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Trial record **1 of 1** for: CRAD001C2325

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Everolimus and Octreotide in Patients With Advanced Carcinoid Tumor (RADIANT-2)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00412061

First received: December 13, 2006
Last updated: November 11, 2014
Last verified: November 2014
History of Changes

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Results First Received: October 25, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Carcinoid Tumor Malignant Carcinoid Syndrome
Interventions:	Drug: Octreotide Drug: Placebo Drug: Everolimus

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Total 429 patients were randomized to double blind phase of treatment. 170 patients moved to the Open Label Phase.

Reporting Groups

	Description
Octreotide+ Everolimus	Everolimus was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity. Each treatment cycle lasted 28 days. Patients received their first dose of everolimus at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1, Day 1.
Octreotide+ Placebo Followed by Open Label Arm	Matching placebo was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity; Each treatment cycle lasted 28 days. Patients received their first dose of matching placebo at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1 Day 1. Open Label - Patients who had progressive disease in this arm, can move to the open label Everolimus + depot octreotide by choice.

Participant Flow for 2 periods

Period 1: Double Blind Phase

	Octreotide+ Everolimus	Octreotide+ Placebo Followed by Open Label Arm
STARTED	216	213
Safety Set	215 [1]	211 [2]
COMPLETED	0	0
NOT COMPLETED	216	213
Disease Progression	101	154
Adverse Event	61	16
Final Primary Analysis	26	14
Withdrawal by Subject	18	20
Death	6	3
Protocol Violation	3	4
New Cander Therapy	1	1
Lost to Follow-up	0	1

[1] 1 patient did not provide at laest one valid post baseline safety assessment.
[2] 1 pt randomized never took drug Another randomized did not have valid post BL safety assessment

Period 2: Open Label Phase

	Octreotide+ Everolimus	Octreotide+ Placebo Followed by Open Label Arm
STARTED	0	170
COMPLETED	0	0
NOT COMPLETED	0	170
Disease Progression	0	86
Adverse Event	0	46
Withdrawal by Subject	0	15

Administrative Problems	**0**	**13**
Death	**0**	**7**
Lost to Follow-up	**0**	**2**
New Cancer Therapy	**0**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Octreotide+ Everolimus	Everolimus was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity. Each treatment cycle lasted 28 days. Patients received their first dose of everolimus at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1, Day 1.
Octreotide+ Placebo	Matching placebo was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity; Each treatment cycle lasted 28 days. Patients received their first dose of matching placebo at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1 Day 1.
Total	Total of all reporting groups

Baseline Measures

	Octreotide+ Everolimus	**Octreotide+ Placebo**	**Total**

Number of Participants [units: participants]	**216**	**213**	**429**
Age [units: years] Mean (Standard Deviation)	**60.1 (10.72)**	**59.4 (11.13)**	**59.8 (10.92)**
Gender [units: Participants]			
Female	**119**	**89**	**208**
Male	**97**	**124**	**221**

Outcome Measures

Hide All Outcome Measures

1. Primary: Progression Free Survival (PFS) as Per Adjudicated Central Radiology Review [Time Frame: Time from randomisation to dates of disease progression, death from any cause or last tumor assessment, reported between day of first patient randomised, 10 January 2007, until cut-off date 02 April 2010]

Measure Type	Primary
Measure Title	Progression Free Survival (PFS) as Per Adjudicated Central Radiology Review
Measure Description	Progression free survival (PFS) is defined as the time from randomization to the date of first documented disease progression or death from any cause. The primary analysis of PFS was based on the independent central adjudicated assessment using Kaplan-Meier method.
Time Frame	Time from randomisation to dates of disease progression, death from any cause or last tumor assessment, reported between day of first patient randomised, 10 January 2007, until cut-off date 02 April 2010
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) consisted of all randomized patients.

Reporting Groups

	Description
Octreotide+ Everolimus	Everolimus was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity. Each treatment cycle lasted 28 days. Patients received their first dose of everolimus at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1, Day 1.
Octreotide+ Placebo	Matching placebo was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity; Each treatment cycle lasted 28 days. Patients received their first dose of matching placebo at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1 Day 1.

Measured Values

	Octreotide+ Everolimus	**Octreotide+ Placebo**
Number of Participants Analyzed [units: participants]	**216**	**213**
Progression Free Survival (PFS) as Per Adjudicated Central Radiology Review [units: Months] Median (95% Confidence Interval)	**16.43 (13.67 to 21.19)**	**11.33 (8.44 to 14.59)**

No statistical analysis provided for Progression Free Survival (PFS) as Per Adjudicated Central Radiology Review

2. Secondary: Best Overall Response Rate as Per Adjudicated Central Radiology Review Based on Response Evaluation Criteria in Solid Tumors (RECIST) [Time Frame: Time from randomisation to dates of disease progression, death from any cause or last tumor assessment, reported between day of first patient randomised, 10 January 2007, until cut-off date 02 April 2010]

Measure Type	Secondary

Measure Title	Best Overall Response Rate as Per Adjudicated Central Radiology Review Based on Response Evaluation Criteria in Solid Tumors (RECIST)
Measure Description	The best overall response rate is defined as the percentage of patients having achieved confirmed Complete Response + Partial Response. Complete Response (CR) = at least two determinations of CR at least 4 weeks apart before progression. • Partial response (PR) = at least two determinations of PR or better at least 4 weeks apart before progression.
Time Frame	Time from randomisation to dates of disease progression, death from any cause or last tumor assessment, reported between day of first patient randomised, 10 January 2007, until cut-off date 02 April 2010
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS; Intent-to-treat Population) consists of all randomized patients.

Reporting Groups

	Description
Octreotide+ Everolimus	Everolimus was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity. Each treatment cycle lasted 28 days. Patients received their first dose of everolimus at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1, Day 1.
Octreotide+ Placebo	Matching placebo was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity; Each treatment cycle lasted 28 days. Patients received their first dose of matching placebo at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1 Day 1.

Measured Values

	Octreotide+ Everolimus	**Octreotide+ Placebo**
Number of Participants Analyzed		

[units: participants]	**216**	**213**
Best Overall Response Rate as Per Adjudicated Central Radiology Review Based on Response Evaluation Criteria in Solid Tumors (RECIST) **[units: Percentage of patients]** **Number (95% Confidence Interval)**	**2.3 (0.8 to 5.30)**	**1.9 (0.5 to 4.7)**

No statistical analysis provided for Best Overall Response Rate as Per Adjudicated Central Radiology Review Based on Response Evaluation Criteria in Solid Tumors (RECIST)

3. Secondary: Progression Free Survival (PFS) as Per Adjudicated Central Review by Baseline 5-hydroxyindoleacetic Acid (5-HIAA) Level [Time Frame: If elevated at baseline, evaluated every cycle visit (28 days/cycle) reported between day of first patient randomised, 10 January 2007, until cut-off date 02 April 2010]

Measure Type	Secondary
Measure Title	Progression Free Survival (PFS) as Per Adjudicated Central Review by Baseline 5-hydroxyindoleacetic Acid (5-HIAA) Level
Measure Description	5-HIAA levels in urine are frequently elevated in patients with advanced carcinoid tumors. Baseline levels of 5-HIAA in urine were defined as ‘High’ if they exceeded the median value, and ‘Low’ if they were lower than or equal to the median.
Time Frame	If elevated at baseline, evaluated every cycle visit (28 days/cycle) reported between day of first patient randomised, 10 January 2007, until cut-off date 02 April 2010
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS; Intent-to-treat Population) consists of all randomized patients. This analysis includes PFS patients with non missing baseline 5-HIAA data.

Reporting Groups

	Description
Octreotide+ Everolimus	Everolimus was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity. Each treatment cycle lasted 28 days. Patients received their first dose of everolimus at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1, Day 1.
Octreotide+ Placebo	Matching placebo was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity; Each treatment cycle lasted 28 days. Patients received their first dose of matching placebo at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1 Day 1.

Measured Values

	Octreotide+ Everolimus	Octreotide+ Placebo
Number of Participants Analyzed [units: participants]	**187**	**191**
Progression Free Survival (PFS) as Per Adjudicated Central Review by Baseline 5-hydroxyindoleacetic Acid (5-HIAA) Level [units: Months] Median (95% Confidence Interval)		
5-HIAA <=median (n=93,96)	**21.75** [1]	**13.90 (8.71 to 22.44)**
5-HIAA > median (n=94,95)	**13.83 (10.61 to 18.63)**	**8.41 (8.08 to 11.33)**

[1] Upper Limit was not applicable or computable as median was just reached.

No statistical analysis provided for Progression Free Survival (PFS) as Per Adjudicated Central Review by Baseline 5-hydroxyindoleacetic Acid (5-HIAA) Level

4. Secondary: Overall Survival Using Kaplan-Meier Methodology [Time Frame: Months 12, 24, 36, 48]

Measure Type	Secondary
Measure Title	Overall Survival Using Kaplan-Meier Methodology
Measure Description	Overall survival was defined as the time from the date of randomization to the date of death from any cause. If a patient was not known to have died, survival was censored at the date of last contact. Kaplan-Meier methodology was used to estimate the median overall survival for each treatment group.
Time Frame	Months 12, 24, 36, 48
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS; Intent-to-treat Population) consists of all randomized patients.

Reporting Groups

	Description
Octreotide+ Everolimus	Everolimus was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity. Each treatment cycle lasted 28 days. Patients received their first dose of everolimus at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1, Day 1.
Octreotide+ Placebo Followed by Open Label Arm	Matching placebo was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity; Each treatment cycle lasted 28 days. Patients received their first dose of matching placebo at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1 Day 1. Open Label - Patients who had progressive disease in this arm, can move

	to the open label Everolimus + depot octreotide by choice.

Measured Values

	Octreotide+ Everolimus	Octreotide+ Placebo Followed by Open Label Arm
Number of Participants Analyzed [units: participants]	**216**	**213**
Overall Survival Using Kaplan-Meier Methodology [units: Percentage of Participants] Number (95% Confidence Interval)		
12 Months	**80.5 (74.5 to 85.3)**	**81.8 (75.8 to 86.4)**
24 Months	**57.0 (49.9 to 63.4)**	**63.6 (56.6 to 69.8)**
36 Months	**42.9 (36.0 to 49.6)**	**48.5 (41.4 to 55.3)**
48 Months	**38.0 (31.2 to 44.7)**	**41.6 (34.6 to 48.5)**

No statistical analysis provided for Overall Survival Using Kaplan-Meier Methodology

5. Secondary: Number of Patients With Adverse Events (AEs), Clinically Notable AE, Death, Serious Adverse Events (SAEs) (Double-Blind Phase) [Time Frame: From first day of treatment up to 28 days after last day of treatment in double blind]

Measure Type	Secondary
Measure Title	Number of Patients With Adverse Events (AEs), Clinically Notable AE, Death, Serious Adverse Events (SAEs) (Double-Blind Phase)
Measure Description	AEs are defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during study, having been absent at baseline, or, if present at baseline, appears to worsen. SAEs are any untoward medical occurrences that result in death, are life threatening,

	require (or prolong) hospitalization, cause persistent or significant disability/incapacity, result in congenital anomalies or birth defects, or are other conditions which in judgment of investigators represent significant hazards.
Time Frame	From first day of treatment up to 28 days after last day of treatment in double blind
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Safety Set consists of all patients who received at least one dose of study drug and who had at least one valid post-baseline safety assessment.

Reporting Groups

	Description
Octreotide+ Everolimus	Everolimus was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity. Each treatment cycle lasted 28 days. Patients received their first dose of everolimus at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1, Day 1.
Octreotide+ Placebo	Matching placebo was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity; Each treatment cycle lasted 28 days. Patients received their first dose of matching placebo at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1 Day 1.

Measured Values

	Octreotide+ Everolimus	**Octreotide+ Placebo**
Number of Participants Analyzed [units: participants]	**215**	**211**
Number of Patients With Adverse Events (AEs), Clinically Notable AE, Death, Serious Adverse Events (SAEs) (Double-Blind Phase) [units: Patients]		

Clinically notable AE	**208**	**146**
Grade 3-4 Adverse Events	**162**	**109**
On treatment death	**19**	**11**
Serious adverse events	**126**	**74**

No statistical analysis provided for Number of Patients With Adverse Events (AEs), Clinically Notable AE, Death, Serious Adverse Events (SAEs) (Double-Blind Phase)

6. Secondary: Number of Patients With Adverse Events (AEs), Clinically Notable AE, Death, Serious Adverse Events (SAEs) (Open Label Phase) [Time Frame: From first day of treatment up to 28 days after last day of treatment in double blind]

Measure Type	Secondary
Measure Title	Number of Patients With Adverse Events (AEs), Clinically Notable AE, Death, Serious Adverse Events (SAEs) (Open Label Phase)
Measure Description	AEs are defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during study, having been absent at baseline, or, if present at baseline, appears to worsen. SAEs are any untoward medical occurrences that result in death, are life threatening, require (or prolong) hospitalization, cause persistent or significant disability/incapacity, result in congenital anomalies or birth defects, or are other conditions which in judgment of investigators represent significant hazards.
Time Frame	From first day of treatment up to 28 days after last day of treatment in double blind
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Safety Set consists of all patients who received at least one dose of study drug and who had at least one valid post-baseline safety assessment.

Reporting Groups

	Description
Everolimus Open Label Arm	Patients who had progressive disease in this arm, can move to the open label Everolimus + depot octreotide by choice.

Measured Values

	Everolimus Open Label Arm
Number of Participants Analyzed [units: participants]	**170**
Number of Patients With Adverse Events (AEs), Clinically Notable AE, Death, Serious Adverse Events (SAEs) (Open Label Phase) [units: Patients]	
Clinically notable AE	**154**
Grade 3-4 Adverse Events	**115**
On treatment death	**22**
Serious adverse events	**93**

No statistical analysis provided for Number of Patients With Adverse Events (AEs), Clinically Notable AE, Death, Serious Adverse Events (SAEs) (Open Label Phase)

7. Secondary: Progression Free Survival (PFS) as Per Adjudicated Central Review by Baseline Chromogranin A (CgA) [Time Frame: If elevated at baseline, evaluated every cycle visit (28 days/cycle) reported between day of first patient randomised, 10 January 2007, until cut-off date 02 April 2010]

Measure Type	Secondary
Measure Title	Progression Free Survival (PFS) as Per Adjudicated Central Review by Baseline Chromogranin A (CgA)

Measure Description	Serum CgA levels in urine are frequently elevated in patients with advanced carcinoid tumors. Baseline levels of serum CgA were characterized relative to the upper limited of normal (ULN). CgA levels exceeding 2 x ULN were considered to be 'Elevated'; otherwise considered as "Non-elevated".
Time Frame	If elevated at baseline, evaluated every cycle visit (28 days/cycle) reported between day of first patient randomised, 10 January 2007, until cut-off date 02 April 2010
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS; Intent-to-treat Population) consists of all randomized patients. This analysis includes PFS patients with non missing baseline CgA data.

Reporting Groups

	Description
Octreotide+ Everolimus	Everolimus was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity. Each treatment cycle lasted 28 days. Patients received their first dose of everolimus at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1, Day 1.
Octreotide+ Placebo	Matching placebo was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity; Each treatment cycle lasted 28 days. Patients received their first dose of matching placebo at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1 Day 1.

Measured Values

	Octreotide+ Everolimus	**Octreotide+ Placebo**
Number of Participants Analyzed [units: participants]	**212**	**208**
Progression Free Survival (PFS) as Per Adjudicated Central Review by Baseline		

Chromogranin A (CgA) **[units: Months]** **Median (95% Confidence Interval)**		
CgA<=2x ULN (n=60,78)	**31.31** **[1]**	**20.07** **[1]**
CgA>2x ULN (n=152,130)	**13.93** **(11.30 to 17.08)**	**8.41** **(7.72 to 11.14)**

[1] Upper Limit was not applicable or computable as median was just reached.

No statistical analysis provided for Progression Free Survival (PFS) as Per Adjudicated Central Review by Baseline Chromogranin A (CgA)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Double blind period, Safety Set consists all patients received at least one dose of study drug and who had at least one valid post-baseline safety assessment. The Open-label Set consists all patients received at least one dose of open-label everolimus and who had at least one valid safety assessment after initiation of open-label treatment

Reporting Groups

	Description
Everolimus + Octreotide	Everolimus was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity. Each treatment cycle lasted 28 days. Patients received their first dose of everolimus at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1, Day 1.
Placebo + Octreotide	Matching placebo was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity; Each treatment cycle lasted 28 days. Patients received their first dose of matching placebo at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1 Day 1.

Everolimus Open Label	Open Label - Patients who had progressive disease in this arm, can move to the open label Everolimus + depot octreotide by choice.

Serious Adverse Events

	Everolimus + Octreotide	Placebo + Octreotide	Everolimus Open Label
Total, serious adverse events			
# participants affected / at risk	**126/215 (58.60%)**	**74/211 (35.07%)**	**93/170 (54.71%)**
Blood and lymphatic system disorders			
Anaemia † [1]			
# participants affected / at risk	**4/215 (1.86%)**	**2/211 (0.95%)**	**4/170 (2.35%)**
Disseminated intravascular coagulation † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Febrile neutropenia † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Haemorrhagic anaemia † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**2/170 (1.18%)**
Leukopenia † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Pancytopenia † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Thrombocytopenia † [1]			
# participants affected / at risk	**3/215 (1.40%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Cardiac disorders			
Acute myocardial infarction † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**

Angina pectoris † 1			
# participants affected / at risk	**2/215 (0.93%)**	**3/211 (1.42%)**	**1/170 (0.59%)**
Aortic valve incompetence † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Arrhythmia † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Atrial fibrillation † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Atrial flutter † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Carcinoid heart disease † 1			
# participants affected / at risk	**2/215 (0.93%)**	**2/211 (0.95%)**	**2/170 (1.18%)**
Cardiac arrest † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Cardiac failure † 1			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Cardiac failure congestive † 1			
# participants affected / at risk	**2/215 (0.93%)**	**2/211 (0.95%)**	**0/170 (0.00%)**
Cardiac valve disease † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Cardio-respiratory arrest † 1			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Cardiopulmonary failure † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Coronary artery disease † 1			

# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Coronary artery occlusion † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Dilatation ventricular † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Left ventricular dysfunction † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Mitral valve stenosis † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Myocardial infarction † 1			
# participants affected / at risk	1/215 (0.47%)	2/211 (0.95%)	1/170 (0.59%)
Myocardial ischaemia † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Palpitations † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Pericardial effusion † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Pulmonary valve incompetence † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Pulmonary valve stenosis † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	1/170 (0.59%)
Right ventricular failure † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Stress cardiomyopathy † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Tachycardia paroxysmal † 1			

# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Tricuspid valve disease † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Tricuspid valve incompetence † 1			
# participants affected / at risk	1/215 (0.47%)	2/211 (0.95%)	0/170 (0.00%)
Tricuspid valve prolapse † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Tricuspid valve stenosis † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Congenital, familial and genetic disorders			
Atrial septal defect † 1			
# participants affected / at risk	2/215 (0.93%)	0/211 (0.00%)	0/170 (0.00%)
Ear and labyrinth disorders			
Vertigo † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Endocrine disorders			
Adrenocortical insufficiency acute † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Carcinoid crisis † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	1/170 (0.59%)
Carcinoid syndrome † 1			
# participants affected / at risk	2/215 (0.93%)	1/211 (0.47%)	2/170 (1.18%)
Eye disorders			
Diplopia † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)

Gastrointestinal disorders			
Abdominal adhesions † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Abdominal distension † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Abdominal hernia † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Abdominal pain † [1]			
# participants affected / at risk	**15/215 (6.98%)**	**11/211 (5.21%)**	**11/170 (6.47%)**
Abdominal pain lower † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Abdominal pain upper † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**2/211 (0.95%)**	**1/170 (0.59%)**
Ascites † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**5/211 (2.37%)**	**0/170 (0.00%)**
Colitis † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Constipation † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Diarrhoea † [1]			
# participants affected / at risk	**9/215 (4.19%)**	**5/211 (2.37%)**	**7/170 (4.12%)**
Duodenal obstruction † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Duodenal stenosis † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**2/170 (1.18%)**

Enteritis † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Faeces discoloured † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Food poisoning † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**2/211 (0.95%)**	**0/170 (0.00%)**
Gastric haemorrhage † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Gastric ulcer † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Gastritis erosive † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Gastrointestinal angiodysplasia † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Gastrointestinal fistula † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Gastrointestinal haemorrhage † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**2/170 (1.18%)**
Gastrooesophageal reflux disease † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Haematemesis † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Haematochezia † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Haemorrhoids † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**0/170 (0.00%)**

Ileus † [1]			
# participants affected / at risk	**5/215 (2.33%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Inguinal hernia, obstructive † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Intestinal angina † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Intestinal obstruction † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**5/211 (2.37%)**	**3/170 (1.76%)**
Intestinal perforation † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**2/170 (1.18%)**
Lip oedema † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Lower gastrointestinal haemorrhage † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Melaena † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Nausea † [1]			
# participants affected / at risk	**4/215 (1.86%)**	**4/211 (1.90%)**	**2/170 (1.18%)**
Oesophageal spasm † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Pancreatitis acute † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Pneumatosis intestinalis † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Rectal haemorrhage † [1]			
# participants affected / at risk	**3/215 (1.40%)**	**0/211 (0.00%)**	**1/170 (0.59%)**

Retroperitoneal haematoma † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Small intestinal haemorrhage † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Small intestinal obstruction † 1			
# participants affected / at risk	**8/215 (3.72%)**	**3/211 (1.42%)**	**4/170 (2.35%)**
Small intestinal stenosis † 1			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Stomatitis † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Subileus † 1			
# participants affected / at risk	**3/215 (1.40%)**	**2/211 (0.95%)**	**0/170 (0.00%)**
Upper gastrointestinal haemorrhage † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Vomiting † 1			
# participants affected / at risk	**7/215 (3.26%)**	**6/211 (2.84%)**	**5/170 (2.94%)**
General disorders			
Asthenia † 1			
# participants affected / at risk	**2/215 (0.93%)**	**3/211 (1.42%)**	**1/170 (0.59%)**
Brain death † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Chest pain † 1			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Chills † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**

Face oedema † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Fatigue † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
General physical health deterioration † [1]			
# participants affected / at risk	**6/215 (2.79%)**	**3/211 (1.42%)**	**5/170 (2.94%)**
Generalised oedema † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Hypothermia † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Malaise † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Non-cardiac chest pain † [1]			
# participants affected / at risk	**3/215 (1.40%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Oedema peripheral † [1]			
# participants affected / at risk	**3/215 (1.40%)**	**4/211 (1.90%)**	**3/170 (1.76%)**
Pain † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**2/211 (0.95%)**	**0/170 (0.00%)**
Performance status decreased † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Pyrexia † [1]			
# participants affected / at risk	**8/215 (3.72%)**	**3/211 (1.42%)**	**3/170 (1.76%)**
Spinal pain † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Sudden death † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**

Hepatobiliary disorders			
Bile duct obstruction † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Cholangitis † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Cholangitis acute † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Cholecystitis † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Cholecystitis acute † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Cholelithiasis † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Cholestasis † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Hepatic failure † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Hepatic function abnormal † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Hepatocellular injury † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Hepatotoxicity † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Hyperbilirubinaemia † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**

Jaundice † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Immune system disorders			
Drug hypersensitivity † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Infections and infestations			
Abdominal wall abscess † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Abscess intestinal † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Arthritis infective † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Aspergillosis † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Bacteraemia † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Bronchiolitis † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Bronchopneumonia † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Cellulitis † [1]			
# participants affected / at risk	**3/215 (1.40%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Cholecystitis infective † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Clostridium difficile colitis † [1]			

# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Diverticulitis † [1]			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Erysipelas † [1]			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)
Escherichia sepsis † [1]			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Gastroenteritis † [1]			
# participants affected / at risk	2/215 (0.93%)	1/211 (0.47%)	2/170 (1.18%)
Gastroenteritis viral † [1]			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	1/170 (0.59%)
Herpes zoster † [1]			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	1/170 (0.59%)
Infected skin ulcer † [1]			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Infection † [1]			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)
Influenza † [1]			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Localised infection † [1]			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	2/170 (1.18%)
Lung infection † [1]			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	2/170 (1.18%)
Osteomyelitis † [1]			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)

Peritonitis † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Pneumonia † 1			
# participants affected / at risk	**9/215 (4.19%)**	**1/211 (0.47%)**	**5/170 (2.94%)**
Pneumonia viral † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Sepsis † 1			
# participants affected / at risk	**2/215 (0.93%)**	**1/211 (0.47%)**	**4/170 (2.35%)**
Sinusitis † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Staphylococcal infection † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Urinary tract infection † 1			
# participants affected / at risk	**2/215 (0.93%)**	**2/211 (0.95%)**	**0/170 (0.00%)**
Urinary tract infection bacterial † 1			
# participants affected / at risk	**0/215 (0.00%)**	**2/211 (0.95%)**	**0/170 (0.00%)**
Urosepsis † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Injury, poisoning and procedural complications			
Bone fissure † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Femoral neck fracture † 1			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Fractured sacrum † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**

Heat exhaustion † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Hip fracture † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Humerus fracture † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Joint injury † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Post procedural complication † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Post procedural haemorrhage † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Pulmonary contusion † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Rib fracture † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Scapula fracture † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Seroma † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Toxicity to various agents † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Traumatic intracranial haemorrhage † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Investigations			

Alanine aminotransferase increased † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Aspartate aminotransferase increased † 1			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Blood alkaline phosphatase increased † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Blood creatinine increased † 1			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**4/170 (2.35%)**
Blood urea increased † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Cardiac murmur † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Coagulation time shortened † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Heart rate increased † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Lipase increased † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Weight decreased † 1			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Metabolism and nutrition disorders			
Cachexia † 1			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Decreased appetite † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**2/170 (1.18%)**

Dehydration † [1]			
# participants affected / at risk	**7/215 (3.26%)**	**1/211 (0.47%)**	**3/170 (1.76%)**
Failure to thrive † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Hypercalcaemia † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Hyperglycaemia † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**3/170 (1.76%)**
Hypocalcaemia † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Hypoglycaemia † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Hypokalaemia † [1]			
# participants affected / at risk	**4/215 (1.86%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Hypomagnesaemia † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Hypophosphataemia † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Malnutrition † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**2/211 (0.95%)**	**0/170 (0.00%)**
Metabolic acidosis † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Type 2 diabetes mellitus † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Musculoskeletal and connective tissue disorders			

Arthralgia † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Arthritis † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Back pain † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**4/211 (1.90%)**	**1/170 (0.59%)**
Bone pain † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Flank pain † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Muscle spasms † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Musculoskeletal chest pain † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Neck pain † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Osteoarthritis † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Osteoporosis † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Pain in extremity † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell type acute leukaemia † [1]			

# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Brain neoplasm malignant † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Cancer pain † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Glioblastoma † 1			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)
Lung infiltration malignant † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Malignant pleural effusion † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Metastatic pain † 1			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)
Pancreatic carcinoma † 1			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)
Tumour compression † 1			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)
Nervous system disorders			
Cerebral ischaemia † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	1/170 (0.59%)
Cerebrovascular accident † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	1/170 (0.59%)
Convulsion † 1			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)
Depressed level of consciousness † 1			

# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Dizziness postural † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Encephalopathy † 1			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Facial paresis † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Grand mal convulsion † 1			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)
Headache † 1			
# participants affected / at risk	0/215 (0.00%)	2/211 (0.95%)	0/170 (0.00%)
Hypoaesthesia † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Intracranial haematoma † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Lethargy † 1			
# participants affected / at risk	1/215 (0.47%)	1/211 (0.47%)	0/170 (0.00%)
Mental impairment † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Metabolic encephalopathy † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Radicular syndrome † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Radiculopathy † 1			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)

Sciatica † 1			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Subarachnoid haemorrhage † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Syncope † 1			
# participants affected / at risk	**2/215 (0.93%)**	**1/211 (0.47%)**	**2/170 (1.18%)**
Psychiatric disorders			
Confusional state † 1			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Depression † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Hallucination † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Mental status changes † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Renal and urinary disorders			
Bladder tamponade † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Calculus ureteric † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Calculus urinary † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Eosinophilic cystitis † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Haematuria † 1			

# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	1/170 (0.59%)
Hydronephrosis † [1]			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)
Nephrolithiasis † [1]			
# participants affected / at risk	1/215 (0.47%)	1/211 (0.47%)	2/170 (1.18%)
Renal failure † [1]			
# participants affected / at risk	4/215 (1.86%)	0/211 (0.00%)	3/170 (1.76%)
Renal failure acute † [1]			
# participants affected / at risk	3/215 (1.40%)	1/211 (0.47%)	1/170 (0.59%)
Renal failure chronic † [1]			
# participants affected / at risk	0/215 (0.00%)	0/211 (0.00%)	1/170 (0.59%)
Renal impairment † [1]			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	1/170 (0.59%)
Renal infarct † [1]			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Ureteric obstruction † [1]			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Urinary bladder haemorrhage † [1]			
# participants affected / at risk	1/215 (0.47%)	0/211 (0.00%)	0/170 (0.00%)
Urinary retention † [1]			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Reproductive system and breast disorders			
Testicular swelling † [1]			
# participants affected / at risk	0/215 (0.00%)	1/211 (0.47%)	0/170 (0.00%)
Respiratory, thoracic and mediastinal disorders			

Acute respiratory failure † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Atelectasis † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Cough † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Dyspnoea † [1]			
# participants affected / at risk	**8/215 (3.72%)**	**2/211 (0.95%)**	**1/170 (0.59%)**
Granulomatous pneumonitis † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Haemoptysis † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Hypoxia † [1]			
# participants affected / at risk	**3/215 (1.40%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Interstitial lung disease † [1]			
# participants affected / at risk	**3/215 (1.40%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Laryngeal oedema † [1]			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Lung infiltration † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Organising pneumonia † [1]			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Pleural effusion † [1]			
# participants affected / at risk	**3/215 (1.40%)**	**0/211 (0.00%)**	**2/170 (1.18%)**
Pneumonitis † [1]			
# participants affected / at risk	**2/215 (0.93%)**	**0/211 (0.00%)**	**2/170 (1.18%)**

Pneumothorax † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Pulmonary embolism † 1			
# participants affected / at risk	**6/215 (2.79%)**	**1/211 (0.47%)**	**3/170 (1.76%)**
Pulmonary hypertension † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Respiratory arrest † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Respiratory distress † 1			
# participants affected / at risk	**0/215 (0.00%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Respiratory failure † 1			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Tachypnoea † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Skin and subcutaneous tissue disorders			
Angioedema † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**1/170 (0.59%)**
Palmar-plantar erythrodysaesthesia syndrome † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Vascular disorders			
Aortic dissection † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Deep vein thrombosis † 1			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**2/170 (1.18%)**
Flushing † 1			

# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Haematoma † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Hypertension † 1			
# participants affected / at risk	**1/215 (0.47%)**	**1/211 (0.47%)**	**1/170 (0.59%)**
Hypotension † 1			
# participants affected / at risk	**0/215 (0.00%)**	**1/211 (0.47%)**	**0/170 (0.00%)**
Jugular vein thrombosis † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Orthostatic hypotension † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**
Phlebitis † 1			
# participants affected / at risk	**1/215 (0.47%)**	**0/211 (0.00%)**	**0/170 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Double blind period, Safety Set consists all patients received at least one dose of study drug and who had at least one valid post-baseline safety assessment. The Open-label Set consists all patients received at least one dose of open-label everolimus and who had at least one valid safety assessment after initiation of open-label treatment

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Everolimus + Octreotide	Everolimus was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity. Each treatment cycle lasted 28 days. Patients received their first dose of everolimus at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1, Day 1.
Placebo + Octreotide	Matching placebo was administered in accordance with a 10-mg daily dosing regimen (two 5-mg tablets) in conjunction with octreotide 30 mg intramuscularly (i.m.) every 28 days. Patients were treated until progression or unacceptable toxicity; Each treatment cycle lasted 28 days. Patients received their first dose of matching placebo at Cycle 1, Day 1. Administration of octreotide was performed every 28 days (± 4 days) starting on Cycle 1 Day 1.
Everolimus Open Label	Open Label - Patients who had progressive disease in this arm, can move to the open label Everolimus + depot octreotide by choice.

Other Adverse Events

	Everolimus + Octreotide	Placebo + Octreotide	Everolimus Open Label
Total, other (not including serious) adverse events			
# participants affected / at risk	**214/215 (99.53%)**	**194/211 (91.94%)**	**162/170 (95.29%)**
Blood and lymphatic system disorders			
Anaemia † [1]			
# participants affected / at risk	**58/215 (26.98%)**	**21/211 (9.95%)**	**34/170 (20.00%)**
Leukopenia † [1]			
# participants affected / at risk	**16/215 (7.44%)**	**2/211 (0.95%)**	**2/170 (1.18%)**
Neutropenia † [1]			
# participants affected / at risk	**18/215 (8.37%)**	**3/211 (1.42%)**	**13/170 (7.65%)**
Thrombocytopenia † [1]			
# participants affected / at risk	**34/215 (15.81%)**	**1/211 (0.47%)**	**15/170 (8.82%)**
Gastrointestinal disorders			

Abdominal distension † 1			
# participants affected / at risk	**12/215 (5.58%)**	**12/211 (5.69%)**	**10/170 (5.88%)**
Abdominal pain † 1			
# participants affected / at risk	**65/215 (30.23%)**	**68/211 (32.23%)**	**43/170 (25.29%)**
Abdominal pain upper † 1			
# participants affected / at risk	**22/215 (10.23%)**	**26/211 (12.32%)**	**16/170 (9.41%)**
Aphthous stomatitis † 1			
# participants affected / at risk	**28/215 (13.02%)**	**3/211 (1.42%)**	**15/170 (8.82%)**
Ascites † 1			
# participants affected / at risk	**17/215 (7.91%)**	**9/211 (4.27%)**	**8/170 (4.71%)**
Constipation † 1			
# participants affected / at risk	**31/215 (14.42%)**	**22/211 (10.43%)**	**17/170 (10.00%)**
Diarrhoea † 1			
# participants affected / at risk	**114/215 (53.02%)**	**77/211 (36.49%)**	**77/170 (45.29%)**
Dry mouth † 1			
# participants affected / at risk	**22/215 (10.23%)**	**6/211 (2.84%)**	**7/170 (4.12%)**
Dysphagia † 1			
# participants affected / at risk	**15/215 (6.98%)**	**5/211 (2.37%)**	**4/170 (2.35%)**
Flatulence † 1			
# participants affected / at risk	**27/215 (12.56%)**	**28/211 (13.27%)**	**12/170 (7.06%)**
Haemorrhoids † 1			
# participants affected / at risk	**17/215 (7.91%)**	**9/211 (4.27%)**	**9/170 (5.29%)**
Mouth ulceration † 1			
# participants affected / at risk	**17/215 (7.91%)**	**5/211 (2.37%)**	**11/170 (6.47%)**
Nausea † 1			

# participants affected / at risk	92/215 (42.79%)	63/211 (29.86%)	60/170 (35.29%)
Stomatitis † [1]			
# participants affected / at risk	109/215 (50.70%)	25/211 (11.85%)	63/170 (37.06%)
Vomiting † [1]			
# participants affected / at risk	69/215 (32.09%)	40/211 (18.96%)	30/170 (17.65%)
General disorders			
Asthenia † [1]			
# participants affected / at risk	51/215 (23.72%)	30/211 (14.22%)	30/170 (17.65%)
Chills † [1]			
# participants affected / at risk	15/215 (6.98%)	10/211 (4.74%)	5/170 (2.94%)
Fatigue † [1]			
# participants affected / at risk	103/215 (47.91%)	91/211 (43.13%)	63/170 (37.06%)
Oedema peripheral † [1]			
# participants affected / at risk	92/215 (42.79%)	47/211 (22.27%)	62/170 (36.47%)
Pyrexia † [1]			
# participants affected / at risk	42/215 (19.53%)	21/211 (9.95%)	32/170 (18.82%)
Infections and infestations			
Bronchitis † [1]			
# participants affected / at risk	11/215 (5.12%)	7/211 (3.32%)	8/170 (4.71%)
Nasopharyngitis † [1]			
# participants affected / at risk	19/215 (8.84%)	26/211 (12.32%)	19/170 (11.18%)
Sinusitis † [1]			
# participants affected / at risk	12/215 (5.58%)	9/211 (4.27%)	17/170 (10.00%)
Upper respiratory tract infection † [1]			
# participants affected / at risk	27/215 (12.56%)	12/211 (5.69%)	11/170 (6.47%)

Urinary tract infection † [1]			
# participants affected / at risk	27/215 (12.56%)	16/211 (7.58%)	19/170 (11.18%)
Investigations			
Alanine aminotransferase increased † [1]			
# participants affected / at risk	9/215 (4.19%)	6/211 (2.84%)	10/170 (5.88%)
Aspartate aminotransferase increased † [1]			
# participants affected / at risk	11/215 (5.12%)	8/211 (3.79%)	8/170 (4.71%)
Blood creatinine increased † [1]			
# participants affected / at risk	15/215 (6.98%)	5/211 (2.37%)	8/170 (4.71%)
Weight decreased † [1]			
# participants affected / at risk	59/215 (27.44%)	31/211 (14.69%)	33/170 (19.41%)
Metabolism and nutrition disorders			
Decreased appetite † [1]			
# participants affected / at risk	64/215 (29.77%)	36/211 (17.06%)	33/170 (19.41%)
Dehydration † [1]			
# participants affected / at risk	17/215 (7.91%)	12/211 (5.69%)	9/170 (5.29%)
Hypercholesterolaemia † [1]			
# participants affected / at risk	17/215 (7.91%)	6/211 (2.84%)	7/170 (4.12%)
Hyperglycaemia † [1]			
# participants affected / at risk	42/215 (19.53%)	9/211 (4.27%)	24/170 (14.12%)
Hyperlipidaemia † [1]			
# participants affected / at risk	15/215 (6.98%)	3/211 (1.42%)	4/170 (2.35%)
Hypocalcaemia † [1]			
# participants affected / at risk	17/215 (7.91%)	4/211 (1.90%)	11/170 (6.47%)
Hypokalaemia † [1]			

# participants affected / at risk	50/215 (23.26%)	8/211 (3.79%)	27/170 (15.88%)
Hypomagnesaemia † [1]			
# participants affected / at risk	15/215 (6.98%)	5/211 (2.37%)	6/170 (3.53%)
Hypophosphataemia † [1]			
# participants affected / at risk	11/215 (5.12%)	6/211 (2.84%)	8/170 (4.71%)
Musculoskeletal and connective tissue disorders			
Arthralgia † [1]			
# participants affected / at risk	38/215 (17.67%)	28/211 (13.27%)	19/170 (11.18%)
Back pain † [1]			
# participants affected / at risk	33/215 (15.35%)	41/211 (19.43%)	18/170 (10.59%)
Muscle spasms † [1]			
# participants affected / at risk	17/215 (7.91%)	13/211 (6.16%)	10/170 (5.88%)
Musculoskeletal chest pain † [1]			
# participants affected / at risk	18/215 (8.37%)	7/211 (3.32%)	11/170 (6.47%)
Musculoskeletal pain † [1]			
# participants affected / at risk	21/215 (9.77%)	21/211 (9.95%)	8/170 (4.71%)
Myalgia † [1]			
# participants affected / at risk	16/215 (7.44%)	14/211 (6.64%)	8/170 (4.71%)
Pain in extremity † [1]			
# participants affected / at risk	32/215 (14.88%)	24/211 (11.37%)	19/170 (11.18%)
Nervous system disorders			
Dizziness † [1]			
# participants affected / at risk	29/215 (13.49%)	24/211 (11.37%)	12/170 (7.06%)
Dysgeusia † [1]			
# participants affected / at risk	42/215 (19.53%)	12/211 (5.69%)	30/170 (17.65%)

Headache † [1]			
# participants affected / at risk	**65/215 (30.23%)**	**49/211 (23.22%)**	**32/170 (18.82%)**
Psychiatric disorders			
Anxiety † [1]			
# participants affected / at risk	**14/215 (6.51%)**	**14/211 (6.64%)**	**12/170 (7.06%)**
Depression † [1]			
# participants affected / at risk	**16/215 (7.44%)**	**11/211 (5.21%)**	**12/170 (7.06%)**
Insomnia † [1]			
# participants affected / at risk	**20/215 (9.30%)**	**15/211 (7.11%)**	**12/170 (7.06%)**
Renal and urinary disorders			
Dysuria † [1]			
# participants affected / at risk	**12/215 (5.58%)**	**5/211 (2.37%)**	**7/170 (4.12%)**
Pollakiuria † [1]			
# participants affected / at risk	**10/215 (4.65%)**	**6/211 (2.84%)**	**11/170 (6.47%)**
Respiratory, thoracic and mediastinal disorders			
Cough † [1]			
# participants affected / at risk	**59/215 (27.44%)**	**32/211 (15.17%)**	**38/170 (22.35%)**
Dyspnoea † [1]			
# participants affected / at risk	**59/215 (27.44%)**	**19/211 (9.00%)**	**27/170 (15.88%)**
Dyspnoea exertional † [1]			
# participants affected / at risk	**9/215 (4.19%)**	**11/211 (5.21%)**	**7/170 (4.12%)**
Epistaxis † [1]			
# participants affected / at risk	**33/215 (15.35%)**	**5/211 (2.37%)**	**24/170 (14.12%)**
Oropharyngeal pain † [1]			
# participants affected / at risk	**20/215 (9.30%)**	**6/211 (2.84%)**	**13/170 (7.65%)**

Pleural effusion † 1			
# participants affected / at risk	**12/215 (5.58%)**	**6/211 (2.84%)**	**7/170 (4.12%)**
Pneumonitis † 1			
# participants affected / at risk	**20/215 (9.30%)**	**2/211 (0.95%)**	**6/170 (3.53%)**
Skin and subcutaneous tissue disorders			
Alopecia † 1			
# participants affected / at risk	**13/215 (6.05%)**	**4/211 (1.90%)**	**7/170 (4.12%)**
Dry skin † 1			
# participants affected / at risk	**23/215 (10.70%)**	**5/211 (2.37%)**	**9/170 (5.29%)**
Erythema † 1			
# participants affected / at risk	**17/215 (7.91%)**	**4/211 (1.90%)**	**7/170 (4.12%)**
Hyperhidrosis † 1			
# participants affected / at risk	**9/215 (4.19%)**	**13/211 (6.16%)**	**5/170 (2.94%)**
Onychoclasis † 1			
# participants affected / at risk	**11/215 (5.12%)**	**1/211 (0.47%)**	**10/170 (5.88%)**
Pruritus † 1			
# participants affected / at risk	**42/215 (19.53%)**	**12/211 (5.69%)**	**18/170 (10.59%)**
Rash † 1			
# participants affected / at risk	**88/215 (40.93%)**	**37/211 (17.54%)**	**59/170 (34.71%)**
Vascular disorders			
Flushing † 1			
# participants affected / at risk	**20/215 (9.30%)**	**20/211 (9.48%)**	**6/170 (3.53%)**
Hypertension † 1			
# participants affected / at risk	**24/215 (11.16%)**	**21/211 (9.95%)**	**16/170 (9.41%)**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Fazio N, Granberg D, Grossman A, Saletan S, Klimovsky J, Panneerselvam A, Wolin EM. Everolimus plus octreotide long-acting repeatable in patients with advanced lung neuroendocrine tumors: analysis of the phase 3, randomized, placebo-controlled RADIANT-2 study. Chest. 2013 Apr;143(4):955-62.

Pavel ME, Hainsworth JD, Baudin E, Peeters M, Hörsch D, Winkler RE, Klimovsky J, Lebwohl D, Jehl V, Wolin EM, Oberg K, Van Cutsem E, Yao JC; RADIANT-2 Study Group. Everolimus plus octreotide long-acting repeatable for the treatment of advanced neuroendocrine tumours associated with carcinoid syndrome (RADIANT-2): a randomised, placebo-controlled, phase 3 study. Lancet. 2011 Dec 10;378(9808):2005-12. doi: 10.1016/S0140-6736(11)61742-X. Epub 2011 Nov 25.

Responsible Party:	Novartis (Novartis Pharmaceuticals)
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