Efficacy and Safety of Oral BG00012 in Relapsing-Remitting Multiple Sclerosis (DEFINE)

This study has been completed.

Sponsor:
Biogen Idec

Information provided by (Responsible Party):
Biogen Idec

ClinicalTrials.gov Identifier:
NCT00420212

First received: January 8, 2007
Last updated: January 13, 2015
Last verified: January 2015
History of Changes

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

Results First Received: May 5, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Relapsing-Remitting Multiple Sclerosis
Interventions:	Drug: BG00012 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
Subjects were screened and enrolled at 198 investigational sites in 28 countries.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
From screening, 1237 eligible subjects were equally randomized. Of these, 1234 subjects received at least one dose of study treatment and comprised the intent-to-treat (ITT) and safety populations.

Reporting Groups

	Description
Placebo	Participants received two placebo capsules orally three times daily (TID)
BG00012 240 mg Twice Daily (BID)	Participants received two 120 mg BG00012 capsules orally twice daily (BID) and two placebo capsules orally once daily (QD)
BG00012 240 mg 3 Times Daily (TID)	Participants received two 120 mg BG00012 capsules orally three times daily (TID)

Participant Flow: Overall Study

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)
STARTED	408 [1]	410 [2]	416 [3]
COMPLETED	317	315	320

NOT COMPLETED	91	95	96
Adverse Event	22	40	36
Lost to Follow-up	9	11	11
Withdrawal by Subject	31	22	19
Physician Decision	4	4	3
Protocol Violation	4	4	8
Death	0	0	1
Other-Unspecified	21	14	18

[1] 408 participants were dosed; 410 participants were randomized
[2] 410 participants were dosed; 411 participants were randomized
[3] 416 participants were dosed; 416 participants were randomized

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
Placebo	Participants received two placebo capsules orally three times daily (TID)
BG00012 240 mg Twice Daily (BID)	Participants received two 120 mg BG00012 capsules orally twice daily (BID) and two placebo capsules orally once daily (QD)
BG00012 240 mg 3 Times Daily (TID)	Participants received two 120 mg BG00012 capsules orally three times daily (TID)
Total	Total of all reporting groups

Baseline Measures

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Total
Number of Participants [units: participants]	408	410	416	1234
Age [units: Years] Mean ± Standard Deviation	38.5 ± 9.14	38.1 ± 9.11	38.8 ± 8.85	38.5 ± 9.03
Gender [units: Participants]				
Female	306	296	306	908
Male	102	114	110	326
Mean Expanded Disability Status Scale (EDSS) score [1] [units: units on a scale] Mean ± Standard Deviation	2.48 ± 1.241	2.40 ± 1.290	2.36 ± 1.188	2.42 ± 1.240

Mean number of relapses within the previous 3 years [units: Number of relapses] Mean ± Standard Deviation	2.5 ± 1.56	2.5 ± 1.44	2.4 ± 1.27	2.5 ± 1.43
Mean number of relapses within the past 12 months [units: Number of relapses] Mean ± Standard Deviation	1.3 ± 0.67	1.3 ± 0.67	1.3 ± 0.60	1.3 ± 0.65
Time since first multiple sclerosis (MS) diagnosis [units: Years] Mean ± Standard Deviation	5.8 ± 5.78	5.6 ± 5.39	5.1 ± 5.29	5.5 ± 5.49
Mean number of gadolinium (Gd) enhancing lesions [2] [units: Number of Gd enhancing lesions] Mean ± Standard Deviation	1.6 ± 3.45	1.2 ± 3.30	1.2 ± 4.10	1.4 ± 3.64

[1] The EDSS scores range from 0.0 (normal exam) to 10.0 (death due to MS).

[2] This baseline measure could only be assessed in the magnetic resonance imaging (MRI) cohort. The MRI cohort included 540 intent-to-treat (ITT) subjects who were enrolled at sites that participated in the MRI portion of the study and who had MRI data (180 placebo, 176 BG00012 BID, 184 BG00012 TID). Sites could participate only if their MRI capability was validated by the independent MRI reading center. Approximately 95% of all subjects enrolled at MRI sites participated in the MRI portion of the study.

Outcome Measures

Hide All Outcome Measures

1. Primary: Proportion of Subjects Relapsed [Time Frame: 2 years]

Measure Type	Primary
Measure Title	Proportion of Subjects Relapsed
Measure Description	A protocol-defined relapse was defined as new or recurrent neurologic symptoms not associated with fever or infection that lasted at least 24 hours, and were separated by at least 30 days from onset of a preceding relapse. All protocol-defined relapses were evaluated by an independent neurolgic evaluation committee. The proportion of subjects with a relapse was estimated using the Kaplan-Meier method, which was based on the time-to-first-relapse survival distribution.
Time Frame	2 years
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 analysis was based on the ITT population, defined as all subjects who were randomized and received at least 1 dose of study medication. Among subjects who switched to an alternative therapy for multiple sclerosis, all the data before the switch were used for the analysis. In all other subjects, all relapses were included in the analysis.

Reporting Groups

	Description
Placebo	Participants received two placebo capsules orally three times daily (TID)
BG00012 240 mg Twice Daily (BID)	Participants received two 120 mg BG00012 capsules orally twice daily (BID) and two placebo capsules orally once daily (QD)
BG00012 240 mg 3 Times Daily (TID)	Participants received two 120 mg BG00012 capsules orally three times daily (TID)

Measured Values

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)
Number of Participants Analyzed [units: participants]	408	410	416
Proportion of Subjects Relapsed [units: Proportion of subjects,confirmed relapse]	0.461	0.270	0.260

No statistical analysis provided for Proportion of Subjects Relapsed

2. Secondary: Number of New or Newly Enlarging T2 Hyperintense Lesions [Time Frame: 2 years]

Measure Type	Secondary
Measure Title	Number of New or Newly Enlarging T2 Hyperintense Lesions
Measure Description	The number of new or newly enlarging T2 hyperintense lesions at 2 years that developed in each subject compared to baseline assessed on brain magnetic resonance imaging (MRI) scans. The estimates of mean T2 lesion count were calculated from a negative binomial regression model adjusted for region and baselineT2 lesion volume
Time Frame	2 years
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.
Of the 540 subjects included in the MRI cohort, 469 subjects (165 placebo, 152 BG00012 BID, 152 BG00012 TID) had post-baseline T2 data and were included in the analysis. Missing data before the use of alternative MS medications and visits after patients switched to alternative MS medications were imputed with the use of a constant rate assumption.

Reporting Groups

	Description
Placebo	Participants received two placebo capsules orally three times daily (TID)
BG00012 240 mg BID	Participants received two 120 mg BG00012 capsules orally twice daily (BID) and two placebo capsules orally once daily (QD)
BG00012 240 mg TID	Participants received two 120 mg BG00012 capsules orally three times daily (TID)

Measured Values

	Placebo	BG00012 240 mg BID	BG00012 240 mg TID
Number of Participants Analyzed [units: participants]	165	152	152
Number of New or Newly Enlarging T2 Hyperintense Lesions [units: Number of lesions] Mean (95% Confidence Interval)	17.0 (12.9 to 22.4)	2.6 (2.0 to 3.5)	4.4 (3.2 to 5.9)

No statistical analysis provided for Number of New or Newly Enlarging T2 Hyperintense Lesions

3. Secondary: Number of Gadolinium-enhancing T1-weighted Lesions [Time Frame: 2 years]

Measure Type	Secondary
Measure Title	Number of Gadolinium-enhancing T1-weighted Lesions
Measure Description	The number of Gd-enhancing lesions was assessed using brain MRI scans following administration of gadolinium, a contrast agent. The mean number of Gd-enhancing lesions at 2 years was the average of the number of lesions at 2 years in a treatment group.
Time Frame	2 years
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.
Of the 540 subjects included in the MRI cohort, 469 (165 placebo,152 BG00012 BID,152 BG00012 TID) had post-baseline Gd-enhancing lesion data & were included in the analysis. Missing data before the use of alternative MS medications & visits after patients switched to alternative MS medications were imputed with the use of a constant rate assumption

Reporting Groups

	Description
Placebo	Participants received two placebo capsules orally three times daily (TID)
BG00012 240 mg BID	Participants received two 120 mg BG00012 capsules orally twice daily (BID) and two placebo capsules orally once daily (QD)
BG00012 240 mg TID	Participants received two 120 mg BG00012 capsules orally three times daily (TID)

Measured Values

	Placebo	BG00012 240 mg BID	BG00012 240 mg TID
Number of Participants Analyzed [units: participants]	165	152	152
Number of Gadolinium-enhancing T1-weighted Lesions [units: Number of lesions] Mean ± Standard Deviation	1.8 ± 4.15	0.1 ± 0.63	0.5 ± 1.73

No statistical analysis provided for Number of Gadolinium-enhancing T1-weighted Lesions

4. Secondary: Number of Subjects With Gadolinium (Gd)-Enhancing Lesions [Time Frame: 2 years]

Measure Type	Secondary
Measure Title	Number of Subjects With Gadolinium (Gd)-Enhancing Lesions
Measure Description	Note: This outcome measure represents the categorical analysis for the previously listed secondary outcome measure "Number of Gadolinium-enhancing T1-weighted lesions"
Time Frame	2 years
Safety Issue	No

Population Description

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

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.
Of the 540 subjects included in the MRI cohort, 469 (165 placebo,152 BG00012 BID,152 BG00012 TID) had post-baseline Gd-enhancing lesion data & were included in the analysis. Missing data before the use of alternative MS medications & visits after patients switched to alternative MS medications were imputed with the use of a constant rate assumption

Reporting Groups

	Description
Placebo	Participants received two placebo capsules orally three times daily (TID)
BG00012 240 mg Twice Daily (BID)	Participants received two 120 mg BG00012 capsules orally twice daily (BID) and two placebo capsules orally once daily (QD)
BG00012 240 mg 3 Times Daily (TID)	Participants received two 120 mg BG00012 capsules orally three times daily (TID)

Measured Values

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)
Number of Participants Analyzed [units: participants]	165	152	152
Number of Subjects With Gadolinium (Gd)-Enhancing Lesions [units: Number of subjects]			
0 lesions	103	142	130
1 lesion	16	8	10
2 lesions	13	1	2
3-4 lesions	15	0	3
>=5 lesions	18	1	7

No statistical analysis provided for Number of Subjects With Gadolinium (Gd)-Enhancing Lesions

5. Secondary: Annualized Relapse Rate [Time Frame: 2 years]

Measure Type	Secondary
Measure Title	Annualized Relapse Rate
Measure Description	A protocol-defined relapse was defined as new or recurrent neurologic symptoms not associated with fever or infection that lasted at least 24 hours, and were separated by at least 30 days from onset of a preceding relapse. All protocol-defined relapses were evaluated by an independent neurologic evaluation committee. The adjusted annualized relapse rate was calculated from a negative binomial regression model, adjusted for baseline EDSS (≤ 2.0 vs. >2.0), age (<40 versus ≥40 years), region, and the number of relapses in the 1 year prior to enrollment.
Time Frame	2 years
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 ITT population was defined as all subjects who were randomized and received at least 1 dose of study medication. Among subjects who switched to an alternative therapy for multiple sclerosis, all the data before the switch were used for the analysis. In all other subjects, all relapses were included in the analysis.

Reporting Groups

	Description
Placebo	Participants received two placebo capsules orally three times daily (TID)
BG00012 240 mg BID	Participants received two 120 mg BG00012 capsules orally twice daily (BID) and two placebo capsules orally once daily (QD)
BG00012 240 mg TID	Participants received two 120 mg BG00012 capsules orally three times daily (TID)

Measured Values

	Placebo	BG00012 240 mg BID	BG00012 240 mg TID
Number of Participants Analyzed [units: participants]	408	410	416
Annualized Relapse Rate [units: Relapses per year] Mean (95% Confidence Interval)	0.364 (0.303 to 0.436)	0.172 (0.138 to 0.214)	0.189 (0.153 to 0.234)

No statistical analysis provided for Annualized Relapse Rate

6. Secondary: Proportion of Subjects Experiencing Progression of Disability Assessed Using the Expanded Disability Status Scale (EDSS) [Time Frame: 2 years]

Measure Type	Secondary
Measure Title	Proportion of Subjects Experiencing Progression of Disability Assessed Using the Expanded Disability Status Scale (EDSS)
Measure Description	The EDSS is based on a standardized neurological examination and focuses on symptoms that commonly occur in MS. EDSS scores range from 0.0 (normal) to 10.0 (death due to MS). Disability progression was defined as ≥ 1.0 point increase in subjects with a baseline EDSS of ≥1.0, or a ≥1.5 point increase in subjects with a baseline EDSS = 0, and required that the increase from baseline was confirmed ≥12 weeks later. The proportion of subjects with confirmed (12-week) disability progression was estimated using the Kaplan-Meier method, which was based on the time-to-first-progression survival distribution.
Time Frame	2 years
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 analysis population consisted of the ITT population (all subjects who were randomized and received at least 1 dose of study medication) who had a baseline EDSS assessment. Analysis were based on all observed data. Onset of disability progression must begin before a subject switched to alternative MS medication.

Reporting Groups

	Description
Placebo	Participants received two placebo capsules orally three times daily (TID)
BG00012 240 mg BID	Participants received two 120 mg BG00012 capsules orally twice daily (BID) and two placebo capsules orally once daily (QD)
BG00012 240 mg TID	Participants received two 120 mg BG00012 capsules orally three times daily (TID)

Measured Values

	Placebo	BG00012 240 mg BID	BG00012 240 mg TID
Number of Participants Analyzed [units: participants]	408	409	416
Proportion of Subjects Experiencing Progression of Disability Assessed Using the Expanded Disability Status Scale (EDSS) [units: Proportion of participants]	0.271	0.164	0.177

No statistical analysis provided for Proportion of Subjects Experiencing Progression of Disability Assessed Using the Expanded Disability Status Scale (EDSS)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	2 years
Additional Description	The safety population consisted of all subjects who received at least 1 dose of study treatment. Safety data were analyzed by actual treatment received. Among subjects who switched to an alternative therapy for MS, all the data before the switch were used for the analysis. In all other subjects, all data were included in the analysis.

Reporting Groups

	Description
Placebo	Participants received two placebo capsules orally three times daily (TID)
BG00012 240 mg Twice Daily (BID)	Participants received two 120 mg BG00012 capsules orally twice daily (BID) and two placebo capsules orally once daily (QD)
BG00012 240 mg 3 Times Daily (TID)	Participants received two 120 mg BG00012 capsules orally three times daily (TID)
Total BG00012	Combined BG00012 240 mg twice daily (BID) dose group and BG00012 240 mg 3 times daily (TID) dose group

Serious Adverse Events

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Total BG00012
Total, serious adverse events				
# participants affected / at risk	86/408 (21.08%)	74/410 (18.05%)	65/416 (15.63%)	139/826 (16.83%)
Blood and lymphatic system disorders				
Anaemia † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Microcytic Anaemia † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Cardiac disorders				
Acute Coronary Syndrome † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)

Cardiac Failure † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Cardiac Failure Congestive † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Congenital, familial and genetic disorders				
Hydrocele † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Ear and labyrinth disorders				
Vertigo Positional † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Endocrine disorders				
Goitre † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	2/416 (0.48%)	2/826 (0.24%)
Endocrinopathy Diencephalic † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Gastrointestinal disorders				
Gastritis † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	3/416 (0.72%)	3/826 (0.36%)
Vomiting † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	1/416 (0.24%)	2/826 (0.24%)
Abdominal Hernia † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Abdominal Pain Lower † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Constipation † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Gastrontestinal Disorder † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Hiatus Hernia † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Colitis † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Colitis Ulcerative † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Gastrointestinal Haemorrhage † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Peritoneal Haemorrhage † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
General disorders				
Pyrexia † 1				

# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	1/416 (0.24%)	2/826 (0.24%)
Non-Cardiac Chest Pain † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Influenza Like Illness † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Pelvic Mass † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Hepatobiliary disorders				
Cholelithiasis † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Hepatitis Cholestatic † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Immune system disorders				
Hypersensitivity † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	1/416 (0.24%)	2/826 (0.24%)
Anaphylactoid Reaction † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Infections and infestations				
Gastroenteritis † 1				
# participants affected / at risk	0/408 (0.00%)	4/410 (0.98%)	1/416 (0.24%)	5/826 (0.61%)
Pneumonia † 1				
# participants affected / at risk	1/408 (0.25%)	2/410 (0.49%)	0/416 (0.00%)	2/826 (0.24%)
Sinusitis † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	1/416 (0.24%)	2/826 (0.24%)
Viral Infection † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	1/416 (0.24%)	2/826 (0.24%)
Appendicitis † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
H1N1 Influenza † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Influenza † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Peritonsillar Abscess † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	0/416 (0.00%)	1/826 (0.12%)
Post Viral Fatigue Syndrome † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Urinary Tract Infection † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Vulval Abscess † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Anal Abscess † 1				

# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Diarrhoea Infectious † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Nasopharyngitis † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Pelvic Inflammatory Disease † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Reiter's Syndrome † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Sepsis † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Tuberculosis Gastrointestinal † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Cellulitis † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Injury, poisoning and procedural complications				
Road Traffic Accident † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	1/416 (0.24%)	2/826 (0.24%)
Ankle Fracture † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Concussion † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Meniscus Lesion † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Postoperative Fever † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Procedural Hypotension † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Radius Fracture † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Traumatic Brain Injury † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Wrist Fracture † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Femoral Neck Fracture † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Tendon Rupture † 1				
# participants affected / at risk	2/408 (0.49%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Tibia Fracture † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Investigations				

Allergy Test † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Blood Glucose Increased † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Colonoscopy † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Investigation † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Medical Observation † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Hepatic Enzyme Increased † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Metabolism and nutrition disorders				
Hypoglycaemia † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Musculoskeletal and connective tissue disorders				
Back Pain † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Sjogren's Syndrome † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Osteoarthritis † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Polyarthritis † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Synovial Cyst † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Benign Lung Neoplasm † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Breast Cancer † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Cervix Carcinoma † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Neurilemmoma † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Transitional Cell Carcinoma † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Uterine Leiomyoma † 1				
# participants affected / at risk	2/408 (0.49%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
† 1				

Basal Cell Carcinoma				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Haemangioma † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Nervous system disorders				
Multiple Sclerosis Relapse † 1				
# participants affected / at risk	60/408 (14.71%)	39/410 (9.51%)	32/416 (7.69%)	71/826 (8.60%)
Headache † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	2/416 (0.48%)	2/826 (0.24%)
Neurological Symptom † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	1/416 (0.24%)	2/826 (0.24%)
Altered State of Conciousness † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Epilepsy † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Glossopharyngeal Neuralgia † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Ischaemic Stroke † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Multiple Sclerosis † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Transient Global Amnesia † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Transient Ischaemic Attack † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Transverse Sinus Thrombosis † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Viith Nerve Paralysis † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Convulsion † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Encephalopathy † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Grand Mal Convulsion † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Loss of Conciousness † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Migraine † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Restless Legs Syndrome † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)

Psychiatric disorders				
Adjustment Disorder with Depressed Mood † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Depression † 1				
# participants affected / at risk	2/408 (0.49%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Generalized Anxiety Disorder † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Mania † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Narcissistic Personality Disorder † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Suicidal Ideation † 1				
# participants affected / at risk	1/408 (0.25%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Renal and urinary disorders				
Renal Colic † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Ureterocele † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Reproductive system and breast disorders				
Ovarian Cyst † 1				
# participants affected / at risk	1/408 (0.25%)	1/410 (0.24%)	2/416 (0.48%)	3/826 (0.36%)
Adenomyosis † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Endometriosis † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Ovarian Cyst Ruptured † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Menstrual Disorder † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Pelvic Pain † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Uterine Haemorrhage † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Respiratory, thoracic and mediastinal disorders				
Pleural Effusion † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Pneumonia Aspiration † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Skin and subcutaneous tissue				

disorders				
Pruritus † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Stevens-Johnson Syndrome † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Dermatitis Allergic † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)
Surgical and medical procedures				
Female Sterilization † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Hysterectomy † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	0/416 (0.00%)	1/826 (0.12%)
Venous Stent Insertion † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Vascular disorders				
Flushing † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	1/416 (0.24%)	2/826 (0.24%)
Varicose Vein † 1				
# participants affected / at risk	0/408 (0.00%)	1/410 (0.24%)	1/416 (0.24%)	2/826 (0.24%)
Deep Vein Thrombosis † 1				
# participants affected / at risk	0/408 (0.00%)	0/410 (0.00%)	1/416 (0.24%)	1/826 (0.12%)
Peripheral Ischaemia † 1				
# participants affected / at risk	1/408 (0.25%)	0/410 (0.00%)	0/416 (0.00%)	0/826 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	2 years
Additional Description	The safety population consisted of all subjects who received at least 1 dose of study treatment. Safety data were analyzed by actual treatment received. Among subjects who switched to an alternative therapy for MS, all the data before the switch were used for the analysis. In all other subjects, all data were included in the analysis.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	Participants received two placebo capsules orally three times daily (TID)
BG00012 240 mg Twice Daily (BID)	Participants received two 120 mg BG00012 capsules orally twice daily (BID) and two placebo capsules orally once daily (QD)

BG00012 240 mg 3 Times Daily (TID)	Participants received two 120 mg BG00012 capsules orally three times daily (TID)
Total BG00012	Combined BG00012 240 mg twice daily (BID) dose group and BG00012 240 mg 3 times daily (TID) dose group

Other Adverse Events

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Total BG00012
Total, other (not including serious) adverse events				
# participants affected / at risk	384/408 (94.12%)	394/410 (96.10%)	393/416 (94.47%)	787/826 (95.28%)
Ear and labyrinth disorders				
VERTIGO † 1				
# participants affected / at risk	15/408 (3.68%)	13/410 (3.17%)	29/416 (6.97%)	42/826 (5.08%)
Gastrointestinal disorders				
DIARRHEA † 1				
# participants affected / at risk	55/408 (13.48%)	62/410 (15.12%)	78/416 (18.75%)	140/826 (16.95%)
NAUSEA † 1				
# participants affected / at risk	38/408 (9.31%)	53/410 (12.93%)	54/416 (12.98%)	107/826 (12.95%)
ABDOMINAL PAIN UPPER † 1				
# participants affected / at risk	28/408 (6.86%)	40/410 (9.76%)	52/416 (12.50%)	92/826 (11.14%)
ABDOMINAL PAIN † 1				
# participants affected / at risk	22/408 (5.39%)	46/410 (11.22%)	37/416 (8.89%)	83/826 (10.05%)
VOMITING † 1				
# participants affected / at risk	24/408 (5.88%)	40/410 (9.76%)	29/416 (6.97%)	69/826 (8.35%)
DYSPEPSIA † 1				
# participants affected / at risk	12/408 (2.94%)	23/410 (5.61%)	24/416 (5.77%)	47/826 (5.69%)
CONSTIPATION † 1				
# participants affected / at risk	19/408 (4.66%)	14/410 (3.41%)	18/416 (4.33%)	32/826 (3.87%)
GASTROINTESTINAL DISORDER † 1				
# participants affected / at risk	6/408 (1.47%)	9/410 (2.20%)	20/416 (4.81%)	29/826 (3.51%)
General disorders				
FATIGUE † 1				
# participants affected / at risk	54/408 (13.24%)	57/410 (13.90%)	63/416 (15.14%)	120/826 (14.53%)
PYREXIA † 1				

# participants affected / at risk	21/408 (5.15%)	16/410 (3.90%)	18/416 (4.33%)	34/826 (4.12%)
Infections and infestations				
NASOPHARYNGITIS † [1]				
# participants affected / at risk	101/408 (24.75%)	108/410 (26.34%)	109/416 (26.20%)	217/826 (26.27%)
UPPER RESPIRATORY TRACT INFECTION † [1]				
# participants affected / at risk	53/408 (12.99%)	63/410 (15.37%)	51/416 (12.26%)	114/826 (13.80%)
URINARY TRACT INFECTION † [1]				
# participants affected / at risk	53/408 (12.99%)	55/410 (13.41%)	54/416 (12.98%)	109/826 (13.20%)
INFLUENZA † [1]				
# participants affected / at risk	39/408 (9.56%)	34/410 (8.29%)	48/416 (11.54%)	82/826 (9.93%)
SINUSITIS † [1]				
# participants affected / at risk	20/408 (4.90%)	17/410 (4.15%)	34/416 (8.17%)	51/826 (6.17%)
BRONCHITIS † [1]				
# participants affected / at risk	18/408 (4.41%)	21/410 (5.12%)	26/416 (6.25%)	47/826 (5.69%)
GASTROENTERITIS † [1]				
# participants affected / at risk	21/408 (5.15%)	26/410 (6.34%)	20/416 (4.81%)	46/826 (5.57%)
RHINITIS † [1]				
# participants affected / at risk	19/408 (4.66%)	12/410 (2.93%)	16/416 (3.85%)	28/826 (3.39%)
Investigations				
ALANINE AMINOTRANSFERASE INCREASED † [1]				
# participants affected / at risk	13/408 (3.19%)	29/410 (7.07%)	27/416 (6.49%)	56/826 (6.78%)
ALBUMIN URINE PRESENT † [1]				
# participants affected / at risk	12/408 (2.94%)	24/410 (5.85%)	22/416 (5.29%)	46/826 (5.57%)
Musculoskeletal and connective tissue disorders				
BACK PAIN † [1]				
# participants affected / at risk	57/408 (13.97%)	59/410 (14.39%)	46/416 (11.06%)	105/826 (12.71%)
ARTHRALGIA † [1]				
# participants affected / at risk	39/408 (9.56%)	46/410 (11.22%)	37/416 (8.89%)	83/826 (10.05%)
PAIN IN EXTREMITY † [1]				
# participants affected / at				

risk	29/408 (7.11%)	37/410 (9.02%)	29/416 (6.97%)	66/826 (7.99%)
MUSCLE SPASMS † 1				
# participants affected / at risk	20/408 (4.90%)	13/410 (3.17%)	27/416 (6.49%)	40/826 (4.84%)
MUSCULAR WEAKNESS † 1				
# participants affected / at risk	26/408 (6.37%)	12/410 (2.93%)	14/416 (3.37%)	26/826 (3.15%)
MUSCULOSKELETAL PAIN † 1				
# participants affected / at risk	21/408 (5.15%)	11/410 (2.68%)	10/416 (2.40%)	21/826 (2.54%)
Nervous system disorders				
MULTIPLE SCLEROSIS RELAPSE † 1				
# participants affected / at risk	181/408 (44.36%)	109/410 (26.59%)	107/416 (25.72%)	216/826 (26.15%)
HEADACHE † 1				
# participants affected / at risk	80/408 (19.61%)	81/410 (19.76%)	78/416 (18.75%)	159/826 (19.25%)
PARAESTHESIA † 1				
# participants affected / at risk	38/408 (9.31%)	35/410 (8.54%)	38/416 (9.13%)	73/826 (8.84%)
HYPOAESTHESIA † 1				
# participants affected / at risk	27/408 (6.62%)	20/410 (4.88%)	24/416 (5.77%)	44/826 (5.33%)
DIZZINESS † 1				
# participants affected / at risk	23/408 (5.64%)	19/410 (4.63%)	22/416 (5.29%)	41/826 (4.96%)
Psychiatric disorders				
DEPRESSION † 1				
# participants affected / at risk	32/408 (7.84%)	29/410 (7.07%)	33/416 (7.93%)	62/826 (7.51%)
INSOMNIA † 1				
# participants affected / at risk	19/408 (4.66%)	20/410 (4.88%)	20/416 (4.81%)	40/826 (4.84%)
Renal and urinary disorders				
PROTEINURIA † 1				
# participants affected / at risk	34/408 (8.33%)	38/410 (9.27%)	50/416 (12.02%)	88/826 (10.65%)
HAEMATURIA † 1				
# participants affected / at risk	19/408 (4.66%)	26/410 (6.34%)	26/416 (6.25%)	52/826 (6.30%)
MICROALBUMINURIA † 1				
# participants affected / at risk	11/408 (2.70%)	21/410 (5.12%)	17/416 (4.09%)	38/826 (4.60%)
Respiratory, thoracic and mediastinal disorders				

OROPHARYNGEAL PAIN † 1				
# participants affected / at risk	19/408 (4.66%)	25/410 (6.10%)	21/416 (5.05%)	46/826 (5.57%)
COUGH † 1				
# participants affected / at risk	18/408 (4.41%)	22/410 (5.37%)	19/416 (4.57%)	41/826 (4.96%)
Skin and subcutaneous tissue disorders				
PRURITIS † 1				
# participants affected / at risk	19/408 (4.66%)	42/410 (10.24%)	33/416 (7.93%)	75/826 (9.08%)
RASH † 1				
# participants affected / at risk	13/408 (3.19%)	34/410 (8.29%)	27/416 (6.49%)	61/826 (7.38%)
ERYTHEMA † 1				
# participants affected / at risk	5/408 (1.23%)	20/410 (4.88%)	33/416 (7.93%)	53/826 (6.42%)
Vascular disorders				
FLUSHING † 1				
# participants affected / at risk	20/408 (4.90%)	153/410 (37.32%)	132/416 (31.73%)	285/826 (34.50%)
HOT FLUSH † 1				
# participants affected / at risk	8/408 (1.96%)	31/410 (7.56%)	29/416 (6.97%)	60/826 (7.26%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (13.1)

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 provisions of the agreements are subject to confidentiality but generally the PI can publish, for noncommercial purposes only, results and methods of the trial, but no other Sponsor Confidential Information. PI must give Sponsor no less than 60 days to review any manuscript for a proposed publication and must delay publication for up to 90 days thereafter if Sponsor needs to file any patent application to protect any of Sponsor's intellectual property contained in the proposed publication.

Results Point of Contact:

Name/Title: Biogen Idec Study Medical Director
Organization: Biogen Idec
e-mail: clinicaltrials@biogenidec.com

No publications provided by Biogen Idec

Publications automatically indexed to this study:

Fox RJ, Kita M, Cohan SL, Henson LJ, Zambrano J, Scannevin RH, O'Gorman J, Novas M, Dawson KT, Phillips JT. BG-12 (dimethyl fumarate): a review of mechanism of action, efficacy, and safety. Curr Med Res Opin. 2014 Feb;30(2):251-62. doi: 10.1185/03007995.2013.849236. Epub 2013 Oct 22.

Gold R, Kappos L, Arnold DL, Bar-Or A, Giovannoni G, Selmaj K, Tornatore C, Sweetser MT, Yang M, Sheikh SI, Dawson KT; DEFINE Study Investigators. Placebo-controlled phase 3 study of oral BG-12 for relapsing multiple sclerosis. N Engl J Med. 2012 Sep 20;367(12):1098-107. Erratum in: N Engl J Med. 2012 Dec 13;367(24):2362.

Responsible Party:	Biogen Idec
ClinicalTrials.gov Identifier:	NCT00420212 History of Changes
Other Study ID Numbers:	109MS301
Study First Received:	January 8, 2007
Results First Received:	May 5, 2014
Last Updated:	January 13, 2015
Health Authority:	Romania: National Medicines Agency France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Ukraine: State Pharmacological Center - Ministry of Health Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Mexico: Federal Commission for Protection Against Health Risks Guatemala: Ministry of Public Health and Social Assistance Australia: Department of Health and Ageing Therapeutic Goods Administration India: Ministry of Health South Africa: Department of Health United States: Institutional Review Board Austria: Agency for Health and Food Safety New Zealand: Medsafe Czech Republic: State Institute for Drug Control Greece: National Organization of Medicines Sweden: Medical Products Agency Slovakia: State Institute for Drug Control Germany: Federal Institute for Drugs and Medical Devices Croatia: Ministry of Health and Social Care Canada: Health Canada United Kingdom: Medicines and Healthcare Products Regulatory Agency Israel: Ethics Commission Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products United States: Food and Drug Administration Belgium: Federal Agency for Medicines and Health Products, FAMHP