urinary tract infection            |                 |                 |  |
| subjects affected / exposed        | 2 / 300 (0.67%) | 1 / 100 (1.00%) |  |
| occurrences (all)                  | 2               | 1               |  |
| Metabolism and nutrition disorders |                 |                 |  |
| Dehydration                        |                 |                 |  |
| subjects affected / exposed        | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences (all)                  | 0               | 1               |  |
| Diabetes mellitus                  |                 |                 |  |
| subjects affected / exposed        | 0 / 300 (0.00%) | 1 / 100 (1.00%) |  |
| occurrences (all)                  | 0               | 1               |  |
| Hyperamylasaemia                   |                 |                 |  |

|                             |                 |                 |
|-----------------------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 300 (0.00%) | 1 / 100 (1.00%) |
| occurrences (all)           | 0               | 1               |
| Hyperglycaemia              |                 |                 |
| subjects affected / exposed | 2 / 300 (0.67%) | 0 / 100 (0.00%) |
| occurrences (all)           | 2               | 0               |
| Hyperkalaemia               |                 |                 |
| subjects affected / exposed | 1 / 300 (0.33%) | 0 / 100 (0.00%) |
| occurrences (all)           | 1               | 0               |
| Hyperlipidaemia             |                 |                 |
| subjects affected / exposed | 1 / 300 (0.33%) | 0 / 100 (0.00%) |
| occurrences (all)           | 1               | 0               |
| Hypernatraemia              |                 |                 |
| subjects affected / exposed | 3 / 300 (1.00%) | 1 / 100 (1.00%) |
| occurrences (all)           | 3               | 1               |
| Hyperlipasaemia             |                 |                 |
| subjects affected / exposed | 0 / 300 (0.00%) | 1 / 100 (1.00%) |
| occurrences (all)           | 0               | 1               |
| Type 2 diabetes mellitus    |                 |                 |
| subjects affected / exposed | 1 / 300 (0.33%) | 1 / 100 (1.00%) |
| occurrences (all)           | 1               | 1               |
| Hypokalaemia                |                 |                 |
| subjects affected / exposed | 1 / 300 (0.33%) | 0 / 100 (0.00%) |
| occurrences (all)           | 1               | 0               |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date            | Amendment   |
|-----------------|---|
| 19 October 2021 | <ul style="list-style-type: none"><li>- The key changes included clarification regarding the laboratory data available at the time of the database lock (DBL), unblinding after DBL, and statistical analysis.</li><li>- For the primary analysis some of the biomarker assessments may not be fully completed. In this context, updates have been made to the unblinding process after the primary analysis for Part A.</li><li>- The primary estimand wording was updated to follow recently published guidelines (FDA 2021). The COVID-19 related hospitalizations were added as intercurrent events for the primary endpoint; a composite strategy was to be used to handle these intercurrent events.</li><li>- The definition of adverse event of special interest was updated and was no longer limited to adverse event onset within 24 h after dosing, it included infusion-site reactions and any type of hypersensitivity reactions (Grade <math>\geq 2</math>). The reporting requirements and follow-up testing for renal events were adjusted.</li><li>- The end of study assessments were clarified per a footnote in the assessment schedule.</li><li>- The study stopping rules were clarified to follow common terminology criteria for adverse events grading and to explicitly include laboratory findings.</li><li>- A clarification was added to distinguish between hospitalizations due to worsening of COVID-19 (secondary endpoint) and between hospitalizations meant for isolating patients following a positive SARS-CoV-2 test (not counted towards secondary endpoint).</li><li>- The requirements for viral genotyping were updated to ensure that all reverse transcription-polymerase chain reaction positive samples at Baseline and from Day 8 onwards, or last positive sample in case of no viral load from Day 8 onwards, were sequenced.</li><li>- In the statistical section, clarification on the multiple comparison procedure-modeling procedure was added and the symptom scores in Long COVID-19 questionnaire were explained.</li><li>- Also, 2 local amendments for the USA and for India were incorporated into this global amendment.</li></ul> |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The Part B of the study was not initiated based on regulatory feedback indicating that with evolving treatment options, a placebo controlled design was no longer considered to be appropriate.

Notes: