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Trial record **2 of 2** for: CFTY720D2301

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Efficacy and Safety of Fingolimod in Patients With Relapsing-remitting Multiple Sclerosis (FREEDOMS)

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00289978

First received: February 9, 2006
Last updated: April 9, 2012
Last verified: April 2012
History of Changes

Full Text View | Tabular View | **Study Results** | Disclaimer | How to Read a Study Record

Results First Received: January 4, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Relapsing-remitting Multiple Sclerosis
Interventions:	Drug: Fingolimod 1.25 mg Drug: Fingolimod 0.5 mg Drug: Placebo

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
Fingolimod 1.25 mg	Patients self-administered fingolimod 1.25 mg capsules orally once daily.
Fingolimod 0.5 mg	Patients self-administered fingolimod 0.5 mg capsules orally once daily.
Placebo	Patients self-administered a fingolimod placebo capsule orally once daily.

Participant Flow: Overall Study

	Fingolimod 1.25 mg	Fingolimod 0.5 mg	Placebo
STARTED	429	425	418
COMPLETED	332 [1]	369 [2]	332 [3]
NOT COMPLETED	97	56	86
Withdrawal by Subject	31	17	28
Adverse Event	22	13	18
Lack of Efficacy	13	6	25

Abnormal laboratory value(s)	**20**	**9**	**1**
Lost to Follow-up	**3**	**5**	**7**
Protocol Violation	**5**	**5**	**4**
Abnormal test procedure result(s)	**2**	**1**	**1**
Death	**1**	**0**	**2**

[1] 296 completed on study drug, 35 completed off study drug.
[2] 345 completed on study drug, 24 completed off study drug.
[3] 303 completed on study drug, 29 completed off study drug.

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
Fingolimod 1.25 mg	Patients self-administered fingolimod 1.25 mg capsules orally once daily.
Fingolimod 0.5 mg	Patients self-administered fingolimod 0.5 mg capsules orally once daily.
Placebo	Patients self-administered a fingolimod placebo capsule orally once daily.
Total	Total of all reporting groups

Baseline Measures

	Fingolimod 1.25 mg	Fingolimod 0.5 mg	Placebo	Total

Number of Participants [units: participants]	**429**	**425**	**418**	**1272**
Age [units: years] Mean (Standard Deviation)	**37.4 (8.91)**	**36.6 (8.77)**	**37.2 (8.60)**	**37.1 (8.76)**
Age, Customized [units: participants]				
<18 years	**1**	**0**	**0**	**1**
18 -30	**107**	**120**	**97**	**324**
31-40	**147**	**162**	**165**	**474**
41-55	**174**	**143**	**156**	**473**
Gender [units: participants]				
Female	**295**	**296**	**298**	**889**
Male	**134**	**129**	**120**	**383**
Duration of multiple sclerosis since first symptoms [units: Years] Mean (Standard Deviation)	**8.4 (6.86)**	**8.0 (6.60)**	**8.1 (6.35)**	**8.2 (6.60)**
Number of relapses in last 2 years [units: relapses] Mean (Standard Deviation)	**1.5 (0.81)**	**1.5 (0.76)**	**1.4 (0.73)**	**1.5 (0.77)**
Expanded Disability Status Scale (EDSS) [1] [units: Units on a scale] Mean (Standard Deviation)	**2.41 (1.36)**	**2.30 (1.29)**	**2.49 (1.29)**	**2.40 (1.32)**

[1] The EDSS is a scale for assessing disability in 8 functional systems (visual, brain stem, pyramidal, cerebellar, sensory, bowel & bladder, cerebral, other functions). Based on scores in these 8 functional systems, an overall score ranging from 0 (normal) to 10 (death due to MS) is assigned. Patients with EDSS scores of 0.0 to 4.5 are fully ambulatory; patients with EDSS scores of 5.0 to 9.5 have impaired ambulation. EDSS was assessed by an evaluating physician at each site.

Outcome Measures

Hide All Outcome Measures

1. Primary: Estimated Annualized Aggregate Relapse Rate (ARR) [Time Frame: Baseline to end of study (Month 24)]

Measure Type	Primary
Measure Title	Estimated Annualized Aggregate Relapse Rate (ARR)
Measure Description	The ARR is defined as the number of confirmed relapses in a year. A relapse is defined as the appearance of a new or worsening of a previously stable or improving pre-existing neurological abnormality, separated by at least 30 days from onset of a preceding relapse. The abnormality must be present for at least 24 hours and occur in the absence of fever or infection. The annualized ARR for each treatment group was the mean of the annualized ARRs for all patients in the group calculated as the total number of confirmed relapses divided by the total number of days on study, multiplied by 365.25.
Time Frame	Baseline to end of study (Month 24)
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.
This analysis was conducted using the Intent-to-treat (ITT) population which includes all patients who were randomized and received at least one dose of study drug.

Reporting Groups

	Description
Fingolimod 1.25 mg	Patients self-administered fingolimod 1.25 mg capsules orally once daily.
Fingolimod 0.5 mg	Patients self-administered fingolimod 0.5 mg capsules orally once daily.
Placebo	Patients self-administered a fingolimod placebo capsule orally once daily.

Measured Values

	Fingolimod 1.25 mg	Fingolimod 0.5 mg	Placebo
Number of Participants Analyzed [units: participants]	**429**	**425**	**418**
Estimated Annualized Aggregate Relapse Rate (ARR) [units: Relapses per year] Number (95% Confidence Interval)	**0.16 (0.13 to 0.19)**	**0.18 (0.15 to 0.22)**	**0.40 (0.34 to 0.47)**

No statistical analysis provided for Estimated Annualized Aggregate Relapse Rate (ARR)

2. Secondary: Percentage of Patients Free of Disability Progression at Month 24 Assessed With the Expanded Disability Status Scale (EDSS) [Time Frame: Baseline to end of study (Month 24)]

Measure Type	Secondary
Measure Title	Percentage of Patients Free of Disability Progression at Month 24 Assessed With the Expanded Disability Status Scale (EDSS)
Measure Description	EDSS assesses disability in 8 functional systems. An overall score ranging from 0 (normal) to 10 (death due to MS) is calculated. Disability progression was determined by the following: One point increase from baseline in patients with baseline EDSS score from 0 to 5.0; or half a point increase in patients with baseline EDSS score of 5.5 or above. A 3-month confirmed disability progression required onset EDSS, 3-month confirming EDSS, and all EDSS in between to meet the disability progression criteria. Percent of free of disability progression was calculated using the Kaplan Meier method.
Time Frame	Baseline to end of study (Month 24)
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.

Intent-to-treat population (ITT): All patients who were randomized and received at least one dose of study medication.

Reporting Groups

	Description
Fingolimod 1.25 mg	Patients self-administered fingolimod 1.25 mg capsules orally once daily.
Fingolimod 0.5 mg	Patients self-administered fingolimod 0.5 mg capsules orally once daily.
Placebo	Patients self-administered a fingolimod placebo capsule orally once daily.

Measured Values

	Fingolimod 1.25 mg	Fingolimod 0.5 mg	Placebo
Number of Participants Analyzed [units: participants]	**429**	**425**	**418**
Percentage of Patients Free of Disability Progression at Month 24 Assessed With the Expanded Disability Status Scale (EDSS) [units: Percentage of participants] Number (95% Confidence Interval)	**83.4 (79.7 to 87.1)**	**82.3 (78.6 to 86.1)**	**75.9 (71.7 to 80.2)**

No statistical analysis provided for Percentage of Patients Free of Disability Progression at Month 24 Assessed With the Expanded Disability Status Scale (EDSS)

3. Secondary: Number of New or Newly Enlarged T2 Lesions at Month 24 in Comparison With Baseline [Time Frame: Baseline to end of study (Month 24)]

Measure Type	Secondary
Measure Title	Number of New or Newly Enlarged T2 Lesions at Month 24 in Comparison With Baseline
Measure Description	The number of new or newly enlarged T2 lesions at Month 24 in comparison to baseline was assessed with T2-weighted magnetic resonance image (MRI) scans. A T2-weighted MRI scan utilizes particular values of the echo time

	(TE) and the repetition time (TR) parameters of image acquisition. Inflammation and tissue damage are seen as bright areas in T2 images and are often referred to as T2 lesions. T2-weighted MRI scans are a sensitive way to evaluate the brain for demyelinating diseases, such as multiple sclerosis.
Time Frame	Baseline to end of study (Month 24)
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.
Intent-to-treat population (ITT): All patients who were randomized and received at least one dose of study medication.

Reporting Groups

	Description
Fingolimod 1.25 mg	Patients self-administered fingolimod 1.25 mg capsules orally once daily.
Fingolimod 0.5 mg	Patients self-administered fingolimod 0.5 mg capsules orally once daily.
Placebo	Patients self-administered a fingolimod placebo capsule orally once daily.

Measured Values

	Fingolimod 1.25 mg	Fingolimod 0.5 mg	Placebo
Number of Participants Analyzed [units: participants]	**429**	**425**	**418**
Number of patients with non-missing values Analyzed [units: patients with non-missing values]	**337**	**370**	**339**
Number of New or Newly Enlarged T2 Lesions at Month 24 in Comparison With Baseline [units: T2 lesions] Mean (Standard Deviation)	**2.5 (5.52)**	**2.5 (7.19)**	**9.8 (13.17)**

No statistical analysis provided for Number of New or Newly Enlarged T2 Lesions at Month 24 in Comparison With Baseline

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	24 Months
Additional Description	Adverse events are reported based on the safety population. The safety population consists of all patients who received at least 1 dose of study drug.

Reporting Groups

	Description
Fingolimod 1.25 mg	Patients self-administered fingolimod 1.25 mg capsules orally once daily.
Fingolimod 0.5 mg	Patients self-administered fingolimod 0.5 mg capsules orally once daily.
Placebo	Patients self-administered a fingolimod placebo capsule orally once daily.

Serious Adverse Events

	Fingolimod 1.25 mg	Fingolimod 0.5 mg	Placebo
Total, serious adverse events			
# participants affected / at risk	**51/429 (11.89%)**	**43/425 (10.12%)**	**56/418 (13.40%)**
Blood and lymphatic system disorders			
Leukopenia † [1]			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Lymphopenia † [1]			
# participants affected / at risk	**2/429 (0.47%)**	**0/425 (0.00%)**	**0/418 (0.00%)**

Thrombocytopenia † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Cardiac disorders			
Angina pectoris † 1			
# participants affected / at risk	**1/429 (0.23%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Atrioventricular block first degree † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Atrioventricular block second degree † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Bradycardia † 1			
# participants affected / at risk	**3/429 (0.70%)**	**4/425 (0.94%)**	**1/418 (0.24%)**
Left ventricular dysfunction † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Myocardial infarction † 1			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**2/418 (0.48%)**
Palpitations † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Pericarditis † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Supraventricular extrasystoles † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Tachycardia paroxysmal † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Ventricular tachycardia † 1			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**1/418 (0.24%)**

Eye disorders			
Eye pain † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Iridocyclitis † 1			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Keratitis † 1			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Macular oedema † 1			
# participants affected / at risk	**3/429 (0.70%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Papilloedema † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Photopsia † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Retinal detachment † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Retinal disorder † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Retinitis † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Gastrointestinal disorders			
Abdominal pain † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**1/418 (0.24%)**
Abdominal pain upper † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Constipation † 1			

# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	1/418 (0.24%)
Diarrhoea † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Dyspepsia † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	1/418 (0.24%)
Gastritis † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Haemorrhoids † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Ileus paralytic † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Inguinal hernia † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Oesophagitis † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Pancreatitis chronic † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Vomiting † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	1/418 (0.24%)
General disorders			
Chest pain † 1			
# participants affected / at risk	0/429 (0.00%)	2/425 (0.47%)	0/418 (0.00%)
Fatigue † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Haemorrhagic cyst † 1			

# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Inflammation † [1]			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Non-cardiac chest pain † [1]			
# participants affected / at risk	0/429 (0.00%)	2/425 (0.47%)	2/418 (0.48%)
Hepatobiliary disorders			
Biliary colic † [1]			
# participants affected / at risk	1/429 (0.23%)	1/425 (0.24%)	0/418 (0.00%)
Cholelithiasis † [1]			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Cytolytic hepatitis † [1]			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Hepatic steatosis † [1]			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Hepatomegaly † [1]			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Infections and infestations			
Abscess † [1]			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Abscess jaw † [1]			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Acute sinusitis † [1]			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Anal abscess † [1]			

# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Appendicitis † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Clostridial infection † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Cystitis † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Dermo-hypodermitis † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Gastroenteritis † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	1/418 (0.24%)
Genital herpes † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Herpes virus infection † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Mastoiditis † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Otitis media acute † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Peritoneal abscess † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Peritonsillitis † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Pharyngitis † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	1/418 (0.24%)

Pharyngotonsillitis † [1]			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Pneumonia † [1]			
# participants affected / at risk	**1/429 (0.23%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Pyelonephritis † [1]			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Pyelonephritis acute † [1]			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Pyelonephritis chronic † [1]			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Respiratory tract infection † [1]			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Sinusitis † [1]			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Streptococcal abscess † [1]			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Tonsillitis † [1]			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Tooth abscess † [1]			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Upper respiratory tract infection † [1]			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Urinary tract infection † [1]			
# participants affected / at risk	**0/429 (0.00%)**	**2/425 (0.47%)**	**0/418 (0.00%)**
Urosepsis † [1]			

# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Injury, poisoning and procedural complications			
Burns second degree † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Fractured coccyx † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Head injury † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	1/418 (0.24%)
Ligament rupture † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Lower limb fracture † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Overdose † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Road traffic accident † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Splenic injury † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Splenic rupture † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Subdural haematoma † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Investigations			
Alanine aminotransferase increased † 1			
# participants affected / at risk	1/429 (0.23%)	1/425 (0.24%)	0/418 (0.00%)

Aspartate aminotransferase increased † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Electrocardiogram PR prolongation † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Electrocardiogram change † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Gamma-glutamyltransferase increased † 1			
# participants affected / at risk	**1/429 (0.23%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Hepatic enzyme increased † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Liver function test abnormal † 1			
# participants affected / at risk	**2/429 (0.47%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Precancerous cells present † 1			
# participants affected / at risk	**1/429 (0.23%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Red blood cell sedimentation rate increased † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Metabolism and nutrition disorders			
Dehydration † 1			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Arthritis † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Back pain † 1			

# participants affected / at risk	0/429 (0.00%)	2/425 (0.47%)	1/418 (0.24%)
Bursitis † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Intervertebral disc protrusion † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	2/418 (0.48%)
Myalgia † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Pain in extremity † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma † 1			
# participants affected / at risk	1/429 (0.23%)	4/425 (0.94%)	2/418 (0.48%)
Benign ovarian tumour † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Bowen's disease † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Brain neoplasm benign † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Breast cancer † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	3/418 (0.72%)
Cervix carcinoma stage 0 † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Endometrial cancer † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Malignant melanoma † 1			

# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	1/418 (0.24%)
Ovarian adenoma † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Prostate cancer † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Uterine leiomyoma † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Nervous system disorders			
Amnesia † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Central nervous system lesion † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Cerebrovascular accident † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Epilepsy † 1			
# participants affected / at risk	2/429 (0.47%)	0/425 (0.00%)	0/418 (0.00%)
Grand mal convulsion † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Headache † 1			
# participants affected / at risk	2/429 (0.47%)	0/425 (0.00%)	0/418 (0.00%)
Ischaemic stroke † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Migraine with aura † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Monoplegia † 1			

# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Multiple sclerosis † [1]			
# participants affected / at risk	0/429 (0.00%)	2/425 (0.47%)	0/418 (0.00%)
Multiple sclerosis relapse † [1]			
# participants affected / at risk	3/429 (0.70%)	2/425 (0.47%)	1/418 (0.24%)
Partial seizures with secondary generalisation † [1]			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Presyncope † [1]			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Sciatica † [1]			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Somnolence † [1]			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Syncope † [1]			
# participants affected / at risk	1/429 (0.23%)	1/425 (0.24%)	1/418 (0.24%)
Pregnancy, puerperium and perinatal conditions			
Abortion † [1]			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	3/418 (0.72%)
Abortion spontaneous † [1]			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Psychiatric disorders			
Acute psychosis † [1]			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Anxiety † [1]			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)

Depression † 1			
# participants affected / at risk	**2/429 (0.47%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Homicidal ideation † 1			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Renal and urinary disorders			
Nephrolithiasis † 1			
# participants affected / at risk	**1/429 (0.23%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Renal colic † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Renal cyst † 1			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Reproductive system and breast disorders			
Cervical dysplasia † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Endometriosis † 1			
# participants affected / at risk	**0/429 (0.00%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Metrorrhagia † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**1/418 (0.24%)**
Ovarian cyst † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**
Ovarian disorder † 1			
# participants affected / at risk	**1/429 (0.23%)**	**0/425 (0.00%)**	**0/418 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Asthma † 1			

# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Dyspnoea exertional † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Pleurisy † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Pneumonia aspiration † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Productive cough † 1			
# participants affected / at risk	1/429 (0.23%)	0/425 (0.00%)	0/418 (0.00%)
Pulmonary embolism † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Pulmonary oedema † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Skin and subcutaneous tissue disorders			
Rash macular † 1			
# participants affected / at risk	0/429 (0.00%)	1/425 (0.24%)	0/418 (0.00%)
Urticaria † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Vascular disorders			
Circulatory collapse † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)
Hypertension † 1			
# participants affected / at risk	0/429 (0.00%)	0/425 (0.00%)	1/418 (0.24%)

Varicose vein † 1			
# participants affected / at risk	**0/429 (0.00%)**	**1/425 (0.24%)**	**0/418 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	24 Months
Additional Description	Adverse events are reported based on the safety population. The safety population consists of all patients who received at least 1 dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Fingolimod 1.25 mg	Patients self-administered fingolimod 1.25 mg capsules orally once daily.
Fingolimod 0.5 mg	Patients self-administered fingolimod 0.5 mg capsules orally once daily.
Placebo	Patients self-administered a fingolimod placebo capsule orally once daily.

Other Adverse Events

	Fingolimod 1.25 mg	Fingolimod 0.5 mg	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**346/429 (80.65%)**	**355/425 (83.53%)**	**323/418 (77.27%)**

Ear and labyrinth disorders			
Vertigo † 1			
# participants affected / at risk	**18/429 (4.20%)**	**18/425 (4.24%)**	**21/418 (5.02%)**
Gastrointestinal disorders			
Diarrhoea † 1			
# participants affected / at risk	**40/429 (9.32%)**	**50/425 (11.76%)**	**30/418 (7.18%)**
Nausea † 1			
# participants affected / at risk	**38/429 (8.86%)**	**38/425 (8.94%)**	**36/418 (8.61%)**
General disorders			
Fatigue † 1			
# participants affected / at risk	**46/429 (10.72%)**	**48/425 (11.29%)**	**45/418 (10.77%)**
Infections and infestations			
Bronchitis † 1			
# participants affected / at risk	**39/429 (9.09%)**	**34/425 (8.00%)**	**15/418 (3.59%)**
Influenza † 1			
# participants affected / at risk	**40/429 (9.32%)**	**55/425 (12.94%)**	**41/418 (9.81%)**
Nasopharyngitis † 1			
# participants affected / at risk	**112/429 (26.11%)**	**115/425 (27.06%)**	**115/418 (27.51%)**
Pharyngitis † 1			
# participants affected / at risk	**25/429 (5.83%)**	**26/425 (6.12%)**	**23/418 (5.50%)**
Rhinitis † 1			
# participants affected / at risk	**18/429 (4.20%)**	**25/425 (5.88%)**	**25/418 (5.98%)**
Sinusitis † 1			
# participants affected / at risk	**27/429 (6.29%)**	**27/425 (6.35%)**	**19/418 (4.55%)**
Upper respiratory tract infection † 1			

# participants affected / at risk	62/429 (14.45%)	73/425 (17.18%)	72/418 (17.22%)
Urinary tract infection † [1]			
# participants affected / at risk	21/429 (4.90%)	34/425 (8.00%)	47/418 (11.24%)
Investigations			
Alanine aminotransferase increased † [1]			
# participants affected / at risk	49/429 (11.42%)	42/425 (9.88%)	16/418 (3.83%)
Gamma-glutamyltransferase increased † [1]			
# participants affected / at risk	31/429 (7.23%)	22/425 (5.18%)	4/418 (0.96%)
Weight increased † [1]			
# participants affected / at risk	14/429 (3.26%)	14/425 (3.29%)	22/418 (5.26%)
Metabolism and nutrition disorders			
Hypercholesterolaemia † [1]			
# participants affected / at risk	26/429 (6.06%)	24/425 (5.65%)	26/418 (6.22%)
Musculoskeletal and connective tissue disorders			
Arthralgia † [1]			
# participants affected / at risk	26/429 (6.06%)	30/425 (7.06%)	33/418 (7.89%)
Back pain † [1]			
# participants affected / at risk	45/429 (10.49%)	49/425 (11.53%)	28/418 (6.70%)
Pain in extremity † [1]			
# participants affected / at risk	24/429 (5.59%)	28/425 (6.59%)	27/418 (6.46%)
Nervous system disorders			
Dizziness † [1]			
# participants affected / at risk	31/429 (7.23%)	31/425 (7.29%)	23/418 (5.50%)
Headache † [1]			

# participants affected / at risk	**113/429 (26.34%)**	**107/425 (25.18%)**	**96/418 (22.97%)**
Paraesthesia † 1			
# participants affected / at risk	**17/429 (3.96%)**	**23/425 (5.41%)**	**18/418 (4.31%)**
Psychiatric disorders			
Depression † 1			
# participants affected / at risk	**25/429 (5.83%)**	**33/425 (7.76%)**	**28/418 (6.70%)**
Insomnia † 1			
# participants affected / at risk	**16/429 (3.73%)**	**21/425 (4.94%)**	**25/418 (5.98%)**
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	**37/429 (8.62%)**	**43/425 (10.12%)**	**34/418 (8.13%)**
Dyspnoea † 1			
# participants affected / at risk	**25/429 (5.83%)**	**30/425 (7.06%)**	**19/418 (4.55%)**
Oropharyngeal pain † 1			
# participants affected / at risk	**17/429 (3.96%)**	**29/425 (6.82%)**	**29/418 (6.94%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**27/429 (6.29%)**	**26/425 (6.12%)**	**15/418 (3.59%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.0

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:

Chinea Martinez AR, Correale J, Coyle PK, Meng X, Tenenbaum N. Efficacy and safety of fingolimod in Hispanic patients with multiple sclerosis: pooled clinical trial analyses. Adv Ther. 2014 Oct;31(10):1072-81. doi: 10.1007/s12325-014-0154-4. Epub 2014 Sep 23.

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Radue EW, O'Connor P, Polman CH, Hohlfeld R, Calabresi P, Selmaj K, Mueller-Lenke N, Agoropoulou C, Holdbrook F, de Vera A, Zhang-Auberson L, Francis G, Burtin P, Kappos L; FTY720 Research Evaluating Effects of Daily Oral Therapy in Multiple Sclerosis (FREEDOMS) Study Group. Impact of fingolimod therapy on magnetic resonance imaging outcomes in patients with multiple sclerosis. Arch Neurol. 2012 Oct;69(10):1259-69.

Devonshire V, Havrdova E, Radue EW, O'Connor P, Zhang-Auberson L, Agoropoulou C, Häring DA, Francis G, Kappos L; FREEDOMS study group. Relapse and disability outcomes in patients with multiple sclerosis treated with fingolimod: subgroup analyses of the double-blind, randomised, placebo-controlled FREEDOMS study. Lancet Neurol. 2012 May;11(5):420-8. doi: 10.1016/S1474-4422(12)70056-X. Epub 2012 Apr 10. Erratum in: Lancet Neurol. 2012 Aug;11(8):658.

Kappos L, Radue EW, O'Connor P, Polman C, Hohlfeld R, Calabresi P, Selmaj K, Agoropoulou C, Leyk M, Zhang-Auberson L, Burtin P; FREEDOMS Study Group. A placebo-controlled trial of oral fingolimod in relapsing multiple sclerosis. N Engl J Med. 2010 Feb 4;362(5):387-401. doi: 10.1056/NEJMoa0909494. Epub 2010 Jan 20.

Responsible Party:	Novartis
ClinicalTrials.gov Identifier:	NCT00289978 History of Changes
Other Study ID Numbers:	**CFTY720D2301**
Study First Received:	February 9, 2006
Results First Received:	January 4, 2011
Last Updated:	April 9, 2012
Health Authority:	Sweden: Regional Ethical Review Board