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Trial record **1 of 1** for: CRAD001C2241

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Efficacy and Safety of Everolimus in Patients With Metastatic Colorectal Cancer Who Have Failed Prior Targeted Therapy and Chemotherapy

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00419159

First received: January 4, 2007
Last updated: November 4, 2011
Last verified: November 2011
History of Changes

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Results First Received: December 17, 2010

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Colorectal Cancer
Intervention:	Drug: Everolimus (RAD001)

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
No text entered.

Reporting Groups

	Description
Everolimus (RAD001) 70 mg/Week	Participants self-administered weekly oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.
Everolimus (RAD001) 10 mg/Day	Participants self-administered daily oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.

Participant Flow: Overall Study

	Everolimus (RAD001) 70 mg/Week	Everolimus (RAD001) 10 mg/Day
STARTED	**99** [1]	**100**
COMPLETED	**0**	**0**
NOT COMPLETED	**99**	**100**
Adverse Event	**7**	**15**
Abnormal laboratory value(s)	**0**	**2**
Subject's no longer requires study drug	**0**	**1**
Protocol Violation	**1**	**0**

Withdrawal by Subject	**10**	**3**
Lost to Follow-up	**0**	**1**
Death	**2**	**2**
Disease progression	**79**	**76**

[1] Full Analysis Set

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
Everolimus (RAD001) 70 mg/Week	Participants self-administered weekly oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.
Everolimus (RAD001) 10 mg/Day	Participants self-administered daily oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.
Total	Total of all reporting groups

Baseline Measures

	Everolimus (RAD001) 70 mg/Week	Everolimus (RAD001) 10 mg/Day	Total
Number of Participants [units: participants]	**99**	**100**	**199**

Age [units: years] Mean (Standard Deviation)	**60.0 (11.5)**	**60.3 (12.1)**	**60.2 (11.8)**
Age, Customized [units: Participants]			
<45 Years	**10**	**10**	**20**
45 to <55 Years	**22**	**17**	**39**
55 to <65 Years	**29**	**33**	**62**
> or = to 65 Years	**38**	**40**	**78**
Gender [units: participants]			
Female	**47**	**48**	**95**
Male	**52**	**52**	**104**

Outcome Measures

Hide All Outcome Measures

1. Primary: Disease Control Rate (DCR) and Objective Response Rate (ORR) According to the Response Evaluation Criteria in Solid Tumors (RECIST) [Time Frame: Imaging every 8 weeks]

Measure Type	Primary
Measure Title	Disease Control Rate (DCR) and Objective Response Rate (ORR) According to the Response Evaluation Criteria in Solid Tumors (RECIST)
Measure Description	RECIST (Response Evaluation Criteria In Solid Tumors) is a set of published rules that define when cancer patients improve ("respond"), stay the same ("stable") or worsen ("progression") during treatments. Disease Control Rate (DCR) defined as the percentage of participants with Disease Control best overall response (complete response, partial response or stable disease)and Objective Response Rate (ORR) defined as the

	percentage of participants with best overall Objective Response (complete response or partial response).
Time Frame	Imaging every 8 weeks
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.
Per Protocol Set

Reporting Groups

	Description
Everolimus (RAD001) 70 mg/Week	Participants self-administered weekly oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.
Everolimus (RAD001) 10 mg/Day	Participants self-administered daily oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.

Measured Values

	Everolimus (RAD001) 70 mg/Week	**Everolimus (RAD001) 10 mg/Day**
Number of Participants Analyzed [units: participants]	**71**	**71**
Disease Control Rate (DCR) and Objective Response Rate (ORR) According to the Response Evaluation Criteria in Solid Tumors (RECIST) [units: Percentage of participants] Number (95% Confidence Interval)		
Disease Control Rate (DCR)	**31.0 (20.5 to 43.1)**	**32.4 (21.8 to 44.5)**
Objective Response Rate (ORR)	**0 (0 to 0)**	**0 (0 to 0)**

No statistical analysis provided for Disease Control Rate (DCR) and Objective Response Rate (ORR) According to the Response Evaluation Criteria in Solid Tumors (RECIST)

2. Primary: The Number of Participants With Best Overall Response: Complete Response (CR, No Lesions), Partial Response (PR, 30% Decrease in Lesions), and Stable Disease (SD, None of the Above) According to Response Evaluation Criteria in Solid Tumors (RECIST) [Time Frame: Imaging every 8 weeks]

Measure Type	Primary
Measure Title	The Number of Participants With Best Overall Response: Complete Response (CR, No Lesions), Partial Response (PR, 30% Decrease in Lesions), and Stable Disease (SD, None of the Above) According to Response Evaluation Criteria in Solid Tumors (RECIST)
Measure Description	RECIST (Response Evaluation Criteria In Solid Tumors) is a set of published rules that define when cancer patients improve ("respond"), stay the same ("stable") or worsen ("progression") during treatments.
Time Frame	Imaging every 8 weeks
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.
Full Analysis Set

Reporting Groups

	Description
Everolimus (RAD001) 70 mg/Week	Participants self-administered weekly oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.
Everolimus (RAD001) 10 mg/Day	Participants self-administered daily oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.

Measured Values

	Everolimus (RAD001) 70 mg/Week	Everolimus (RAD001) 10 mg/Day
Number of Participants Analyzed [units: participants]	**99**	**100**
The Number of Participants With Best Overall Response: Complete Response (CR, No Lesions), Partial Response (PR, 30% Decrease in Lesions), and Stable Disease (SD, None of the Above) According to Response Evaluation Criteria in Solid Tumors (RECIST) [units: Participants]		
Complete Response (CR)	**0**	**0**
Partial Response (PR)	**0**	**0**
Stable Disease (SD)	**25**	**26**
Progressive Disease (PD)	**58**	**55**
Disease Control (CR or PR or SD)	**25**	**26**
Objective Response (CR or PR)	**0**	**0**
Unknown	**16**	**19**

No statistical analysis provided for The Number of Participants With Best Overall Response: Complete Response (CR, No Lesions), Partial Response (PR, 30% Decrease in Lesions), and Stable Disease (SD, None of the Above) According to Response Evaluation Criteria in Solid Tumors (RECIST)

3. Secondary: Progression-free Survival (PFS) [Time Frame: Imaging every 8 weeks]

Measure Type	Secondary
Measure Title	Progression-free Survival (PFS)

Measure Description	Duration in months from the date of first study treatment to the date of the first documented disease progression or death due to any cause.
Time Frame	Imaging every 8 weeks
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.
Progression- Free Survival (PFS) was analyzed in Full Analysis Set [FAS].

Reporting Groups

	Description
Everolimus (RAD001) 70 mg/Week	Participants self-administered weekly oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.
Everolimus (RAD001) 10 mg/Day	Participants self-administered daily oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.

Measured Values

	Everolimus (RAD001) 70 mg/Week	**Everolimus (RAD001) 10 mg/Day**
Number of Participants Analyzed [units: participants]	**99**	**100**
Progression-free Survival (PFS) [units: Months] Median (95% Confidence Interval)	**1.77 (1.68 to 1.84)**	**1.77 (1.68 to 1.87)**

No statistical analysis provided for Progression-free Survival (PFS)

4. Secondary: Overall Survival (OS) [Time Frame: Every 3 months]

Measure Type	Secondary
Measure Title	Overall Survival (OS)
Measure Description	Overall survival defined as the time from date of first study treatment to the date of death due to any cause.
Time Frame	Every 3 months
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.
Overall Survival [OS] was analyzed in Full Analysis Set [FAS].

Reporting Groups

	Description
Everolimus (RAD001) 70 mg/Week	Participants self-administered weekly oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.
Everolimus (RAD001) 10 mg/Day	Participants self-administered daily oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.

Measured Values

	Everolimus (RAD001) 70 mg/Week	**Everolimus (RAD001) 10 mg/Day**
Number of Participants Analyzed [units: participants]	**99**	**100**
Overall Survival (OS) [units: Months] Median (95% Confidence Interval)	**4.90 (4.04 to 6.60)**	**5.88 (4.70 to 7.06)**

No statistical analysis provided for Overall Survival (OS)

5. Secondary: Number of Patients Who Died, Had an Serious Adverse Event (SAE), Had Grade 3 to 4 Adverse Event (AE), Discontinued Due to an AE, or Had a Clinical Notable AE by Treatment (tr). [Time Frame: From the first day of treatment until 28 days after discontinuation of study treatment]

Measure Type	Secondary
Measure Title	Number of Patients Who Died, Had an Serious Adverse Event (SAE), Had Grade 3 to 4 Adverse Event (AE), Discontinued Due to an AE, or Had a Clinical Notable AE by Treatment (tr).
Measure Description	Toxicity assessed using the NIH-NCI Common Terminology Criteria for Adverse Events, Version 3.0 (CTCAEv3.0). On treatment death defined as deaths occurring no more than 28 days after the discontinuation of study treatment.
Time Frame	From the first day of treatment until 28 days after discontinuation of study treatment
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.
Safety set analysis

Reporting Groups

	Description
Everolimus (RAD001) 70 mg/Week	Participants self-administered weekly oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.
Everolimus (RAD001) 10 mg/Day	Participants self-administered daily oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.

Measured Values

	Everolimus (RAD001) 70 mg/Week	Everolimus (RAD001) 10 mg/Day
Number of Participants Analyzed [units: participants]	**99**	**100**
Number of Patients Who Died, Had an Serious Adverse Event (SAE), Had Grade 3 to 4 Adverse Event (AE), Discontinued Due to an AE, or Had a Clinical Notable AE by Treatment (tr). [units: Participants]		
Deaths	**86**	**65**
On-treatment Death	**11**	**14**
SAE regardless of relationship to study treatment	**34**	**22**
SAE with suspected relationship to study treatment	**7**	**6**
AE Grade 3-4, regardless of relationship to study	**58**	**50**
AE Grade 3-4, suspected relationship to study tr	**31**	**26**
AE leading to discontinuation	**9**	**20**
Clinically notable adverse event	**85**	**76**

No statistical analysis provided for Number of Patients Who Died, Had an Serious Adverse Event (SAE), Had Grade 3 to 4 Adverse Event (AE), Discontinued Due to an AE, or Had a Clinical Notable AE by Treatment (tr).

6. Secondary: Biomarkers Predictive of Clinical Benefit on Everolimus (RAD001) [Time Frame: Screening and Day 1 of cycles 2, 3, 4 and end of treatment]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events occurring up to 28 days after the discontinuation of study treatment.
Additional Description	No text entered.

Reporting Groups

	Description
Everolimus (RAD001) 70 mg/Week	Participants self-administered weekly oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.
Everolimus (RAD001) 10 mg/Day	Participants self-administered daily oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.

Serious Adverse Events

	Everolimus (RAD001) 70 mg/Week	Everolimus (RAD001) 10 mg/Day
Total, serious adverse events		
# participants affected / at risk	**34/99 (34.34%)**	**22/100 (22.00%)**
Blood and lymphatic system disorders		
Anaemia † [1]		
# participants affected / at risk	**2/99 (2.02%)**	**0/100 (0.00%)**
Thrombocytopenia † [1]		
# participants affected / at risk	**0/99 (0.00%)**	**2/100 (2.00%)**
Gastrointestinal disorders		
Abdominal pain † [1]		
# participants affected / at risk	**3/99 (3.03%)**	**3/100 (3.00%)**
Abdominal pain upper † [1]		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Ascites † [1]		
# participants affected / at risk	**1/99 (1.01%)**	**1/100 (1.00%)**

Constipation † 1		
# participants affected / at risk	**4/99 (4.04%)**	**0/100 (0.00%)**
Diarrhoea † 1		
# participants affected / at risk	**3/99 (3.03%)**	**0/100 (0.00%)**
Gastrointestinal pain † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Ileus † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Intestinal obstruction † 1		
# participants affected / at risk	**2/99 (2.02%)**	**1/100 (1.00%)**
Malabsorption † 1		
# participants affected / at risk	**0/99 (0.00%)**	**1/100 (1.00%)**
Nausea † 1		
# participants affected / at risk	**5/99 (5.05%)**	**0/100 (0.00%)**
Small intestinal obstruction † 1		
# participants affected / at risk	**2/99 (2.02%)**	**3/100 (3.00%)**
Stomatitis † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Vomiting † 1		
# participants affected / at risk	**5/99 (5.05%)**	**1/100 (1.00%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**3/99 (3.03%)**	**0/100 (0.00%)**
Chest pain † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**

Multi-organ failure † 1		
# participants affected / at risk	**0/99 (0.00%)**	**2/100 (2.00%)**
Non-cardiac chest pain † 1		
# participants affected / at risk	**0/99 (0.00%)**	**1/100 (1.00%)**
Pain † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Pyrexia † 1		
# participants affected / at risk	**5/99 (5.05%)**	**1/100 (1.00%)**
Hepatobiliary disorders		
Cholangitis acute † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Hepatic failure † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Hyperbilirubinaemia † 1		
# participants affected / at risk	**0/99 (0.00%)**	**1/100 (1.00%)**
Jaundice † 1		
# participants affected / at risk	**2/99 (2.02%)**	**1/100 (1.00%)**
Infections and infestations		
Catheter related infection † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Central line infection † 1		
# participants affected / at risk	**0/99 (0.00%)**	**1/100 (1.00%)**
Herpes zoster † 1		
# participants affected / at risk	**0/99 (0.00%)**	**1/100 (1.00%)**
Infection † 1		

# participants affected / at risk	0/99 (0.00%)	1/100 (1.00%)
Pneumonia † 1		
# participants affected / at risk	2/99 (2.02%)	0/100 (0.00%)
Pneumonia klebsiella † 1		
# participants affected / at risk	0/99 (0.00%)	1/100 (1.00%)
Septic shock † 1		
# participants affected / at risk	0/99 (0.00%)	1/100 (1.00%)
Urinary tract infection † 1		
# participants affected / at risk	1/99 (1.01%)	0/100 (0.00%)
Injury, poisoning and procedural complications		
Stent occlusion † 1		
# participants affected / at risk	1/99 (1.01%)	0/100 (0.00%)
Investigations		
Blood alkaline phosphatase increased † 1		
# participants affected / at risk	0/99 (0.00%)	1/100 (1.00%)
Blood bilirubin increased † 1		
# participants affected / at risk	1/99 (1.01%)	0/100 (0.00%)
Blood creatinine increased † 1		
# participants affected / at risk	1/99 (1.01%)	0/100 (0.00%)
Gamma-glutamyltransferase increased † 1		
# participants affected / at risk	1/99 (1.01%)	0/100 (0.00%)
International normalised ratio increased † 1		
# participants affected / at risk	1/99 (1.01%)	0/100 (0.00%)
Lipase increased † 1		
# participants affected / at risk	1/99 (1.01%)	0/100 (0.00%)

Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Dehydration † 1		
# participants affected / at risk	**4/99 (4.04%)**	**0/100 (0.00%)**
Hypercreatininaemia † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Hyperglycaemia † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Hyperkalaemia † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Hypokalaemia † 1		
# participants affected / at risk	**1/99 (1.01%)**	**1/100 (1.00%)**
Hypomagnesaemia † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Hyponatraemia † 1		
# participants affected / at risk	**2/99 (2.02%)**	**0/100 (0.00%)**
Hypovolaemia † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Metabolic acidosis † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Nervous system disorders		

Central nervous system lesion † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Hepatic encephalopathy † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Psychiatric disorders		
Confusional state † 1		
# participants affected / at risk	**2/99 (2.02%)**	**0/100 (0.00%)**
Renal and urinary disorders		
Haematuria † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Hydronephrosis † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Renal failure † 1		
# participants affected / at risk	**1/99 (1.01%)**	**1/100 (1.00%)**
Renal failure acute † 1		
# participants affected / at risk	**0/99 (0.00%)**	**2/100 (2.00%)**
Ureteric obstruction † 1		
# participants affected / at risk	**0/99 (0.00%)**	**1/100 (1.00%)**
Reproductive system and breast disorders		
Pelvic pain † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Dyspnoea † 1		

# participants affected / at risk	**3/99 (3.03%)**	**2/100 (2.00%)**
Epistaxis † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Hydropneumothorax † 1		
# participants affected / at risk	**0/99 (0.00%)**	**1/100 (1.00%)**
Lung infiltration † 1		
# participants affected / at risk	**0/99 (0.00%)**	**1/100 (1.00%)**
Pleural effusion † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Pneumonitis † 1		
# participants affected / at risk	**1/99 (1.01%)**	**1/100 (1.00%)**
Respiratory alkalosis † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**
Vascular disorders		
Deep vein thrombosis † 1		
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.X

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events occurring up to 28 days after the discontinuation of study treatment.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Everolimus (RAD001) 70 mg/Week	Participants self-administered weekly oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.
Everolimus (RAD001) 10 mg/Day	Participants self-administered daily oral dose of Everolimus (RAD001). Drug supplied as 5 mg tablets in blister packs.

Other Adverse Events

	Everolimus (RAD001) 70 mg/Week	Everolimus (RAD001) 10 mg/Day
Total, other (not including serious) adverse events		
# participants affected / at risk	**99/99 (100.00%)**	**98/100 (98.00%)**
Blood and lymphatic system disorders		
Anaemia † [1]		
# participants affected / at risk	**25/99 (25.25%)**	**19/100 (19.00%)**
Lymphopenia † [1]		
# participants affected / at risk	**9/99 (9.09%)**	**4/100 (4.00%)**
Neutropenia † [1]		
# participants affected / at risk	**2/99 (2.02%)**	**5/100 (5.00%)**
Thrombocytopenia † [1]		
# participants affected / at risk	**16/99 (16.16%)**	**18/100 (18.00%)**
Gastrointestinal disorders		
Abdominal distension † [1]		
# participants affected / at risk	**7/99 (7.07%)**	**5/100 (5.00%)**

Abdominal pain † 1		
# participants affected / at risk	**18/99 (18.18%)**	**13/100 (13.00%)**
Abdominal pain upper † 1		
# participants affected / at risk	**6/99 (6.06%)**	**5/100 (5.00%)**
Ascites † 1		
# participants affected / at risk	**6/99 (6.06%)**	**2/100 (2.00%)**
Constipation † 1		
# participants affected / at risk	**20/99 (20.20%)**	**13/100 (13.00%)**
Diarrhoea † 1		
# participants affected / at risk	**27/99 (27.27%)**	**26/100 (26.00%)**
Dry mouth † 1		
# participants affected / at risk	**3/99 (3.03%)**	**7/100 (7.00%)**
Dyspepsia † 1		
# participants affected / at risk	**6/99 (6.06%)**	**3/100 (3.00%)**
Flatulence † 1		
# participants affected / at risk	**0/99 (0.00%)**	**5/100 (5.00%)**
Nausea † 1		
# participants affected / at risk	**40/99 (40.40%)**	**22/100 (22.00%)**
Stomatitis † 1		
# participants affected / at risk	**17/99 (17.17%)**	**22/100 (22.00%)**
Vomiting † 1		
# participants affected / at risk	**25/99 (25.25%)**	**13/100 (13.00%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**14/99 (14.14%)**	**23/100 (23.00%)**

Chills † 1		
# participants affected / at risk	**5/99 (5.05%)**	**5/100 (5.00%)**
Fatigue † 1		
# participants affected / at risk	**50/99 (50.51%)**	**37/100 (37.00%)**
Mucosal inflammation † 1		
# participants affected / at risk	**17/99 (17.17%)**	**11/100 (11.00%)**
Oedema peripheral † 1		
# participants affected / at risk	**16/99 (16.16%)**	**14/100 (14.00%)**
Pyrexia † 1		
# participants affected / at risk	**12/99 (12.12%)**	**15/100 (15.00%)**
Hepatobiliary disorders		
Hyperbilirubinaemia † 1		
# participants affected / at risk	**5/99 (5.05%)**	**1/100 (1.00%)**
Infections and infestations		
Urinary tract infection † 1		
# participants affected / at risk	**4/99 (4.04%)**	**6/100 (6.00%)**
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	**8/99 (8.08%)**	**2/100 (2.00%)**
Aspartate aminotransferase increased † 1		
# participants affected / at risk	**8/99 (8.08%)**	**5/100 (5.00%)**
Blood alkaline phosphatase increased † 1		
# participants affected / at risk	**8/99 (8.08%)**	**6/100 (6.00%)**
Gamma-glutamyltransferase increased † 1		
# participants affected / at risk	**8/99 (8.08%)**	**13/100 (13.00%)**

Weight decreased † 1		
# participants affected / at risk	**14/99 (14.14%)**	**14/100 (14.00%)**
Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	**30/99 (30.30%)**	**25/100 (25.00%)**
Dehydration † 1		
# participants affected / at risk	**10/99 (10.10%)**	**11/100 (11.00%)**
Hypercholesterolaemia † 1		
# participants affected / at risk	**13/99 (13.13%)**	**10/100 (10.00%)**
Hyperglycaemia † 1		
# participants affected / at risk	**13/99 (13.13%)**	**9/100 (9.00%)**
Hypertriglyceridaemia † 1		
# participants affected / at risk	**6/99 (6.06%)**	**3/100 (3.00%)**
Hypokalaemia † 1		
# participants affected / at risk	**6/99 (6.06%)**	**3/100 (3.00%)**
Hypophosphataemia † 1		
# participants affected / at risk	**5/99 (5.05%)**	**5/100 (5.00%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**5/99 (5.05%)**	**4/100 (4.00%)**
Back pain † 1		
# participants affected / at risk	**10/99 (10.10%)**	**8/100 (8.00%)**
Bone pain † 1		
# participants affected / at risk	**5/99 (5.05%)**	**3/100 (3.00%)**
Myalgia † 1		

# participants affected / at risk	2/99 (2.02%)	5/100 (5.00%)
Pain in extremity † 1		
# participants affected / at risk	2/99 (2.02%)	8/100 (8.00%)
Nervous system disorders		
Dysgeusia † 1		
# participants affected / at risk	6/99 (6.06%)	6/100 (6.00%)
Headache † 1		
# participants affected / at risk	10/99 (10.10%)	7/100 (7.00%)
Psychiatric disorders		
Anxiety † 1		
# participants affected / at risk	2/99 (2.02%)	5/100 (5.00%)
Insomnia † 1		
# participants affected / at risk	9/99 (9.09%)	6/100 (6.00%)
Renal and urinary disorders		
Dysuria † 1		
# participants affected / at risk	5/99 (5.05%)	1/100 (1.00%)
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	13/99 (13.13%)	16/100 (16.00%)
Dyspnoea † 1		
# participants affected / at risk	18/99 (18.18%)	19/100 (19.00%)
Epistaxis † 1		
# participants affected / at risk	5/99 (5.05%)	10/100 (10.00%)
Pleural effusion † 1		
# participants affected / at risk	6/99 (6.06%)	2/100 (2.00%)

Skin and subcutaneous tissue disorders		
Dry skin † 1		
# participants affected / at risk	**5/99 (5.05%)**	**7/100 (7.00%)**
Erythema † 1		
# participants affected / at risk	**5/99 (5.05%)**	**3/100 (3.00%)**
Pruritus † 1		
# participants affected / at risk	**8/99 (8.08%)**	**5/100 (5.00%)**
Rash † 1		
# participants affected / at risk	**34/99 (34.34%)**	**29/100 (29.00%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**3/99 (3.03%)**	**5/100 (5.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.X

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

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00419159 History of Changes
Other Study ID Numbers:	**CRAD001C2241**
Study First Received:	January 4, 2007
Results First Received:	December 17, 2010
Last Updated:	November 4, 2011
Health Authority:	United States: Food and Drug Administration Canada: Health Canada

Italy: Ministry of Health
Spain: Spanish Agency of Medicines