NOVARTIS

Clinical Trial Results Database

Sponsor

Novartis

Generic Drug Name

Pasireotide

Trial Indication(s)

Neuroendocrine tumors (NETs)

Protocol Number

CSOM230D2101

Protocol Title

A phase I, multi-center, open-label, dose-escalation study of pasireotide (SOM230) LAR in patients with advanced neuroendocrine tumors (NETs)

Clinical Trial Phase

Phase I

Phase of Drug Development

Phase I

Study Start/End Dates

23-Aug-2011 to 06-Apr-2016

Reason for Termination (If applicable)

Not applicable

Study Design/Methodology

This was a Phase I, multi-center, open-label, dose-escalation study investigating the safety and tolerability, PK/PD, and preliminary efficacy of pasireotide LAR (also called pasireotide long-acting) in patients with advanced NETs. Pasireotide long-acting was administered im q28 days.

Centers

4 centers in 1 country: United States (4).

Objectives:

Primary objective:

- To determine the maximum tolerated dose/recommended phase 2 dose (MTD/RP2D) of pasireotide LAR when administered intramuscularly (im) q28 days to patients with advanced neuroendocrine tumor (NETs).

Secondary objectives:

- To assess the safety and tolerability of pasireotide LAR.
- To assess the pharmacokinetics (PK) of pasireotide LAR;
- To assess the pharmacodynamics (PD) of pasireotide LAR;
- To assess the preliminary efficacy (anti-tumor activity) of pasireotide LAR.

Test Product (s), Dose(s), and Mode(s) of Administration

Pasireotide long-acting was supplied to the investigators at dose strengths of 20, 40, and 60 mg (vials). Patients received at least one intramuscular dose of Pasireotide long-acting. Patients continued to receive treatment until disease progression, occurrence of unacceptable toxicity, or consent withdrawal.

Statistical Methods

An adaptive Bayesian logistic regression models (BLRM) guided by the escalation with overdose control (EWOC) principle were used to make dose recommendations and estimate the MTD during the dose-escalation phase of the study.

PK parameters were summarized based on each individual plasma concentration-time profile of patients.

Preliminary tumor activity was assessed using disease control rate (DCR), Overall response rate (ORR) and progression free survival (PFS) times. PFS times were summarized in each dose group according to Kaplan-Meier methodology. Two-sided 95% confidence intervals based on Clopper-Pearson method were obtained for the DCR and ORR.

All safety analyses were carried out using descriptive statistics only.

Safety analyses was carried out in Safety set. BLRM analysis for dose escalation and MTD decisions were based on dose determining set. PK analysis were carried out based on PK analysis set. All other analyses were carried out in Full analysis set.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria

- Male or female aged 18 years or older
- Histologically confirmed advanced (unresectable and/or metastatic) well or moderately differentiated (low or intermediate grade) neuroendocrine tumor/carcinoma, independent of primary tumor location and functional hormone status and a World Health Organization (WHO) performance status of 0-2

NOVARTIS

Clinical Trial Results Database

Participant Flow Table

Patient disposition by treatment group – All enrolled patients.

Disposition Reason	SOM230 LAR 80 mg N=13 n (%)	SOM230 LAR 120 mg N=16 n (%)	All patients N=29 n (%)
Patients treated			
Treatment ongoing*	0	0	0
End of treatment	13 (100.0)	16 (100.0)	29 (100.0)
Primary reason for end of treatment			
Adverse Event(s)	4 (30.8)	4 (25.0)	8 (27.6)
Subject withdrew consent	2 (15.4)	2 (12.5)	4 (13.8)
Administrative problems	0	2 (12.5)	2 (6.9)
Death	0	1 (6.3)	1 (3.4)
Disease progression	7 (53.8)	7 (43.8)	14 (48.3)
Study evaluation after end of treatment			
Patients no longer being followed for study evaluation	3 (23.1)	4 (25.0)	7 (24.1)
Patients continuing to be followed for study evaluation	10 (76.9)	12 (75.0)	22 (75.9)
Primary reason for study evaluation completion			
Adverse Event(s)	2 (15.4)	0	2 (6.9)
Subject withdrew consent	1 (7.7)	2 (12.5)	3 (10.3)
Lost to follow-up	1 (7.7)	0	1 (3.4)
Death	1 (7.7)	0	1 (3.4)
Disease progression	3 (23.1)	2 (12.5)	5 (17.2)
Follow up phase completed as per protocol	2 (15.4)	8 (50.0)	10 (34.5)

*Patients ongoing at the time of the cut-off 06-Apr-2016.
Percentage is based on N.

NOVARTIS

Clinical Trial Results Database

Baseline Characteristics

Demographics by treatment group – Full analysis set

	SOM 230 LAR 80 mg N=13	SOM 230 LAR 120 mg N=16	All patients N=29
Age (years)			
n	13	16	29
Mean(SD)	57.4 (10.71)	61.3 (10.10)	59.6 (10.38)
Median	58.0	60.0	58.0
Min – Max	42-78	44-76	42-78
Age category (years) – n (%)			
<65	10 (76.9)	10 (62.5)	20 (69.0)
>= 65	3 (23.1)	6 (37.5)	9 (31.0)
Sex – n (%)			
Male	4 (30.8)	5 (31.3)	9 (31.0)
Female	9 (69.2)	11 (68.8)	20 (69.0)
Race - n (%)			
Caucasian	11 (84.6)	13 (81.3)	24 (82.8)
Black	2 (15.4)	1 (6.3)	3 (10.3)
Asian	0	1 (6.3)	1 (3.4)
Other	0	1 (6.3)	1 (3.4)
Ethnicity - n (%)			
Mixed Ethnicity	0	1 (6.3)	1 (3.4)
Other	13 (100.0)	15 (93.8)	28 (96.6)
Weight (kg)			
n	13	16	29
Mean(SD)	76.66 (19.146)	75.28 (19.696)	75.90 (19.116)
Median	72.80	70.95	72.10

	SOM 230 LAR 80 mg N=13	SOM 230 LAR 120 mg N=16	All patients N=29
Min - Max	53.8-124.9	44.6-107.7	44.6-124.9
Height (cm)			
n	13	16	29
Mean(SD)	163.87 (7.861)	167.54 (11.539)	165.90 (10.064)
Median	161.20	164.85	163.00
Min - Max	154.2-177.2	148.5-191.7	148.5-191.7
Body mass index (kg/m^2)			
n	13	16	29
Mean(SD)	28.35 (5.626)	26.79 (6.823)	27.49 (6.256)
Median	27.10	25.90	26.10
Min - Max	21.4-40.7	18.6-45.1	18.6-45.1
WHO performance status - n (%)			
No restrictions	6 (46.2)	8 (50.0)	14 (48.3)
Only light work	7 (53.8)	8 (50.0)	15 (51.7)

Summary of Efficacy

Primary Outcome Result(s)

Refer to Safety Result section for primary outcome result.

Secondary Outcome Result(s)

Best overall response as per local radiological review by treatment group - Full analysis set

	SOM230 LAR 80 mg N=13 n (%)	SOM230 LAR 120 mg N=16 n (%)
Best overall response		
Complete Response (CR)	0	0
Partial Response (PR)	0	2 (12.5)
Stable Disease (SD)	10 (76.9)	13 (81.3)
Progressive Disease (PD)	3 (23.1)	0
Unknown	0	1 (6.3)
Overall response rate (ORR: CR+PR)	0	2 (12.5)
95% CI for ORR	(0, 24.7)	(1.6, 38.4)
Disease control rate (DCR: CR+PR+SD)	10 (76.9)	15 (93.8)
95% CI for DCR	(46.2, 95.0)	(69.8, 99.8)

Tumor evaluation is based on RECIST v1.0
95% CI are based on Clopper Pearson method.
CI: Confidence interval.

NOVARTIS

Clinical Trial Results Database

Gap analysis: Summary of gap time (months) for PFS follow-up as compared to cut-off date in patients who are censored – Full analysis set

	SOM230 LAR 80 mg N=13	SOM230 LAR 120 mg N=16
Patients with event - n (%)	7 (53.8)	9 (56.3)
Patients who are censored - n (%)[1]	6 (46.2)	7 (43.8)
Gap time (months)[2]		
25th percentile	30.85	2.60
Median	44.78	19.98
75th percentile	47.15	37.16
Min - Max	9.0-48.8	0.9-38.2
Gap time (month category) - n (%)[2]		
<3	0	2 (12.5)
3-<6	0	0
6-<12	1 (7.7)	1 (6.3)
12-<18	0	0
18-<24	0	1 (6.3)
24-<36	1 (7.7)	0
36-<48	3 (23.1)	3 (18.8)
48-<60	1 (7.7)	0
>=60	0	0

All percentages are based on N.
1. Patients who are censored regardless of follow-up status.
2. Gap time (month) = (study cut-off date – censoring date)/30.4375.

NOVARTIS

Clinical Trial Results Database

Summary of Safety

Safety Results

Patients who had grade 3/4 AEs, SAEs, AEs leading to treatment discontinuation or other significant AEs by treatment group - Safety analysis set

	SOM230 LAR 80 mg N=13		SOM230 LAR 120 mg N=16		All Patients N=29	
Category	**All grades n (%)**	**Grade 3/4 n (%)**	**All grades n (%)**	**Grade 3/4 n (%)**	**All grades n (%)**	**Grade 3/4 n (%)**
Adverse events	12 (92.3)	9 (69.2)	16 (100)	11 (68.8)	28 (96.6)	20 (69.0)
Suspected to be drug-related	9 (69.2)	2 (15.4)	14 (87.5)	5 (31.3)	23 (79.3)	7 (24.1)
Serious adverse events	6 (46.2)	4 (30.8)	7 (43.8)	6 (37.5)	13 (44.8)	10 (34.5)
Suspected to be drug-related	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
AEs leading to treatment discontinuation	4 (30.8)	2 (15.4)	4 (25.0)	3 (18.8)	8 (27.6)	5 (17.2)
Suspected to be drug-related	2 (15.4)	1 (7.7)	2 (12.5)	1 (6.3)	4 (13.8)	2 (6.9)
AEs requiring dose interruption and/or change	3 (23.1)	3 (23.1)	3 (18.8)	3 (18.8)	6 (20.7)	6 (20.7)
AEs requiring additional therapy	11 (84.6)	6 (46.2)	16 (100)	8 (50.0)	27 (93.1)	14 (48.3)
Suspected to be drug-related	7 (53.8)	1 (7.7)	13 (81.3)	3 (18.8)	20 (69.0)	4 (13.8)
AEs of special interest	12 (92.3)	4 (30.8)	14 (87.5)	7 (43.8)	26 (89.7)	11 (37.9)
Suspected to be drug-related	8 (61.5)	2 (15.4)	14 (87.5)	5 (31.3)	22 (75.9)	7 (24.1)
DLT	0	0	0	0	0	0

Categories are not mutually exclusive. Patients with multiple events in the same category are counted only once in that category. Patients with events in more than 1 category are counted once in each of those categories.
AEs with starting date occurring up to last dosing date +56 days or safety follow up date whichever is the latest are included.
Additional therapy includes all non-drug therapy and concomitant medications.

NOVARTIS

Clinical Trial Results Database

Adverse events regardless of study drug relationship, by preferred term, maximum grade and treatment group (cut-off: frequency [all grades]>30% in at least one dose group) - Safety analysis set

	SOM230 LAR 80 mg N=13		SOM230 LAR 120 mg N=16		All patients N=29	
	All grades	Grades 3/4	All grades	Grades 3/4	All grades	Grades 3/4
Preferred term	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
-Total	**12 (92.3)**	**9 (69.2)**	**16 (100)**	**11 (68.8)**	**28 (96.6)**	**20 (69.0)**
Hyperglycaemia	10 (76.9)	2 (15.4)	13 (81.3)	1 (6.3)	23 (79.3)	3 (10.3)
Fatigue	7 (53.8)	0	8 (50.0)	0	15 (51.7)	0
Diarrhoea	5 (38.5)	0	8 (50.0)	1 (6.3)	13 (44.8)	1 (3.4)
Abdominal pain	6 (46.2)	1 (7.7)	6 (37.5)	0	12 (41.4)	1 (3.4)
Nausea	7 (53.8)	0	5 (31.3)	0	12 (41.4)	0
Dizziness	2 (15.4)	0	6 (37.5)	0	8 (27.6)	0
Constipation	4 (30.8)	0	3 (18.8)	0	7 (24.1)	0
Lipase increased	5 (38.5)	1 (7.7)	2 (12.5)	1 (6.3)	7 (24.1)	2 (6.9)
Upper respiratory tract infection	1 (7.7)	0	5 (31.3)	0	6 (20.7)	0
Decreased appetite	5 (38.5)	0	0	0	5 (17.2)	0

Preferred terms are sorted in descending frequency of All grades column, as reported in the 120 mg Group.
A patient with multiple occurrences of an AE under one category is counted only once in that AE category.
A patient with multiple adverse events is counted only once in the total row.
AEs with start date beyond 56 days from last dosing have been excluded.

Serious adverse events, regardless of study drug relationship by preferred term and treatment group -Safety analysis set

	SOM230 LAR 80 mg N=13		SOM230 LAR 120 mg N=16		All patients N=29	
	All grades	Grades 3/4	All grades	Grades 3/4	All grades	Grades 3/4
Preferred term	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Any primary system organ class	**6 (46.2)**	**4 (30.8)**	**7 (43.8)**	**6 (37.5)**	**13 (44.8)**	**10 (34.5)**
Abdominal pain	3 (23.1)	1 (7.7)	0	0	3 (10.3)	1 (3.4)
Atrioventricular block complete	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)

	SOM230 LAR 80 mg N=13		SOM230 LAR 120 mg N=16		All patients N=29	
Preferred term	**All grades n (%)**	**Grades 3/4 n (%)**	**All grades n (%)**	**Grades 3/4 n (%)**	**All grades n (%)**	**Grades 3/4 n (%)**
Bacteraemia	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Bile duct stenosis	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Bronchial obstruction	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Cellulitis	1 (7.7)	1 (7.7)	0	0	1 (3.4)	1 (3.4)
Cholangitis	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Concussion	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Diarrhoea	1 (7.7)	0	0	0	1 (3.4)	0
Diverticulitis	1 (7.7)	1 (7.7)	0	0	1 (3.4)	1 (3.4)
Erysipelas	1 (7.7)	0	0	0	1 (3.4)	0
Escherichia bacteraemia	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Hepatic failure	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Hepatorenal failure	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Hypertension	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Hypoglycaemia	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Impaired gastric emptying	0	0	1 (6.3)	0	1 (3.4)	0
Intestinal obstruction	1 (7.7)	0	0	0	1 (3.4)	0
Intestinal perforation	1 (7.7)	1 (7.7)	0	0	1 (3.4)	1 (3.4)
Jaw fracture	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Klebsiella bacteraemia	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Leukocytosis	1 (7.7)	1 (7.7)	0	0	1 (3.4)	1 (3.4)
Pancreatic duct stenosis	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Pneumonia	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Procedural pain	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Renal failure	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)

Preferred term	SOM230 LAR 80 mg N=13 All grades n (%)	SOM230 LAR 80 mg N=13 Grades 3/4 n (%)	SOM230 LAR 120 mg N=16 All grades n (%)	SOM230 LAR 120 mg N=16 Grades 3/4 n (%)	All patients N=29 All grades n (%)	All patients N=29 Grades 3/4 n (%)
Sepsis	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Septic shock	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Somnolence	1 (7.7)	0	0	0	1 (3.4)	0

Preferred terms are sorted in descending frequency of 'all grade', as reported in the '120 mg' column.
A patient with multiple occurrences of an AE under one category is counted only once in that AE category.
A patient with multiple adverse events is counted only once in the total row.
AEs with starting date up to last dosing date +56 days or safety follow up date whichever is the latest are included.

Adverse events of special interest, regardless of study drug relationship, by category, preferred term and dose regimen - Safety analysis set

Primary system organ class Preferred term	SOM230 LAR 80 mg N=13 All Grades n (%)	SOM230 LAR 80 mg N=13 Grade 3/4 n (%)	SOM230 LAR 120 mg N=16 All Grades n (%)	SOM230 LAR 120 mg N=16 Grade 3/4 n (%)	All patients N=29 All Grades n (%)	All patients N=29 Grade 3/4 n (%)
Any primary system organ class						
Total	12 (92.3)	4 (30.8)	14 (87.5)	7 (43.8)	26 (89.7)	11 (37.9)
AESI suspected to be drug related						
Total	8 (61.5)	2 (15.4)	14 (87.5)	5 (31.3)	22 (75.9)	7 (24.1)
AESI leading to treatment discontinuation						
Total	1 (7.7)	1 (7.7)	3 (18.8)	2 (12.5)	4 (13.8)	3 (10.3)
Hyperglycemia-related AE's						
Total	10 (76.9)	2 (15.4)	13 (81.3)	2 (12.5)	23 (79.3)	4 (13.8)
Hyperglycaemia	10 (76.9)	2 (15.4)	13 (81.3)	1 (6.3)	23 (79.3)	3 (10.3)
Type 1 diabetes mellitus	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)

NOVARTIS

Clinical Trial Results Database

	SOM230 LAR 80 mg N=13		SOM230 LAR 120 mg N=16		All patients N=29	
AESI suspected to be drug related (total)	8 (61.5)	2 (15.4)	13 (81.3)	1 (6.3)	21 (72.4)	3 (10.3)
AESI leading to treatment discontinuation	0	0	1 (6.3)	0	1 (3.4)	0
Low blood cell related AE's						
Total	4 (30.8)	2 (15.4)	4 (25.0)	1 (6.3)	8 (27.6)	3 (10.3)
Anaemia	3 (23.1)	0	2 (12.5)	0	5 (17.2)	0
Leukopenia	2 (15.4)	0	1 (6.3)	0	3 (10.3)	0
Lymphopenia	2 (15.4)	2 (15.4)	1 (6.3)	0	3 (10.3)	2 (6.9)
Neutropenia	0	0	1 (6.3)	0	1 (3.4)	0
Thrombocytopenia	3 (23.1)	0	1 (6.3)	1 (6.3)	4 (13.8)	1 (3.4)
AESI suspected to be drug related (total)	0	0	0	0	0	0
AESI leading to treatment discontinuation	0	0	0	0	0	0
Pancreatitis related AE's	5 (38.5)	1 (7.7)	2 (12.5)	1 (6.3)	7 (24.1)	2 (6.9)
Lipase increased	5 (38.5)	1 (7.7)	2 (12.5)	1 (6.3)	7 (24.1)	2 (6.9)
AESI suspected to be drug related (total)	3 (23.1)	1 (7.7)	1 (6.3)	1 (6.3)	4 (13.8)	2 (6.9)
AESI leading to treatment discontinuation	1 (7.7)	1 (7.7)	0	0	1 (3.4)	1 (3.4)
Gallbladder and biliary related AE's						
Total	2 (15.4)	1 (7.7)	5 (31.3)	2 (12.5)	7 (24.1)	3 (10.3)
Blood alkaline phosphatase increased	2 (15.4)	1 (7.7)	3 (18.8)	0	5 (17.2)	1 (3.4)
Bile duct stenosis	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Blood bilirubin increased	0	0	1 (6.3)	0	1 (3.4)	0
Cholelithiasis	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
AESI suspected to be drug related (total)	0	0	3 (18.8)	1 (6.3)	3 (10.3)	1 (3.4)
AESI leading to treatment discontinuation	0	0	0	0	0	0
Liver safety related AE's						
Total	2 (15.4)	1 (7.7)	3 (18.8)	2 (12.5)	5 (17.2)	3 (10.3)
Gamma-glutamyltransferase increased	1 (7.7)	1 (7.7)	2 (12.5)	2 (12.5)	3 (10.3)	3 (10.3)

	SOM230 LAR 80 mg N=13		SOM230 LAR 120 mg N=16		All patients N=29	
Aspartate aminotransferase increased	1 (7.7)	0	1 (6.3)	0	2 (6.9)	0
AESI suspected to be drug related (total)	1 (7.7)	0	2 (12.5)	1 (6.3)	3 (10.3)	1 (3.4)
AESI leading to treatment discontinuation	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Hypotension related AE's						
Total	2 (15.4)	0	1 (6.3)	0	3 (10.3)	0
Hypotension	2 (15.4)	0	1 (6.3)	0	3 (10.3)	0
AESI suspected to be drug related (total)	0	0	0	0	0	0
AESI leading to treatment discontinuation	0	0	0	0	0	0
Bradycardia related AEs						
Total	1 (7.7)	0	1 (6.3)	1 (6.3)	2 (6.9)	1 (3.4)
Atrioventricular block complete	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Atrioventricular block second degree	0	0	1 (6.3)	0	1 (3.4)	0
Sinus bradycardia	1 (7.7)	0	1 (6.3)	1 (6.3)	2 (6.9)	1 (3.4)
AESI suspected to be drug related (total)	0	0	0	0	0	0
AESI leading to treatment discontinuation	0	0	1 (6.3)	1 (6.3)	1 (3.4)	1 (3.4)
Coagulation related AEs						
Total	1 (7.7)	1 (7.7)	0	0	1 (3.4)	1 (3.4)
Blood fibrinogen decreased	1 (7.7)	1 (7.7)	0	0	1 (3.4)	1 (3.4)
AESI suspected to be drug related (total)	1 (7.7)	1 (7.7)	0	0	1 (3.4)	1 (3.4)
AESI leading to treatment discontinuation	0	0	0	0	0	0
Hypothyroidism related AE's						
Total	0	0	1 (6.3)	0	1 (3.4)	0
Blood thyroid stimulating hormone decreased	0	0	1 (6.3)	0	1 (3.4)	0
AESI suspected to be drug related (total)	0	0	0	0	0	0
AESI leading to treatment discontinuation	0	0	0	0	0	0

	SOM230 LAR 80 mg N=13	SOM230 LAR 120 mg N=16	All patients N=29

Primary system organ classes are presented alphabetically; preferred terms are sorted within primary system organ class in descending frequency of All grade AEs, as reported in the 120 mg column.
A patient with multiple occurrences of an AE under one category is counted only once in that AE category.
A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
AEs with starting date up to last dosing date +56 days or safety follow up date whichever is the latest are included.

Other Relevant Findings

NA

Conclusion:

The primary objective of this study was to determine the MTD/RP2D of pasireotide long-acting when administered im q28 days to patients with advanced NETs. Pasireotide long-acting 120 mg was declared as MTD. No RP2D was established. For safety, overall, the adverse events in this study were consistent with the currently labeled safety profile of pasireotide long-acting and no new signals were observed. However, in the 120 mg dose group, there was a higher incidence of severe adverse events and a higher frequency of drug-related events. The median PFS, overall response, and disease control rate suggested a better efficacy with the 120 mg dose. However, the 80 mg dose was better tolerated.

Date of Clinical Trial Report

22-Dec-2016