



## Clinical trial results:

**DANSAC-RCT: Fosaprepitant in patients with advanced cancer not receiving chemotherapy or irradiation; A multicenter, randomized, double-blind, placebo-controlled study.**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2015-003070-33 |
| Trial protocol           | DK             |
| Global end of trial date | 31 July 2017   |

### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1 (current)    |
| This version publication date  | 29 October 2017 |
| First version publication date | 29 October 2017 |

### Trial information

#### Trial identification

|                       |            |
|-----------------------|------------|
| Sponsor protocol code | DANSAC-RCT |
|-----------------------|------------|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Odense University Hospital  |
| Sponsor organisation address | Sdr Boulevard 29, Odense C, Denmark, 5000                                   |
| Public contact               | Signe Harder, Odense University Hospital, 45 25382590, signe.harder@rsyd.dk |
| Scientific contact           | Signe Harder, Odense University Hospital, 45 25382590, signe.harder@rsyd.dk |

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                       | 02 October 2017 |
| Is this the analysis of the primary completion data? | Yes             |
| Primary completion date                              | 31 July 2017    |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 31 July 2017    |
| Was the trial ended prematurely?                     | No              |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective is to compare whether the administration of the neurokinin1-receptor antagonist (NK1-RA) fosaprepitant dimeglumine results in a significant improvement in nausea scores from baseline to 24 hours as compared with placebo. In patients included because of vomiting only (nausea score less than moderate), the primary parameter will be change in number of emetic episodes from baseline to 24 hours.

Protection of trial subjects:

Patients were followed up at 24 hours and 7 days and were given contact information to study personnel available around the clock.

Background therapy: -

Evidence for comparator: -

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 01 February 2016 |
| 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 | Denmark: 3 |
| Worldwide total number of subjects   | 3          |
| EEA total number of subjects         | 3          |

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)                      | 2 |
| From 65 to 84 years                       | 1 |
| 85 years and over                         | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Patients recruited from hospitals, 3 study sites opened, all 3 recruited patients included by 1 study site.

### Pre-assignment

Screening details: -

### Pre-assignment period milestones

|                              |   |
|------------------------------|---|
| Number of subjects started   | 3 |
| Number of subjects completed | 3 |

### Period 1

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

Blinding implementation details:

All personell blinded except two study nurses in charge of mixing the active/placebo drug and one monitor checking for correct assignment during first controlvisit.

Subjects were unblinded after all records had been electronic entered and locked

### Arms

|                              |        |
|------------------------------|--------|
| Are arms mutually exclusive? | Yes    |
| <b>Arm title</b>             | Active |

Arm description:

Fosaprepitant 150 ml infused over 30 min

|  |  |
|--|--|
| Arm type                               | Experimental   |
| Investigational medicinal product name | fosaprepitant  |
| Investigational medicinal product code |  |
| Other name                             |  |
| Pharmaceutical forms                   | Powder and solvent for solution for injection/infusion |
| Routes of administration               | Intravenous use  |

Dosage and administration details:

150 mg given as a 30 min infusion

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

Arm description:

Saline

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

Dosage and administration details:

Matching saline

| <b>Number of subjects in period 1</b> | Active | Placebo |
|---------------------------------------|--------|---------|
| Started                               | 1      | 2       |
| Completed                             | 1      | 2       |

## Baseline characteristics

### Reporting groups

|                       |         |
|-----------------------|---------|
| Reporting group title | Overall |
|-----------------------|---------|

Reporting group description: -

| Reporting group values                                | Overall  | Total |  |
|---|----------|-------|--|
| Number of subjects                                    | 3        | 3     |  |
| 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)                                 | 0        | 0     |  |
| Adolescents (12-17 years)                             | 0        | 0     |  |
| Adults (18-64 years)                                  | 2        | 2     |  |
| From 65-84 years                                      | 1        | 1     |  |
| 85 years and over                                     | 0        | 0     |  |
| Age continuous  |          |       |  |
| Units: years  |          |       |  |
| arithmetic mean                                       | 60       |       |  |
| full range (min-max)                                  | 43 to 72 | -     |  |
| Gender categorical                                    |          |       |  |
| Units: Subjects                                       |          |       |  |
| Female  | 1        | 1     |  |
| Male  | 2        | 2     |  |

## End points

### End points reporting groups

|  |         |
|--|---------|
| Reporting group title  | Active  |
| Reporting group description:<br>Fosaprepitant 150 ml infused over 30 min |         |
| Reporting group title  | Placebo |
| Reporting group description:<br>Saline                                   |         |

### Primary: Nausea at 24 hours compared to baseline

|                                    |  |
|------------------------------------|--|
| End point title                    | Nausea at 24 hours compared to baseline <sup>[1]</sup> |
| End point description:             |  |
| End point type                     | Primary  |
| End point timeframe:<br>0-24 hours |  |

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: Very low number of patientes included, no analyses performed

| End point values            | Active          | Placebo         |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 1               | 2               |  |  |
| Units: 0-4                  |                 |                 |  |  |
| number (not applicable)     | 0               | 0.5             |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

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

Timeframe for reporting adverse events:

7 days

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

### Dictionary used

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

|                    |     |
|--------------------|-----|
| Dictionary version | 4.0 |
|--------------------|-----|

### Reporting groups

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

Reporting group description: -

|                       |        |
|-----------------------|--------|
| Reporting group title | Active |
|-----------------------|--------|

Reporting group description: -

| Serious adverse events                            | Placebo       | Active        |  |
|---|---------------|---------------|--|
| Total subjects affected by serious adverse events |               |               |  |
| subjects affected / exposed                       | 0 / 2 (0.00%) | 0 / 1 (0.00%) |  |
| number of deaths (all causes)                     | 0             | 0             |  |
| number of deaths resulting from adverse events    | 0             | 0             |  |

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

| Non-serious adverse events                            | Placebo       | Active        |  |
|---|---------------|---------------|--|
| Total subjects affected by non-serious adverse events |               |               |  |
| subjects affected / exposed                           | 0 / 2 (0.00%) | 0 / 1 (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: Very low number of patients included, no adverse events recorded

## 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.

|   |
|---|
| Very early termination due to a very low number of patients included, no analyses done on the data. |
|---|

Notes: