



## Clinical trial results:

### Tracleer - Therapie bei Patienten mit Downsyndrom und Eisenmengerreaktion: Verträglichkeit und hämodynamische Wirkungen. Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2005-005584-28 |
| Trial protocol           | AT             |
| Global end of trial date | 30 June 2006   |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 13 December 2021 |
| First version publication date | 13 December 2021 |

#### Trial information

##### Trial identification

|                       |                     |
|-----------------------|---------------------|
| Sponsor protocol code | Version 1 4.11.2005 |
|-----------------------|---------------------|

##### Additional study identifiers

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

Notes:

#### Sponsors

|                              |                                                                                                                                         |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Medical University Innsbruck                                                                                                            |
| Sponsor organisation address | Christoph-Probst-Platz 1, Innrain 52, Innsbruck, Austria, 6020                                                                          |
| Public contact               | Univ.Prof. Dr. Ralf Geiger, Paediatrics III,<br>Anichstrasse 35,<br>6020 Innsbruck, +43 (0)512-504-23510, ralf.geiger@tirol-kliniken.at |
| Scientific contact           | Univ.Prof. Dr. Ralf Geiger, Paediatrics III,<br>Anichstrasse 35,<br>6020 Innsbruck, +43 (0)512-504-23510, ralf.geiger@tirol-kliniken.at |

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? | Yes |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No  |

Notes:

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**Results analysis stage**

|                                                      |              |
|------------------------------------------------------|--------------|
| Analysis stage                                       | Final        |
| Date of interim/final analysis                       | 30 June 2006 |
| Is this the analysis of the primary completion data? | No           |
| Global end of trial reached?                         | Yes          |
| Global end of trial date                             | 30 June 2006 |
| Was the trial ended prematurely?                     | Yes          |

Notes:

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**General information about the trial**

Main objective of the trial:

1. Dokumentation der Effekte von Tracleer auf die systemische Sauerstoffsättigung bei Patienten mit Downsyndrom und Eisenmenger-Reaktion

Protection of trial subjects:

Trial has never been started.

Background therapy:

-

Evidence for comparator:

-

|                                                           |               |
|-----------------------------------------------------------|---------------|
| Actual start date of recruitment                          | 13 March 2006 |
| Long term follow-up planned                               | No            |
| Independent data monitoring committee (IDMC) involvement? | No            |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |                |
|--------------------------------------|----------------|
| Country: Number of subjects enrolled | Austria: 99999 |
| Worldwide total number of subjects   | 99999          |
| EEA total number of subjects         | 99999          |

Notes:

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**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)                     | 99999 |
| 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:

Trial has never been started. "99999" is a value for 0 participants.

### Pre-assignment

Screening details:

Trial has never been started. "99999" is a value for 0 participants.

### Period 1

|                              |                            |
|------------------------------|----------------------------|
| Period 1 title               | Treatment (overall period) |
| Is this the baseline period? | Yes                        |
| Allocation method            | Not applicable             |
| Blinding used                | Not blinded                |

Blinding implementation details:

Trial has never been started. "99999" is a value for 0 participants.

### Arms

|           |          |
|-----------|----------|
| Arm title | Tracleer |
|-----------|----------|

Arm description:

Trial has never been started. "99999" is a value for 0 participants.

|                                        |               |
|----------------------------------------|---------------|
| Arm type                               | Experimental  |
| Investigational medicinal product name | Tracleer      |
| Investigational medicinal product code |               |
| Other name                             |               |
| Pharmaceutical forms                   | Coated tablet |
| Routes of administration               | Oral use      |

Dosage and administration details:

Trial has never been started, administration details are not available.

|                                       |          |
|---------------------------------------|----------|
| <b>Number of subjects in period 1</b> | Tracleer |
| Started                               | 99999    |
| Completed                             | 99999    |

## Baseline characteristics

### Reporting groups

| Reporting group title          | Treatment |
|--------------------------------|-----------|
| Reporting group description: - |           |

| Reporting group values                                | Treatment | Total |  |
|-------------------------------------------------------|-----------|-------|--|
| Number of subjects                                    | 99999     | 99999 |  |
| Age categorical                                       |           |       |  |
| Units: Subjects                                       |           |       |  |
| In utero                                              | 0         | 0     |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0         | 0     |  |
| Newborns (0-27 days)                                  | 0         | 0     |  |
| Infants and toddlers (28 days-23<br>months)           | 0         | 0     |  |
| Children (2-11 years)                                 | 99999     | 99999 |  |
| Adolescents (12-17 years)                             | 0         | 0     |  |
| Adults (18-64 years)                                  | 0         | 0     |  |
| From 65-84 years                                      | 0         | 0     |  |
| 85 years and over                                     | 0         | 0     |  |
| Age continuous                                        |           |       |  |
| Units: years                                          |           |       |  |
| arithmetic mean                                       | 0         |       |  |
| standard deviation                                    | ± 0       | -     |  |
| Gender categorical                                    |           |       |  |
| Units: Subjects                                       |           |       |  |
| Female                                                | 99999     | 99999 |  |
| Male                                                  | 0         | 0     |  |

## End points

### End points reporting groups

|                                                                                                      |          |
|------------------------------------------------------------------------------------------------------|----------|
| Reporting group title                                                                                | Tracleer |
| Reporting group description:<br>Trial has never been started. "99999" is a value for 0 participants. |          |

### Primary: Systemic oxygen saturation

|                                                                             |                                           |
|-----------------------------------------------------------------------------|-------------------------------------------|
| End point title                                                             | Systemic oxygen saturation <sup>[1]</sup> |
| End point description:<br>Effects of Tracleer on systemic oxygen saturation |                                           |
| End point type                                                              | Primary                                   |
| End point timeframe:<br>N/A                                                 |                                           |

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: Trial has never been started. Therefore no statistical analysis has been done.

| End point values            | Tracleer             |  |  |  |
|-----------------------------|----------------------|--|--|--|
| Subject group type          | Reporting group      |  |  |  |
| Number of subjects analysed | 99999 <sup>[2]</sup> |  |  |  |
| Units: N/A                  |                      |  |  |  |
| number (not applicable)     | 99999                |  |  |  |

Notes:

[2] - Trial has never been started. "99999" is a value for 0 participants.

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

13.03.2006- 30.06.2006

Adverse event reporting additional description:

Trial has never been started, therefore no AEs and SAEs have been reported.

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

### Dictionary used

|                 |       |
|-----------------|-------|
| Dictionary name | CTCAE |
|-----------------|-------|

|                    |     |
|--------------------|-----|
| Dictionary version | 2.0 |
|--------------------|-----|

### Reporting groups

|                       |          |
|-----------------------|----------|
| Reporting group title | Tracleer |
|-----------------------|----------|

Reporting group description:

Trial has never been started. "99999" is a value for 0 participants.

| Serious adverse events                            | Tracleer          |  |  |
|---------------------------------------------------|-------------------|--|--|
| Total subjects affected by serious adverse events |                   |  |  |
| subjects affected / exposed                       | 0 / 99999 (0.00%) |  |  |
| number of deaths (all causes)                     | 0                 |  |  |
| number of deaths resulting from adverse events    | 0                 |  |  |

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

| Non-serious adverse events                            | Tracleer          |  |  |
|-------------------------------------------------------|-------------------|--|--|
| Total subjects affected by non-serious adverse events |                   |  |  |
| subjects affected / exposed                           | 0 / 99999 (0.00%) |  |  |

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Trial has never been started, therefore no AEs and SAEs have been reported.

## 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

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

|                                                                      |
|----------------------------------------------------------------------|
| Trial has never been started. "99999" is a value for 0 participants. |
|----------------------------------------------------------------------|

Notes: