



## Clinical trial results:

**A trial comparing the efficacy and safety of once weekly dosing of somapacitan with daily Norditropin® in Chinese children with growth hormone deficiency**

### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2020-002974-28   |
| Trial protocol           | Outside EU/EEA   |
| Global end of trial date | 18 December 2023 |

### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 04 July 2024 |
| First version publication date | 04 July 2024 |

### Trial information

#### Trial identification

|                       |             |
|-----------------------|-------------|
| Sponsor protocol code | NN8640-4468 |
|-----------------------|-------------|

#### Additional study identifiers

|                                    |                 |
|------------------------------------|-----------------|
| ISRCTN number                      | -               |
| ClinicalTrials.gov id (NCT number) | NCT04970654     |
| WHO universal trial number (UTN)   | U1111-1250-7530 |

Notes:

### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Novo Nordisk A/S  |
| Sponsor organisation address | Novo Alle, Bagsvaerd, Denmark, 2880   |
| Public contact               | Clinical Reporting Office (2834), Novo Nordisk A/S,<br>clinicaltrials@novonordisk.com |
| Scientific contact           | Clinical Reporting Office (2834), Novo Nordisk A/S,<br>clinicaltrials@novonordisk.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? | Yes |

Notes:

## Results analysis stage

|  |                  |
|--|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 05 February 2024 |
| Is this the analysis of the primary completion data? | No               |

|                                  |                  |
|----------------------------------|------------------|
| Global end of trial reached?     | Yes              |
| Global end of trial date         | 18 December 2023 |
| Was the trial ended prematurely? | No               |

Notes:

## General information about the trial

Main objective of the trial:

To compare efficacy of somapacitan vs Norditropin on longitudinal growth in Chinese children with growth hormone deficiency (GHD)

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki (October 2013) and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (November 2016) including archiving of essential documents.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

|   |              |
|---|--------------|
| Actual start date of recruitment                          | 22 July 2021 |
| Long term follow-up planned                               | No           |
| Independent data monitoring committee (IDMC) involvement? | No           |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |            |
|--------------------------------------|------------|
| Country: Number of subjects enrolled | China: 110 |
| Worldwide total number of subjects   | 110        |
| EEA total number of subjects         | 0          |

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)                     | 110 |
| Adolescents (12-17 years)                 | 0   |
| Adults (18-64 years)                      | 0   |
| From 65 to 84 years                       | 0   |

|                   |   |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

## Subject disposition

### Recruitment

Recruitment details:

The trial was conducted at 20 sites in China.

### Pre-assignment

Screening details:

A total of 110 subjects were randomised in a 2:1 ratio to receive either somapacitan or Norditropin.

### Period 1

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

### Arms

|                              |     |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

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

Arm description:

Subjects received Norditropin 0.034 milligrams per kilogram (mg/kg) subcutaneously (s.c.) once daily with prefilled pen-injector for 52 weeks.

|  |                        |
|--|------------------------|
| Arm type                               | Active comparator      |
| Investigational medicinal product name | Norditropin            |
| Investigational medicinal product code |                        |
| Other name                             | Norditropin FlexPro    |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Subcutaneous use       |

Dosage and administration details:

Norditropin 0.034 milligrams per kilogram (mg/kg) given subcutaneously (s.c.) once daily with prefilled pen-injector for 52 weeks.

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

Arm description:

Subjects received somapacitan 0.16 milligrams per kilogram (mg/kg) s.c. once weekly with prefilled pen-injector for 52 weeks.

|  |                        |
|--|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | Somapacitan            |
| Investigational medicinal product code |                        |
| Other name                             | Sogroya                |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Subcutaneous use       |

Dosage and administration details:

Somapacitan 0.16 milligrams per kilogram (mg/kg) given s.c. once weekly with prefilled pen-injector for 52 weeks.

| <b>Number of subjects in period 1</b> | Norditropin | Somapacitan |
|---------------------------------------|-------------|-------------|
| Started                               | 36          | 74          |
| Completed                             | 32          | 71          |
| Not completed                         | 4           | 3           |
| Unspecified                           | 2           | 1           |
| Lost to follow-up                     | 1           | -           |
| Withdrawal by parent/guardian         | 1           | 2           |

## Baseline characteristics

### Reporting groups

|                       |             |
|-----------------------|-------------|
| Reporting group title | Norditropin |
|-----------------------|-------------|

Reporting group description:

Subjects received Norditropin 0.034 milligrams per kilogram (mg/kg) subcutaneously (s.c.) once daily with prefilled pen-injector for 52 weeks.

|                       |             |
|-----------------------|-------------|
| Reporting group title | Somapacitan |
|-----------------------|-------------|

Reporting group description:

Subjects received somapacitan 0.16 milligrams per kilogram (mg/kg) s.c. once weekly with prefilled pen-injector for 52 weeks.

| Reporting group values                             | Norditropin | Somapacitan | Total |
|--|-------------|-------------|-------|
| Number of subjects                                 | 36          | 74          | 110   |
| Age Categorical                                    |             |             |       |
| Units: Subjects                                    |             |             |       |
| In utero   | 0           | 0           | 0     |
| Preterm newborn infants (gestational age < 37 wks) | 0           | 0           | 0     |
| Newborns (0-27 days)                               | 0           | 0           | 0     |
| Infants and toddlers (28 days-23 months)           | 0           | 0           | 0     |
| Children (2-11 years)                              | 36          | 74          | 110   |
| Adolescents (12-17 years)                          | 0           | 0           | 0     |
| Adults (18-64 years)                               | 0           | 0           | 0     |
| From 65-84 years                                   | 0           | 0           | 0     |
| 85 years and over                                  | 0           | 0           | 0     |
| Age Continuous                                     |             |             |       |
| Units: years                                       |             |             |       |
| arithmetic mean                                    | 6.5         | 6.6         |       |
| standard deviation                                 | ± 2.3       | ± 2.1       | -     |
| Gender Categorical                                 |             |             |       |
| Units: Subjects                                    |             |             |       |
| Female   | 6           | 9           | 15    |
| Male   | 30          | 65          | 95    |

## End points

### End points reporting groups

|  |             |
|--|-------------|
| Reporting group title  | Norditropin |
| Reporting group description:<br>Subjects received Norditropin 0.034 milligrams per kilogram (mg/kg) subcutaneously (s.c.) once daily with prefilled pen-injector for 52 weeks. |             |
| Reporting group title  | Somapacitan |
| Reporting group description:<br>Subjects received somapacitan 0.16 milligrams per kilogram (mg/kg) s.c. once weekly with prefilled pen-injector for 52 weeks.                  |             |

### Primary: Height Velocity

|   |                 |
|---|-----------------|
| End point title   | Height Velocity |
| End point description:<br>Height velocity (HV) at week 52 is reported and was derived from height measurements taken at baseline and week 52 visit in the following way: $HV = (\text{height at 52 weeks visit} - \text{height at baseline}) / (\text{time from baseline to 52 weeks visit in years})$ . Full analysis set included all subjects randomised. Number of Subjects Analyzed = subjects who were evaluated for this endpoint. |                 |
| End point type  | Primary         |
| End point timeframe:<br>Height velocity (annualised) at week 52   |                 |

| End point values                      | Norditropin       | Somapacitan       |  |  |
|---------------------------------------|-------------------|-------------------|--|--|
| Subject group type                    | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed           | 32                | 71                |  |  |
| Units: centimetres per year (cm/year) |                   |                   |  |  |
| arithmetic mean (standard deviation)  | 10.5 ( $\pm$ 2.3) | 11.0 ( $\pm$ 2.1) |  |  |

### Statistical analyses

|   |                                |
|---|--------------------------------|
| Statistical analysis title  | Statistical analysis 1         |
| Statistical analysis description:<br>Height velocity at 52 weeks was analysed using a mixed model for repeated measurements, with treatment, gender, age group, growth hormone peak group and gender by age group interaction term as factors and baseline height as a covariate, all nested within week as a factor. |                                |
| Comparison groups   | Norditropin v Somapacitan      |
| Number of subjects included in analysis   | 103                            |
| Analysis specification  | Pre-specified                  |
| Analysis type   | non-inferiority <sup>[1]</sup> |
| Parameter estimate  | Treatment difference           |
| Point estimate  | 0.6                            |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -0.2    |
| upper limit         | 1.3     |

Notes:

[1] - The non-inferiority margin of -2.0 cm/year was used in the trial. Subjects in this analysis were 110 (as analysis is based on repeated measurements, all data till week 52 is included in the analysis), incorrectly displayed as 103.

### Secondary: Change in Height Standard Deviation Score (HSDS)

|                 |  |
|-----------------|--|
| End point title | Change in Height Standard Deviation Score (HSDS) |
|-----------------|--|

End point description:

Change from baseline in HSDS at week 52 is reported. HSDS was derived using Chinese general population standards as reference data. The range for HSDS was -10 to +10. Negative scores indicated a height below the mean height for a child with the same age and gender, whereas positive scores indicated a height above the mean height for a child with the same age and gender. Positive value in change from baseline in HSDS indicated that HSDS was better than baseline HSDS. Data is reported for 'on-treatment' observation period. On-treatment observation period: from first administration and up until last trial contact, visit 7 (week 52) or 14 days after last administration, whichever came first. Full analysis set included all subjects randomised. Number of Subjects Analyzed = subjects who were evaluated for this endpoint.

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

End point timeframe:

From baseline (week 0) to week 52

| End point values                     | Norditropin     | Somapacitan     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 32              | 69              |  |  |
| Units: Standard deviation score      |                 |                 |  |  |
| arithmetic mean (standard deviation) | 1.13 (± 0.48)   | 1.21 (± 0.46)   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change in Bone Age

|                 |                    |
|-----------------|--------------------|
| End point title | Change in Bone Age |
|-----------------|--------------------|

End point description:

Change in bone age from visit 1 (week -14) to week 52 is reported. X-rays of left hand and wrist for bone age assessment according to the Greulich and Pyle atlas were taken. Data is reported for 'on-treatment' observation period. On-treatment observation period: from first administration and up until last trial contact, visit 7 (week 52) or 14 days after last administration, whichever came first. Full analysis set included all subjects randomised. Number of Subjects Analyzed = subjects who were evaluated for this endpoint.

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

End point timeframe:

From visit 1 (week -14) to week 52



| End point values                     | Norditropin      | Somapacitan      |  |  |
|--------------------------------------|------------------|------------------|--|--|
| Subject group type                   | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed          | 32               | 68               |  |  |
| Units: Years                         |                  |                  |  |  |
| arithmetic mean (standard deviation) | 1.3 ( $\pm$ 0.6) | 1.2 ( $\pm$ 0.9) |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change in Height Velocity Standard Deviation Score (HV SDS)

|                 |   |
|-----------------|---|
| End point title | Change in Height Velocity Standard Deviation Score (HV SDS) |
|-----------------|---|

End point description:

Change from baseline in HV SDS at week 52 is reported. HV SDS was derived using Prader standards as reference data & calculated as (height velocity - mean)/standard deviation (SD), where height velocity (HV) was the HV variable measured, mean and SD of HV by gender and age for the reference population. The range for HV SDS was -10 to +10. Negative scores indicated a HV below the mean HV for a child with the same age and gender, whereas positive scores indicated a HV above the mean HV for a child with the same age and gender. Positive value in change from baseline in HV SDS indicated that HV SDS was better than baseline HV SDS. Data is reported for 'on-treatment' observation period. On-treatment observation period: from first administration and up until last trial contact, visit 7 (week 52) or 14 days after last administration, whichever came first. Full analysis set included all subjects randomised. Number of Subjects Analyzed = subjects who were evaluated for this endpoint.

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

End point timeframe:

From baseline (week 0) to week 52

| End point values                     | Norditropin        | Somapacitan        |  |  |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type                   | Reporting group    | Reporting group    |  |  |
| Number of subjects analysed          | 32                 | 69                 |  |  |
| Units: Standard deviation score      |                    |                    |  |  |
| arithmetic mean (standard deviation) | 8.34 ( $\pm$ 3.01) | 8.96 ( $\pm$ 3.53) |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change in Glycated Haemoglobin (HbA1c)

|                 |  |
|-----------------|--|
| End point title | Change in Glycated Haemoglobin (HbA1c) |
|-----------------|--|

End point description:

Change from baseline in HbA1c at week 52 is reported. Data is reported for 'on-treatment' observation period. On-treatment observation period: from first administration and up until last trial contact, visit 7

(week 52) or 14 days after last administration, whichever came first. Safety analysis set included all subjects randomly assigned to trial treatment & who took at least 1 dose of trial product. Number of Subjects Analyzed = subjects who were evaluated for this endpoint.

|                                   |           |
|-----------------------------------|-----------|
| End point type                    | Secondary |
| End point timeframe:              |           |
| From baseline (week 0) to week 52 |           |

| End point values                     | Norditropin        | Somapacitan        |  |  |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type                   | Reporting group    | Reporting group    |  |  |
| Number of subjects analysed          | 32                 | 69                 |  |  |
| Units: Percentage of HbA1c           |                    |                    |  |  |
| arithmetic mean (standard deviation) | 0.09 ( $\pm$ 0.31) | 0.19 ( $\pm$ 0.25) |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change in Fasting Plasma Glucose (FPG)

|  |  |
|--|--|
| End point title  | Change in Fasting Plasma Glucose (FPG) |
| End point description:   |  |
| Change from baseline in FPG at week 52 is reported. Data is reported for 'on-treatment' observation period. On-treatment observation period: from first administration and up until last trial contact, visit 7 (week 52) or 14 days after last administration, whichever came first. Safety analysis set included all subjects randomly assigned to trial treatment & who took at least 1 dose of trial product. Number of Subjects Analyzed = subjects who were evaluated for this endpoint. |  |
| End point type   | Secondary                              |
| End point timeframe:   |  |
| From baseline (week 0) to week 52  |  |

| End point values                     | Norditropin          | Somapacitan          |  |  |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type                   | Reporting group      | Reporting group      |  |  |
| Number of subjects analysed          | 32                   | 68                   |  |  |
| Units: Millimoles per litre (mmol/L) |                      |                      |  |  |
| arithmetic mean (standard deviation) | 0.541 ( $\pm$ 0.523) | 0.304 ( $\pm$ 0.521) |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change in Insulin-like Growth Factor I (IGF-I) Standard Deviation Score (SDS)

|   |   |
|---|---|
| End point title   | Change in Insulin-like Growth Factor I (IGF-I) Standard Deviation Score (SDS) |
| End point description:  |   |
| Change from baseline in IGF-I SDS at week 52 is reported. The range for IGF-I SDS was from -10 to +10. Negative scores indicated a IGF-I below the mean IGF-I for a child with the same age and gender, whereas positive scores indicated a IGF-I above the mean IGF-I for a child with the same age and gender. For subjects with low IGF-I SDS at baseline, a positive change from baseline in IGF-I SDS indicated a better outcome. Data is reported for 'on-treatment' observation period. On-treatment observation period: from first administration and up until last trial contact, visit 7 (week 52) or 14 days after last administration, whichever came first. Full analysis set included all subjects randomised. Number of Subjects Analyzed = subjects who were evaluated for this endpoint. |   |
| End point type  | Secondary   |
| End point timeframe:  |   |
| From baseline (week 0) to week 52   |   |

| End point values                     | Norditropin        | Somapacitan        |  |  |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type                   | Reporting group    | Reporting group    |  |  |
| Number of subjects analysed          | 32                 | 67                 |  |  |
| Units: Standard deviation score      |                    |                    |  |  |
| arithmetic mean (standard deviation) | 1.73 ( $\pm$ 1.00) | 2.09 ( $\pm$ 1.28) |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change in Insulin-like Growth Factor Binding Protein 3 (IGFBP-3) Standard Deviation Score (SDS)

|   |   |
|---|---|
| End point title   | Change in Insulin-like Growth Factor Binding Protein 3 (IGFBP-3) Standard Deviation Score (SDS) |
| End point description:  |   |
| Change from baseline in IGFBP-3 SDS at week 52 is reported. The range for IGFBP-3 SDS was from -10 to +10. Negative scores indicated a IGFBP-3 below the mean IGFBP-3 for a child with the same age and gender, whereas positive scores indicated a IGFBP-3 above the mean IGFBP-3 for a child with the same age and gender. For subjects with low IGFBP-3 SDS at baseline, a positive change from baseline in IGFBP-3 SDS indicated a better outcome. Data is reported for 'on-treatment' observation period. On-treatment observation period: from first administration and up until last trial contact, visit 7 (week 52) or 14 days after last administration, whichever came first. Full analysis set included all subjects randomised. Number of Subjects Analyzed = subjects who were evaluated for this endpoint. |   |
| End point type  | Secondary   |
| End point timeframe:  |   |
| From baseline (week 0) to week 52   |   |

|                                      |                 |                 |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| <b>End point values</b>              | Norditropin     | Somapacitan     |  |  |
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 32              | 67              |  |  |
| Units: Standard deviation score      |                 |                 |  |  |
| arithmetic mean (standard deviation) | 0.93 (± 0.75)   | 1.06 (± 0.87)   |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to week 70

Adverse event reporting additional description:

All presented adverse events are treatment emergent, defined as adverse events with onset after the first administration of trial product & up until 14 days after last trial drug administration. Safety analysis set included all subjects randomly assigned to trial treatment & who took at least 1 dose of trial product.

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

### Dictionary used

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

|                    |    |
|--------------------|----|
| Dictionary version | 22 |
|--------------------|----|

### Reporting groups

|                       |             |
|-----------------------|-------------|
| Reporting group title | somapacitan |
|-----------------------|-------------|

Reporting group description:

Subjects received somapacitan 0.16 milligrams per kilogram (mg/kg) s.c. once weekly with prefilled pen-injector for 52 weeks.

|                       |             |
|-----------------------|-------------|
| Reporting group title | Norditropin |
|-----------------------|-------------|

Reporting group description:

Subjects received Norditropin subcutaneous (s.c.) 0.034 milligrams per kilogram (mg/kg) once daily with prefilled pen-injector for 52 weeks.

| Serious adverse events                               | somapacitan     | Norditropin    |  |
|--|-----------------|----------------|--|
| Total subjects affected by serious adverse events    |                 |                |  |
| subjects affected / exposed                          | 8 / 74 (10.81%) | 1 / 36 (2.78%) |  |
| number of deaths (all causes)                        | 0               | 0              |  |
| number of deaths resulting from adverse events       | 0               | 0              |  |
| General disorders and administration site conditions |                 |                |  |
| Oedema   |                 |                |  |
| subjects affected / exposed                          | 1 / 74 (1.35%)  | 0 / 36 (0.00%) |  |
| occurrences causally related to treatment / all      | 1 / 1           | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0          |  |
| Gastrointestinal disorders                           |                 |                |  |
| Gastritis  |                 |                |  |
| subjects affected / exposed                          | 1 / 74 (1.35%)  | 0 / 36 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 1           | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0          |  |
| Inguinal hernia                                      |                 |                |  |

|   |                |                |  |
|---|----------------|----------------|--|
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 36 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Upper gastrointestinal haemorrhage              |                |                |  |
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 36 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Respiratory, thoracic and mediastinal disorders |                |                |  |
| Adenoidal hypertrophy                           |                |                |  |
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 36 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Tonsillar hypertrophy                           |                |                |  |
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 36 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Infections and infestations                     |                |                |  |
| Adenovirus infection                            |                |                |  |
| subjects affected / exposed                     | 1 / 74 (1.35%) | 0 / 36 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Bronchitis                                      |                |                |  |
| subjects affected / exposed                     | 2 / 74 (2.70%) | 0 / 36 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pneumonia                                       |                |                |  |
| subjects affected / exposed                     | 2 / 74 (2.70%) | 0 / 36 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Tonsillitis                                     |                |                |  |
| subjects affected / exposed                     | 0 / 74 (0.00%) | 1 / 36 (2.78%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

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

| <b>Non-serious adverse events</b>                     | somapacitan      | Norditropin      |  |
|---|------------------|------------------|--|
| Total subjects affected by non-serious adverse events |                  |                  |  |
| subjects affected / exposed                           | 60 / 74 (81.08%) | 29 / 36 (80.56%) |  |
| Investigations  |                  |                  |  |
| Blood glucose increased                               |                  |                  |  |
| subjects affected / exposed                           | 2 / 74 (2.70%)   | 2 / 36 (5.56%)   |  |
| occurrences (all)                                     | 3                | 2                |  |
| General disorders and administration site conditions  |                  |                  |  |
| Influenza like illness                                |                  |                  |  |
| subjects affected / exposed                           | 0 / 74 (0.00%)   | 2 / 36 (5.56%)   |  |
| occurrences (all)                                     | 0                | 2                |  |
| Pyrexia   |                  |                  |  |
| subjects affected / exposed                           | 18 / 74 (24.32%) | 6 / 36 (16.67%)  |  |
| occurrences (all)                                     | 23               | 9                |  |
| Gastrointestinal disorders                            |                  |                  |  |
| Diarrhoea   |                  |                  |  |
| subjects affected / exposed                           | 3 / 74 (4.05%)   | 2 / 36 (5.56%)   |  |
| occurrences (all)                                     | 3                | 2                |  |
| Dyspepsia   |                  |                  |  |
| subjects affected / exposed                           | 4 / 74 (5.41%)   | 2 / 36 (5.56%)   |  |
| occurrences (all)                                     | 4                | 2                |  |
| Gastritis   |                  |                  |  |
| subjects affected / exposed                           | 2 / 74 (2.70%)   | 2 / 36 (5.56%)   |  |
| occurrences (all)                                     | 2                | 2                |  |
| Respiratory, thoracic and mediastinal disorders       |                  |                  |  |
| Cough   |                  |                  |  |
| subjects affected / exposed                           | 12 / 74 (16.22%) | 7 / 36 (19.44%)  |  |
| occurrences (all)                                     | 22               | 12               |  |
| Rhinorrhoea   |                  |                  |  |

|   |                        |                        |  |
|---|------------------------|------------------------|--|
| subjects affected / exposed<br>occurrences (all)                          | 1 / 74 (1.35%)<br>1    | 2 / 36 (5.56%)<br>3    |  |
| Tonsillar hypertrophy<br>subjects affected / exposed<br>occurrences (all) | 0 / 74 (0.00%)<br>0    | 2 / 36 (5.56%)<br>2    |  |
| Infections and infestations   |                        |                        |  |
| COVID-19  |                        |                        |  |
| subjects affected / exposed<br>occurrences (all)                          | 11 / 74 (14.86%)<br>11 | 7 / 36 (19.44%)<br>7   |  |
| Influenza   |                        |                        |  |
| subjects affected / exposed<br>occurrences (all)                          | 3 / 74 (4.05%)<br>3    | 3 / 36 (8.33%)<br>4    |  |
| Respiratory tract infection   |                        |                        |  |
| subjects affected / exposed<br>occurrences (all)                          | 9 / 74 (12.16%)<br>17  | 5 / 36 (13.89%)<br>9   |  |
| Rhinitis  |                        |                        |  |
| subjects affected / exposed<br>occurrences (all)                          | 1 / 74 (1.35%)<br>1    | 3 / 36 (8.33%)<br>3    |  |
| Tonsillitis   |                        |                        |  |
| subjects affected / exposed<br>occurrences (all)                          | 4 / 74 (5.41%)<br>4    | 1 / 36 (2.78%)<br>1    |  |
| Upper respiratory tract infection   |                        |                        |  |
| subjects affected / exposed<br>occurrences (all)                          | 40 / 74 (54.05%)<br>74 | 15 / 36 (41.67%)<br>24 |  |
| Bronchitis  |                        |                        |  |
| subjects affected / exposed<br>occurrences (all)                          | 7 / 74 (9.46%)<br>7    | 4 / 36 (11.11%)<br>8   |  |
| Metabolism and nutrition disorders  |                        |                        |  |
| Hypertriglyceridaemia   |                        |                        |  |
| subjects affected / exposed<br>occurrences (all)                          | 0 / 74 (0.00%)<br>0    | 2 / 36 (5.56%)<br>2    |  |



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported