Clinical trial results:
AN INTERNATIONAL, MULTICENTRIC, PROSPECTIVE, OPEN LABEL STUDY TO ASSESS THE EFFICACY AND SAFETY OF LANREOTIDE AUTOGEL® 120 MG ASSOCIATED TO STANDARD OF CARE IN THE TREATMENT OF CLINICAL SYMPTOMS ASSOCIATED WITH INOPERABLE MALIGNANT INTESTINAL OBSTRUCTION

Summary

EudraCT number	2013-002174-43
Trial protocol	BE
Global end of trial date	09 November 2017

Results information

Result version number	v1 (current)
This version publication date	20 January 2019
First version publication date	20 January 2019

Trial information

Trial identification

Sponsor protocol code	A-48-52030-269

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02275338
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ipsen
Sponsor organisation address	Guldensporenpark 87, Merelbeke, Belgium, B-9820
Public contact	Medical Director, Ipsen, clinical.trials@ipsen.com
Scientific contact	Medical Director, Ipsen, clinical.trials@ipsen.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	09 November 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 November 2017
Global end of trial reached?	Yes
Global end of trial date	09 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of lanreotide Autogel® 120 milligrams (mg) for the relief of vomiting due to inoperable malignant intestinal obstruction in subjects without nasogastric tube (NGT) and to assess the efficacy of lanreotide Autogel® 120 mg to remove a NGT without the recurrence of vomiting in subjects with an inoperable malignant intestinal obstruction with a NGT.

Protection of trial subjects:

The study was conducted under the provisions of the Declaration of Helsinki, in accordance with the International Conference on Harmonisation Consolidated Guideline on Good Clinical Practice and in compliance with IECs and informed consent regulations.

Background therapy:

During treatment with lanreotide Autogel®120 mg, all subjects were also required to take intravenous (IV) corticoids and IV H2 antihistamines.
If there was insufficient efficacy at Day 7, step-up medication, butylhyoscine bromide (Buscopan) subcutaneous or IV and Haloperidol IV was also to be taken.

Evidence for comparator: -

Actual start date of recruitment	19 November 2014
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	Belgium: 52
Worldwide total number of subjects	52
EEA total number of subjects	52

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)	21
From 65 to 84 years	28
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

Subjects diagnosed with inoperable malignant intestinal obstruction were recruited into this single arm, open label study in 15 study centres in Belgium between November 2014 and November 2017.

Pre-assignment

Screening details:

Overall, 52 subjects were enrolled into this 2 phase study.

Period 1

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

Arms

Arm title	Lanreotide Autogel® 120 mg - All Subjects

Arm description:

All subjects were administered an initial injection of lanreotide Autogel® 120 mg via subcutaneous injection at Day 0 (Phase 1).
Subjects who completed the 28 days of Phase 1 and who were responders as defined by the protocol, had the opportunity to enter Phase 2 and receive a second subcutaneous injection of lanreotide Autogel® 120 mg.
All subjects continued to receive standard of care throughout the study.

Arm type	Experimental
Investigational medicinal product name	Lanreotide Autogel®
Investigational medicinal product code	
Other name	Somatuline Autogel
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

120 mg lanreotide Autogel® was administered via subcutaneous injection in the upper outer quadrant of the buttock on Day 0 and on Day 28 if continuing in Phase 2.

Number of subjects in period 1	Lanreotide Autogel® 120 mg - All Subjects
Started	52
Completed Phase 1	25
Started Phase 2	21
Completed	19
Not completed	33
Consent withdrawn by subject	4
Ineligible to start Phase 2	4
Adverse event, non-fatal	15
Disease progression (death)	1
Reason not specified	5

Does not meet entry criteria	1
Lack of efficacy	3

Baseline characteristics

Reporting groups	
Reporting group title	Lanreotide Autogel® 120 mg - All Subjects

Reporting group description:

All subjects were administered an initial injection of lanreotide Autogel® 120 mg via subcutaneous injection at Day 0 (Phase 1).
Subjects who completed the 28 days of Phase 1 and who were responders as defined by the protocol, had the opportunity to enter Phase 2 and receive a second subcutaneous injection of lanreotide Autogel® 120 mg.
All subjects continued to receive standard of care throughout the study.

Reporting group values	Lanreotide Autogel® 120 mg - All Subjects	Total	
Number of subjects	52	52	
Age categorical Units: Subjects			
<40 years	1	1	
40-49 years	3	3	
50-59 years	9	9	
60-69 years	17	17	
>= 70 years	22	22	
Age continuous Units: years			
arithmetic mean	66.6		
standard deviation	± 12.1	-	
Gender categorical Units: Subjects			
Female	41	41	
Male	11	11	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	1	1	
White	51	51	
More than one race	0	0	
Unknown or Not Reported	0	0	
NGT Status at Baseline Units: Subjects			
With NGT at baseline	35	35	
Without NGT at baseline	17	17	

End points

End points reporting groups

Reporting group title	Lanreotide Autogel® 120 mg - All Subjects

Reporting group description:

All subjects were administered an initial injection of lanreotide Autogel® 120 mg via subcutaneous injection at Day 0 (Phase 1).
Subjects who completed the 28 days of Phase 1 and who were responders as defined by the protocol, had the opportunity to enter Phase 2 and receive a second subcutaneous injection of lanreotide Autogel® 120 mg.
All subjects continued to receive standard of care throughout the study.

Primary: Percentage of Responders Before or at Day 7

End point title	Percentage of Responders Before or at Day 7[1]

End point description:

The primary endpoint assessed the percentage of responding subjects before or at Day 7. A responder was defined as a subject experiencing ≤2 vomiting episodes/day during at least 3 consecutive days at any timepoint between Day 0 and Day 7 (for subjects without NGT at baseline), or as a subject in whom the NGT had been removed during at least 3 consecutive days at any timepoint between Day 0 and Day 7 without vomiting recurrence (for subjects with NGT at baseline), as recorded on diary cards which were completed every day.

A 1 sided binomial test to compare percentage of responding subjects to theoretical proportion of 30% resulted in p value= 0.0055. The expected proportion of responders using Lanreotide was 50%, 1 sided test, 2.5% significance level alpha and power of 80% using Z-test for binomial proportion.

All subjects who received at least 1 dose of study medication (intention-to-treat [ITT] population) are presented.

End point type	Primary

End point timeframe:

From Day 0 to Day 7

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: As this was a single arm study no comparative analyses were performed.

End point values	Lanreotide Autogel® 120 mg - All Subjects			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: percentage of responders				
number (not applicable)				
Without NGT at Baseline (n=17)	88.2			
With NGT at Baseline (n=35)	25.7			
All Subjects (n=52)	46.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Responders in Phase 1

End point title	Percentage of Responders in Phase 1

End point description:

This endpoint assessed the overall percentage of responding subjects at the Phase 1 timepoints of Days 14 and 28. A responder was defined as a subject experiencing ≤ 2 vomiting episodes/day during at least 3 consecutive days at any timepoint between Day 0 and Days 14 or 28 (for subjects without NGT at baseline) or as a subject in whom the NGT has been removed, during at least 3 consecutive days without vomiting recurrence, at any timepoint between Day 0 and Days 14 and 28 (for subjects with NGT at baseline), as recorded on diary cards which were completed every day.
Results are presented for all subjects who received at least 1 dose of study medication (ITT population).

End point type	Secondary

End point timeframe:

From Day 0 to Day 28

End point values	Lanreotide Autogel® 120 mg - All Subjects			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: percentage of responders				
number (not applicable)				
By Day 14: Without NGT at Baseline (n=17)	88.2			
By Day 14: With NGT at Baseline (n=35)	45.7			
By Day 14: All Subjects (n=52)	59.6			
By Day 28: Without NGT at Baseline (n=17)	88.2			
By Day 28: With NGT at Baseline (n=35)	54.3			
By Day 28: All Subjects (n=52)	65.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Median Time Between First Lanreotide Autogel® Injection and Clinical Response in Phase 1

End point title	Median Time Between First Lanreotide Autogel® Injection and Clinical Response in Phase 1

End point description:

The time for clinical response in Phase 1 (up to Day 28) was defined as the time from inclusion (Day 0) to the date of clinical response. A response was defined as occurrence of ≤ 2 vomiting episodes/day for at least 3 consecutive days at any timepoint between Day 0 and Day 28 (for patients without NGT use at baseline) or the removal of NGT for at least 3 consecutive days at any timepoint between Day 0 and Day 28 without vomiting recurrence (for patients with NGT use at baseline). The Kaplan-Meier estimate of median time to clinical response are presented for all subjects who received at least 1 dose of study medication (ITT population).

End point type	Secondary

End point timeframe:

From Day 0 to Day 28

End point values	Lanreotide Autogel® 120 mg - All Subjects			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: days				
median (confidence interval 95%)	9.00 (5.00 to 14.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Median Change From Baseline in Quality of Life as Assessed by Edmonton Symptom Assessment System (ESAS) in Phase 1

End point title	Median Change From Baseline in Quality of Life as Assessed by Edmonton Symptom Assessment System (ESAS) in Phase 1

End point description:

Quality of Life was assessed by both subject and investigator based on the ESAS. The ESAS scale evaluates 9 symptoms common in cancer subjects: pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, wellbeing and shortness of breath. The severity at the time of assessment of each symptom is rated from 0 to 10 on a numerical scale; 0 = symptom is absent and 10 = worst possible severity. Each symptom rating was interpreted independently and a total symptom distress score was calculated for both subject and investigator assessed scores as the sum of the 9 items. Median change from baseline (Day 0) in total symptom distress score, at each of the Phase 1 timepoints is presented and a positive change indicates a worsening condition.
All subjects who received at least 1 dose of study medication (ITT population) and with data available for analysis at each timepoint are presented.

End point type	Secondary

End point timeframe:

Days 0, 7, 14 and 28

End point values	Lanreotide Autogel® 120 mg - All Subjects			
Subject group type	Reporting group			
Number of subjects analysed	52[2]			
Units: units on a scale				
median (inter-quartile range (Q1-Q3))				
Day 7 - assessed by subject	-3.0 (-11.0 to 1.0)			
Day 7 - assessed by investigator	-4.5 (-14.0 to 3.0)			
Day 14 - assessed by subject	-2.0 (-14.0 to 1.0)			
Day 14 - assessed by investigator	-7.5 (-17.0 to 2.0)			

Day 28 - assessed by subject	-5.5 (-14.0 to -1.0)			
Day 28 - assessed by investigator	-5.0 (-14.0 to 5.5)			

Notes:

[2] - Subject: Day 7 n=33, Day 14 n=34, Day 28 n=18
Investigator: Day 7 n=28, Day 14 n=28, Day 28 n=20

Statistical analyses

No statistical analyses for this end point

Secondary: Median Change From Baseline in General Activity as Assessed by the Karnofsky Performance Status (KPS) Scale in Phase 1

End point title	Median Change From Baseline in General Activity as Assessed by the Karnofsky Performance Status (KPS) Scale in Phase 1

End point description:

The KPS scale was used to quantify subject's general well-being and activities of daily life. Subjects were classified based on their functional impairment and KPS scores range from 0 (death) to 100 (no evidence of disease). KPS scores are classified as 0-40 = unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly; 50-70 = unable to work; able to live at home and care for most personal needs; varying amount of assistance needed; 80-100 = able to carry on normal activity and to work; no special care needed. Median change from baseline (Day 0) at each of the Phase 1 timepoints is presented and a negative change indicates a worsening condition. All subjects who received at least 1 dose of study medication (ITT population) and with data available for analysis at each timepoint are presented.

End point type	Secondary

End point timeframe:

Days 0, 7, 14 and 28

End point values	Lanreotide Autogel® 120 mg - All Subjects			
Subject group type	Reporting group			
Number of subjects analysed	52[3]			
Units: units on a scale				
median (inter-quartile range (Q1-Q3))				
At Day 7	0.0 (0.0 to 10.0)			
At Day 14	0.0 (0.0 to 20.0)			
At Day 28	10.0 (0.0 to 30.0)			

Notes:

[3] - Day 7, n=41
Day 14, n=36
Day 28, n=25

Statistical analyses

No statistical analyses for this end point

Secondary: Median Change From Baseline in Number of Daily Episodes of Nausea in Phase 1

End point title	Median Change From Baseline in Number of Daily Episodes of

	Nausea in Phase 1

End point description:

The mean number of daily episodes of nausea were calculated as the sum of episodes of nausea reported the last 3 days before the corresponding visit, divided by 3.
The median change from baseline (Day 0) at each of the Phase 1 timepoints is presented and a positive change indicates a worsening condition.
All subjects who received at least 1 dose of study medication (ITT population) and with data available for analysis at each timepoint are presented.

End point type	Secondary

End point timeframe:

Days 0, 7, 14 and 28

End point values	Lanreotide Autogel® 120 mg - All Subjects			
Subject group type	Reporting group			
Number of subjects analysed	52[4]			
Units: Daily episodes of nausea				
median (inter-quartile range (Q1-Q3))				
At Day 7	-0.17 (-1.67 to 0.00)			
At Day 14	-1.50 (-4.00 to 0.00)			
At Day 28	-1.5 (-3.67 to 0.00)			

Notes:

[4] - Day 7, n=16
Day 14, n=14
Day 28, n=12

Statistical analyses

No statistical analyses for this end point

Secondary: Median Change From Baseline in Abdominal Pain Scores Assessed Using Visual Analogue Scale (VAS) in Phase 1

End point title	Median Change From Baseline in Abdominal Pain Scores Assessed Using Visual Analogue Scale (VAS) in Phase 1

End point description:

Abdominal pain was assessed using the VAS numeric pain distress scale. The VAS is a 100-millimetre (10-centimetre) scoring scale on which subjects marked on their perceived level of pain. Score range on VAS is from 0 to 100 where 0 = no pain and 100 = unbearable pain. The median change from baseline (Day 0) at each of the Phase 1 timepoints is presented and a positive change indicates a worsening condition.
All subjects who received at least 1 dose of study medication (ITT population) and with data available for analysis at each timepoint are presented.

End point type	Secondary

End point timeframe:

Days 0, 7, 14 and 28

End point values	Lanreotide Autogel® 120 mg - All Subjects			
Subject group type	Reporting group			
Number of subjects analysed	52[5]			
Units: units on a scale				
median (inter-quartile range (Q1-Q3))				
At Day 7	-3.0 (-13.0 to 0.0)			
At Day 14	-1.0 (-9.0 to 6.0)			
At Day 28	0.0 (-9.0 to 10.0)			

Notes:

[5] - Day 7, n=39
Day 14, n=37
Day 28, n=23

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Responders Before or at Phase 2 Timepoints

End point title	Percentage of Responders Before or at Phase 2 Timepoints

End point description:

This endpoint assessed the overall percentage of subjects continuing from Phase 1 and confirmed as a responder at the end of Phase 1, showing a continued response at Days 35, 42 and 56. A responder was defined as a subject experiencing ≤2 vomiting episodes/day during at least 3 consecutive days at any timepoint between Day 0 and Days 35, 42, 56 (for subjects without NGT at baseline), or as a subject in whom the NGT had been removed during at least 3 consecutive days at any timepoint between Day 0 and Days 35, 42, 56 without vomiting recurrence (for subjects with NGT at baseline) as recorded on diary cards which were completed every day.
Results are presented for subjects who received at least 1 dose of study medication (ITT population) and were continuing in Phase 2 of the study.

End point type	Secondary

End point timeframe:

From Day 0 to Day 56

End point values	Lanreotide Autogel® 120 mg - All Subjects			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: percentage of responders				
number (not applicable)				
By Day 35: Without NGT at Baseline (n=10)	100			
By Day 35: With NGT at Baseline (n=11)	100			
By Day 35: All Subjects (n=21)	100			
By Day 42: Without NGT at Baseline (n=10)	100			
By Day 42: With NGT at Baseline (n=11)	100			

By Day 42: All Subjects (n=21)	100			
By Day 56: Without NGT at Baseline (n=10)	100			
By Day 56: With NGT at Baseline (n=11)	100			
By Day 56: All Subjects (n=21)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Median Change From Baseline in Quality of Life as Assessed by ESAS at Phase 2 Timepoints

End point title	Median Change From Baseline in Quality of Life as Assessed by ESAS at Phase 2 Timepoints

End point description:

Quality of Life was assessed by both subject and investigator based on the ESAS. The ESAS scale evaluates 9 symptoms common in cancer subjects: pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, wellbeing and shortness of breath. The severity at the time of assessment of each symptom is rated from 0 to 10 on a numerical scale, 0 = symptom is absent and 10 = worst possible severity. Each symptom rating was interpreted independently and a total symptom distress score was calculated for both subject and investigator assessed scores as the sum of the 9 items. Median change from baseline (Day 0) in total symptom distress score, at each of the Phase 2 timepoints is presented for all subjects who received at least 1 dose of study medication (ITT population) and were continuing in Phase 2 of the study. Only subjects with data available for analysis at each timepoint are presented.

End point type	Secondary

End point timeframe:

Days 0, 35, 42 and 56

End point values	Lanreotide Autogel® 120 mg - All Subjects			
Subject group type	Reporting group			
Number of subjects analysed	21[6]			
Units: units on a scale				
median (inter-quartile range (Q1-Q3))				
Day 35 - assessed by subject	-4.0 (-22.0 to 1.0)			
Day 35 - assessed by investigator	-12.0 (-18.0 to -2.0)			
Day 42 - assessed by subject	-10.5 (-16.0 to 0.0)			
Day 42 - assessed by investigator	-13.5 (-19.0 to -3.0)			
Day 56 - assessed by subject	-8.0 (-17.0 to -1.0)			
Day 56 - assessed by investigator	-9.0 (-17.0 to -2.0)			

Notes:

[6] - Subject: Day 35 n=18, Day 42 n=16, Day 56 n=17
Investigator: Day 35 n=18, Day 42 n=14, Day 56 n=17

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events and deaths due to all causes were recorded from the time the subject gave informed consent (Day 0) and throughout the study up to Day 56.

Adverse event reporting additional description:

The safety analysis population includes all subjects who received at least 1 dose of study medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Lanreotide Autogel® 120 mg - All Subjects

Reporting group description:

All subjects were administered an initial injection of lanreotide Autogel® 120 mg via subcutaneous injection at Day 0 (Phase 1).
Subjects who completed the 28 days of the Phase 1 and who were responders as defined by the protocol, had the opportunity to enter Phase 2 and receive a second subcutaneous injection of lanreotide Autogel® 120 mg.
All subjects continued to receive standard of care throughout the study.

Serious adverse events	Lanreotide Autogel® 120 mg - All Subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	29 / 52 (55.77%)		
number of deaths (all causes)	15		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Explorative laparotomy			

subjects affected / exposed	1 / 52 (1.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small intestinal resection				
subjects affected / exposed	1 / 52 (1.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Disease progression				
subjects affected / exposed	9 / 52 (17.31%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 7			
General physical health deterioration				
subjects affected / exposed	3 / 52 (5.77%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 2			
Inflammation				
subjects affected / exposed	1 / 52 (1.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Multiple organ dysfunction syndrome				
subjects affected / exposed	1 / 52 (1.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Respiratory, thoracic and mediastinal disorders				
Hypoventilation				
subjects affected / exposed	1 / 52 (1.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Investigations				
Liver function test abnormal				

subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Paresis			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	2 / 52 (3.85%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Large intestine perforation			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mesenteric vein thrombosis			

subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	2 / 52 (3.85%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Skin and subcutaneous tissue disorders			
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Infections and infestations			
Abscess intestinal			

subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia sepsis			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Septic shock			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Urinary tract infection			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Electrolyte imbalance			
subjects affected / exposed	2 / 52 (3.85%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		

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

Non-serious adverse events	Lanreotide Autogel® 120 mg - All Subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 52 (73.08%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 52 (5.77%)		
occurrences (all)	3		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	10 / 52 (19.23%)		
occurrences (all)	24		
Neutropenia			
subjects affected / exposed	5 / 52 (9.62%)		
occurrences (all)	15		
Thrombocytopenia			
subjects affected / exposed	5 / 52 (9.62%)		
occurrences (all)	8		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 52 (9.62%)		
occurrences (all)	5		
Fatigue			
subjects affected / exposed	6 / 52 (11.54%)		
occurrences (all)	6		
Inflammation			
subjects affected / exposed	3 / 52 (5.77%)		
occurrences (all)	3		
Oedema peripheral			
subjects affected / exposed	5 / 52 (9.62%)		
occurrences (all)	5		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	9 / 52 (17.31%)		
occurrences (all)	11		
Abdominal pain upper			

subjects affected / exposed	3 / 52 (5.77%)		
occurrences (all)	3		
Constipation			
subjects affected / exposed	5 / 52 (9.62%)		
occurrences (all)	6		
Dry mouth			
subjects affected / exposed	4 / 52 (7.69%)		
occurrences (all)	4		
Nausea			
subjects affected / exposed	9 / 52 (17.31%)		
occurrences (all)	10		
Stomatitis			
subjects affected / exposed	3 / 52 (5.77%)		
occurrences (all)	3		
Vomiting			
subjects affected / exposed	3 / 52 (5.77%)		
occurrences (all)	3		
Diarrhoea			
subjects affected / exposed	10 / 52 (19.23%)		
occurrences (all)	12		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	4 / 52 (7.69%)		
occurrences (all)	4		
Psychiatric disorders			
Depression			
subjects affected / exposed	3 / 52 (5.77%)		
occurrences (all)	3		
Insomnia			
subjects affected / exposed	4 / 52 (7.69%)		
occurrences (all)	5		
Anxiety			
subjects affected / exposed	10 / 52 (19.23%)		
occurrences (all)	13		
Renal and urinary disorders			

Pollakiuria subjects affected / exposed occurrences (all)	3 / 52 (5.77%) 3		
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	4 / 52 (7.69%) 4		
Metabolism and nutrition disorders Hypokalaemia subjects affected / exposed occurrences (all)	9 / 52 (17.31%) 10		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

Results from outcome measures regarding change from baseline in quality of life (ESAS scale), general activity (KPS Scale) and daily episodes of nausea should be interpreted with caution due to small sample sizes.

Notes: