



Clinical trial results: Anamorelin HCl in the Treatment of Non-Small Cell Lung Cancer – Cachexia (NSCLC-C): An Extension Study Summary

| | |
|--------------------------|-------------------------------|
| EudraCT number | 2010-023650-36 |
| Trial protocol | HU BE NL GB ES CZ PL DE IT SI |
| Global end of trial date | 22 April 2014 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 |
| This version publication date | 30 June 2016 |
| First version publication date | 30 June 2016 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | HT-ANAM-303 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|-----------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01395914 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Other: ROMANA 3 |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Helsinn Therapeutics (US), Inc. |
| Sponsor organisation address | 170 Wood Avenue South, 5th Floor, Iselin, United States, 08830 |
| Public contact | Richard K. Bourne, Ph.D., Helsinn Therapeutics (US), Inc., +1 732-603-2852, richard.bourne@helsinn.com |
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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 | 04 December 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 22 April 2014 |
| Global end of trial reached? | Yes |
| Global end of trial date | 22 April 2014 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of Anamorelin HCl

Protection of trial subjects:

The study was designed and monitored in accordance with Sponsor procedures, which comply with the ethical principles of Good Clinical Practice (GCP) as required by the major regulatory authorities, and in accordance with the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 14 November 2011 |
| 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 | Poland: 167 |
| Country: Number of subjects enrolled | Slovenia: 1 |
| Country: Number of subjects enrolled | Spain: 7 |
| Country: Number of subjects enrolled | Belgium: 4 |
| Country: Number of subjects enrolled | Czech Republic: 14 |
| Country: Number of subjects enrolled | France: 3 |
| Country: Number of subjects enrolled | Germany: 3 |
| Country: Number of subjects enrolled | Hungary: 55 |
| Country: Number of subjects enrolled | Italy: 1 |
| Country: Number of subjects enrolled | Netherlands: 1 |
| Country: Number of subjects enrolled | Canada: 4 |
| Country: Number of subjects enrolled | United States: 20 |
| Country: Number of subjects enrolled | Belarus: 14 |
| Country: Number of subjects enrolled | Israel: 6 |
| Country: Number of subjects enrolled | Serbia: 6 |
| Country: Number of subjects enrolled | Ukraine: 97 |
| Country: Number of subjects enrolled | Russian Federation: 100 |
| Country: Number of subjects enrolled | Australia: 10 |
| Worldwide total number of subjects | 513 |
| EEA total number of subjects | 256 |

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) | 356 |
| From 65 to 84 years | 157 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Patients who completed dosing in either of the original trials of anamorelin HCl in the treatment of NSCLC-C (HT-ANAM-301 or HT-ANAM-302) were able to enroll in this study and continue to receive the study drug to which they were assigned, either anamorelin HCl 100 mg or placebo QD for an additional 12 weeks.

Pre-assignment

Screening details:

The primary purpose of this extension study was to permit patients who completed dosing in the original 12-week trials to have the option of continuing to receive randomized study drug for an additional 12 weeks, to further evaluate the safety and tolerability of anamorelin HCl.

Period 1

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

Arms

| | |
|------------------------------|----------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Anamorelin HCl |

Arm description:

Active drug

| | |
|--|----------------|
| Arm type | Experimental |
| Investigational medicinal product name | Anamorelin HCl |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Anamorelin HCl; 100 mg tablets; oral administration QD for 12 weeks, at least 1 hour before the first meal of the day.

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Placebo

| | |
|--|----------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Matching placebo tablets

| Number of subjects in period 1 | Anamorelin HCl | Placebo |
|---------------------------------------|----------------|---------|
| Started | 345 | 168 |
| Completed | 273 | 131 |
| Not completed | 72 | 37 |
| Lost to follow-up | 6 | 2 |
| Unrelated to study drug AE | 6 | 1 |
| Study drug-related AE | 1 | - |
| Death | 23 | 17 |
| Other | 9 | 3 |
| Withdrawal by patient | 27 | 14 |

Baseline characteristics

Reporting groups

| | |
|------------------------------|----------------|
| Reporting group title | Anamorelin HCl |
| Reporting group description: | |
| Active drug | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Placebo | |

| Reporting group values | Anamorelin HCl | Placebo | Total |
|---|----------------|---------|-------|
| Number of subjects | 345 | 168 | 513 |
| Age categorical | | | |
| Units: Subjects | | | |
| ≤ 65 years | 236 | 120 | 356 |
| > 65 years | 109 | 48 | 157 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 83 | 43 | 126 |
| Male | 262 | 125 | 387 |
| Race | | | |
| Units: Subjects | | | |
| White | 344 | 166 | 510 |
| Asian | 0 | 1 | 1 |
| Native Hawaiian or Other Pacific Islander | 1 | 0 | 1 |
| Missing | 0 | 1 | 1 |
| Geographic region | | | |
| Units: Subjects | | | |
| North America | 19 | 5 | 24 |
| West Europe | 135 | 72 | 207 |
| East Europe + Russia | 184 | 88 | 272 |
| Australia | 7 | 3 | 10 |

End points

End points reporting groups

| | |
|---|--------------------|
| Reporting group title | Anamorelin HCl |
| Reporting group description: | |
| Active drug | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Placebo | |
| Subject analysis set title | ITT Population |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| The Intent-to-Treat (ITT) Population includes all enrolled patients of the extension trial. | |
| Subject analysis set title | Safety Population |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: | |
| The Safety Population includes all patients who received any extension trial study drug. | |

Primary: To evaluate the safety and tolerability of anamorelin HCl

| | |
|------------------------|--|
| End point title | To evaluate the safety and tolerability of anamorelin HCl ^[1] |
| End point description: | |

| | |
|-----------------------------------|---------|
| End point type | Primary |
| End point timeframe: | |
| Over the 12-week treatment period | |

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 primary purpose of this extension study was to permit patients who completed dosing in the original 12-week trials to have the option of continuing to receiving study drug for an additional 12 weeks to further evaluate the safety and tolerability of anamorelin HCl. Therefore, no formal statistical hypothesis testing or sample size calculation was conducted.

| End point values | Anamorelin HCl | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 179 | 93 | | |
| Units: Percent | 52 | 56 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Body Weight

| | |
|------------------------|-----------------------|
| End point title | Change in Body Weight |
| End point description: | |
| | |
| End point type | Secondary |

End point timeframe:

Change in body weight from baseline of the original trial and baseline of the extension trial to Weeks 4, 8, and 12.

| End point values | Anamorelin HCl | Placebo | ITT Population | |
|-------------------------------------|---------------------|---------------------|----------------------|--|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 320 | 158 | 513 | |
| Units: kg | | | | |
| least squares mean (standard error) | 3.06 (\pm 0.631) | 0.92 (\pm 0.697) | 2.13 (\pm 0.451) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Handgrip Strength of the Non-Dominant Hand

| | |
|-----------------|--|
| End point title | Change in Handgrip Strength of the Non-Dominant Hand |
|-----------------|--|

End point description:

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

End point timeframe:

Change and percent change in HGS of the non-dominant hand from baseline of the original trial and baseline of the extension trial to Weeks 8 and 12.

| End point values | Anamorelin HCl | Placebo | ITT Population | |
|-------------------------------------|----------------------|----------------------|----------------------|--|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 287 | 141 | 513 | |
| Units: kg | | | | |
| least squares mean (standard error) | -0.83 (\pm 0.929) | -0.55 (\pm 1.036) | -0.28 (\pm 0.646) | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events that occurred during the clinical trial, commenced with the first dose of study drug through the 28 day post-treatment follow-up visit.

Adverse event reporting additional description:

Adverse events that occurred following the signature of the informed consent, but prior to the first dose of study drug were not reported as adverse events in this trial. The adverse event reporting period also ended if the patient began an alternative therapy within 28 days of the last administration of study drug.

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

Dictionary used

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

| | |
|--------------------|----|
| Dictionary version | 14 |
|--------------------|----|

Reporting groups

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

Reporting group description: -

| | |
|-----------------------|----------------|
| Reporting group title | Anamorelin HCl |
|-----------------------|----------------|

Reporting group description: -

| | |
|-----------------------|-----------------------------------|
| Reporting group title | Total: Placebo and Anamorelin HCl |
|-----------------------|-----------------------------------|

Reporting group description:

TEAEs were defined as AEs with an onset date on or after the first dose date of the extension trial study drug and up to and including 7 days post-last dose date of the extension trial study drug.

| Serious adverse events | Placebo | Anamorelin HCl | Total: Placebo and Anamorelin HCl |
|---|-------------------|-------------------|-----------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 21 / 167 (12.57%) | 44 / 343 (12.83%) | 65 / 510 (12.75%) |
| number of deaths (all causes) | 22 | 35 | 57 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Colon cancer metastatic | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neoplasm progression | | | |
| subjects affected / exposed | 7 / 167 (4.19%) | 16 / 343 (4.66%) | 23 / 510 (4.51%) |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 16 | 0 / 23 |
| deaths causally related to treatment / all | 0 / 7 | 0 / 16 | 0 / 23 |
| Tumour haemorrhage | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| Injury, poisoning and procedural complications | | | |
| Splenic rupture | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| Tracheo-oesophageal fistula | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Angina unstable | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiopulmonary failure | | | |
| subjects affected / exposed | 1 / 167 (0.60%) | 0 / 343 (0.00%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 1 / 167 (0.60%) | 0 / 343 (0.00%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Convulsion | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorder | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 167 (0.60%) | 3 / 343 (0.87%) | 4 / 510 (0.78%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 1 / 167 (0.60%) | 1 / 343 (0.29%) | 2 / 510 (0.39%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 2 / 167 (1.20%) | 1 / 343 (0.29%) | 3 / 510 (0.59%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 1 / 167 (0.60%) | 1 / 343 (0.29%) | 2 / 510 (0.39%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Death | | | |
| subjects affected / exposed | 3 / 167 (1.80%) | 1 / 343 (0.29%) | 4 / 510 (0.78%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 3 | 0 / 1 | 0 / 4 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Multi-organ failure | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| Sudden death | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| Gastrointestinal disorders | | | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 1 / 167 (0.60%) | 1 / 343 (0.29%) | 2 / 510 (0.39%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 2 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic obstructive pulmonary disease | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 167 (0.60%) | 2 / 343 (0.58%) | 3 / 510 (0.59%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 167 (0.60%) | 0 / 343 (0.00%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| Respiratory failure | | | |
| subjects affected / exposed | 1 / 167 (0.60%) | 2 / 343 (0.58%) | 3 / 510 (0.59%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 3 |
| Musculoskeletal and connective tissue disorders | | | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 1 / 343 (0.29%) | 1 / 510 (0.20%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 167 (0.00%) | 4 / 343 (1.17%) | 4 / 510 (0.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |

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

| Non-serious adverse events | Placebo | Anamorelin HCl | Total: Placebo and Anamorelin HCl |
|---|-------------------|--------------------|-----------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 72 / 167 (43.11%) | 135 / 343 (39.36%) | 207 / 510 (40.59%) |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 25 / 167 (14.97%) | 45 / 343 (13.12%) | 70 / 510 (13.73%) |
| occurrences (all) | 37 | 56 | 93 |
| Neutropenia | | | |
| subjects affected / exposed | 8 / 167 (4.79%) | 18 / 343 (5.25%) | 26 / 510 (5.10%) |
| occurrences (all) | 8 | 21 | 29 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 14 / 167 (8.38%) | 19 / 343 (5.54%) | 33 / 510 (6.47%) |
| occurrences (all) | 14 | 20 | 34 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 10 / 167 (5.99%) | 12 / 343 (3.50%) | 22 / 510 (4.31%) |
| occurrences (all) | 10 | 13 | 23 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|--------------------|
| 22 March 2012 | Protocol amendment |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported