Efficacy and Safety Study of Oral BG00012 With Active Reference in Relapsing-Remitting Multiple Sclerosis (CONFIRM)

This study has been completed.

Sponsor:
Biogen Idec

Information provided by (Responsible Party):
Biogen Idec

ClinicalTrials.gov Identifier:
NCT00451451

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History of Changes

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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 Drug: Glatiramer Acetate

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 randomized at 205 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, 1430 eligible subjects were equally randomized. Of these, 1417 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)
Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)	Participants received glatiramer acetate (GA) 20 mg subcutaneous injection once daily (QD)

Participant Flow: Overall Study

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)
STARTED	363 [1]	359 [2]	345 [3]	350 [4]
COMPLETED	278	284	273	292
NOT COMPLETED	85	75	72	58
Adverse Event	11	21	26	10
Lost to Follow-up	11	9	8	11
Consent Withdrawn	14	9	17	17
Investigator Decision	6	2	1	2
Subject Non-Compliance	8	4	3	3
Death	1	0	0	1
Other Reasons for Not Completing Study	34	30	17	14

[1] 363 participants were dosed; 363 participants were randomized
[2] 359 participants were dosed; 362 participants were randomized
[3] 345 participants were dosed; 345 participants were randomized
[4] 350 participants were dosed; 360 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)
Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)	Participants received glatiramer acetate (GA) 20 mg subcutaneous injection once daily (QD)
Total	Total of all reporting groups

Baseline Measures

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)	Total
Number of Participants [units: participants]	363	359	345	350	1417
Age [units: Years] Mean ± Standard Deviation	36.9 ± 9.24	37.8 ± 9.35	37.8 ± 9.39	36.7 ± 9.06	37.3 ± 9.26
Gender [units: Participants]					
Female	251	245	250	247	993
Male	112	114	95	103	424
Mean Expanded Disability Status Scale (EDSS) score [1] [units: units on a scale] Mean ± Standard Deviation	2.59 ± 1.170	2.56 ± 1.202	2.52 ± 1.185	2.57 ± 1.223	2.56 ± 1.194
Mean number of relapses within the previous 3 years [units: Number of relapses] Mean ± Standard Deviation	2.5 ± 1.46	2.4 ± 1.27	2.6 ± 1.50	2.4 ± 1.32	2.5 ± 1.39
Mean number of relapses within the past 12 months [units: Number of relapses] Mean ± Standard Deviation	1.4 ± 0.80	1.3 ± 0.63	1.4 ± 0.72	1.4 ± 0.64	1.4 ± 0.70
Time since first multiple sclerosis (MS) diagnosis [units: years] Mean ± Standard Deviation	4.8 ± 5.01	4.9 ± 5.11	4.6 ± 5.23	4.4 ± 4.70	4.7 ± 5.01
Mean number of Gadolinium(Gd)-enhancing T1-weighted lesions [2] [units: Number of Gd enhancing lesions] Mean ± Standard Deviation	2.7 ± 7.71	2.7 ± 6.22	1.9 ± 5.02	2.4 ± 6.81	2.4 ± 6.51

[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 681 intent-to-treat (ITT) subjects who were enrolled at sites that participated in the MRI portion of the study and who had MRI data (167 placebo, 169 BG00012 BID, 170 BG00012 TID, and 175 GA). 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: Annualized Relapse Rate [Time Frame: 2 years]

Measure Type	Primary
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 Expanded Disability Status Scale (EDSS) score(≤2.0 versus>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 intent-to-treat (ITT) population was defined as all subjects who were randomized and received at least 1 dose of study treatment. 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)
Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)	Participants received Glatiramer acetate (GA) 20 mg subcutaneous injection once daily (QD)

Measured Values

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)
Number of Participants Analyzed [units: participants]	363	359	345	350
Annualized Relapse Rate [units: Relapses Per Year] Mean (95% Confidence Interval)	0.401 (0.329 to 0.488)	0.224 (0.179 to 0.282)	0.198 (0.156 to 0.252)	0.286 (0.232 to 0.353)

No statistical analysis provided for Annualized Relapse Rate

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 hyperintense lesion count were calculated from a negative binomial regression model adjusted for region and baseline T2 hyperintense 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 681 subjects in the MRI cohort, 572 (139 placebo, 140 BG00012 BID, 140 BG00012 TID, 153 GA) had post-baseline T2 hyperintense data & were included in the analysis. Missing data before the use of alternative MS medications & visits after subjects 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)
Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)	Participants received glatiramer acetate (GA) 20 mg subcutaneous injection once daily (QD)

Measured Values

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)
Number of Participants Analyzed [units: participants]	139	140	140	153
Number of New or Newly Enlarging T2 Hyperintense Lesions [units: Number of lesions] Mean (95% Confidence Interval)	17.4 (13.5 to 22.4)	5.1 (3.9 to 6.6)	4.7 (3.6 to 6.2)	8.0 (6.3 to 10.2)

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

3. Secondary: Number of New T1 Hypointense Lesions [Time Frame: 2 years]

Measure Type	Secondary
Measure Title	Number of New T1 Hypointense Lesions
Measure Description	The number of new T1 hypointense lesions at 2 years that developed in each subject compared to baseline assessed on brain magnetic resonance imaging (MRI) scans. The estimates of mean T1 hypointense lesion count were calculated from a negative binomial regression model adjusted for region and baseline T1 hypointense 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 681 subjects in the MRI cohort, 573 (139 placebo,140 BG00012 BID,140 BG00012 TID,154 GA) had post-baseline new T1 hypointense data & were included in the analysis. Missing data before the use of alternative MS medications & visits after subjects 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)
Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)	Participants received glatiramer acetate (GA) 20 mg subcutaneous injection once daily (QD)

Measured Values

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)
Number of Participants Analyzed [units: participants]	139	140	140	153
Number of New T1 Hypointense Lesions [units: Number of lesions] Mean (95% Confidence Interval)	7.0 (5.3 to 9.2)	3.0 (2.3 to 4.0)	2.4 (1.8 to 3.2)	4.1 (3.2 to 5.3)

No statistical analysis provided for Number of New T1 Hypointense Lesions

4. Secondary: Proportion of Subjects Relapsed [Time Frame: 2 years]

Measure Type	Secondary
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 neurologic 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 treatment. 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 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)
Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)	Participants received glatiramer acetate (GA) 20 mg subcutaneous injection once daily (QD)

Measured Values

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)
Number of Participants Analyzed [units: participants]	363	359	345	350
Proportion of Subjects Relapsed [units: Proportion of subjects,confirmed relapse]	0.410	0.291	0.241	0.321

No statistical analysis provided for Proportion of Subjects Relapsed

5. 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	EDSS is based on a standardized neurological exam and focuses on symptoms that commonly occur in MS. 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 ≥1.5 point increase in subjects with a baseline EDSS=0, and required that the increase from baseline was confirmed ≥ 12weeks 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 intent-to-treat (ITT) population (all subjects who were randomized and received at least 1 dose of study treatment) who had a baseline EDSS assessment. Analyses 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 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)
Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)	Participants received glatiramer acetate (GA) 20 mg subcutaneous injection once daily (QD)

Measured Values

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)
Number of Participants Analyzed [units: participants]	363	359	345	350
Proportion of Subjects Experiencing Progression of Disability Assessed Using the Expanded Disability Status Scale (EDSS) [units: Proportion of Participants]	0.169	0.128	0.130	0.156

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. One patient randomly assigned to the BG00012 TID group & included in the group of the ITT population took GA throughout the study and was therefore counted in the GA group of the safety population.

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
Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)	Participants received glatiramer acetate (GA) 20 mg subcutaneous injection once daily (QD)

Serious Adverse Events

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Total BG00012	Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)
Total, serious adverse events					
# participants affected / at risk	79/363 (21.76%)	61/359 (16.99%)	54/344 (15.70%)	115/703 (16.36%)	60/351 (17.09%)
Cardiac disorders					
BRADYCARDIA † 1					

# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
MYOCARDITIS † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
Ear and labyrinth disorders					
VESTIBULAR ATAXIA † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
Eye disorders					
EYE PAIN † [1]					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
HOLMES-ADIE PUPIL † [1]					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
VISUAL ACUITY REDUCED † [1]					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
Gastrointestinal disorders					
ABDOMINAL PAIN † [1]					
# participants affected / at risk	0/363 (0.00%)	2/359 (0.56%)	0/344 (0.00%)	2/703 (0.28%)	0/351 (0.00%)
VOMITING † [1]					
# participants affected / at risk	1/363 (0.28%)	1/359 (0.28%)	1/344 (0.29%)	2/703 (0.28%)	0/351 (0.00%)
DIVERTICULAR PERFORATION † [1]					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
DUODENITIS † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
GASTROINTESTINAL HAEMORRHAGE † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
INTESTINAL OBSTRUCTION † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
NAUSEA † [1]					
# participants affected / at risk	1/363 (0.28%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
UMBILICAL HERNIA † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)

PANCREATITIS ACUTE † [1]					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
General disorders					
ASTHENIA † [1]					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
HERNIA OBSTRUCTIVE † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
OEDEMA PERIPHERAL † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	1/351 (0.28%)
PYREXIA † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
Hepatobiliary disorders					
BILE DUCT STONE † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
CHOLELITHIASIS † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	1/351 (0.28%)
Immune system disorders					
ANAPHYLACTIC REACTION † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	2/351 (0.57%)
HYPERSENSITIVITY † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
Infections and infestations					
GASTROENTERITIS † [1]					
# participants affected / at risk	0/363 (0.00%)	2/359 (0.56%)	2/344 (0.58%)	4/703 (0.57%)	0/351 (0.00%)
CELLULITIS † [1]					
# participants affected / at risk	0/363 (0.00%)	2/359 (0.56%)	1/344 (0.29%)	3/703 (0.43%)	0/351 (0.00%)
URINARY TRACT INFECTION † [1]					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	1/344 (0.29%)	2/703 (0.28%)	0/351 (0.00%)
DOUGLAS' ABSCESS † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
GASTROENTERITIS VIRAL † [1]					

# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
H1N1 INFLUENZA † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
PELVIC INFLAMMATORY DISEASE † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
PYELONEPHRITIS ACUTE † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
VIRAL INFECTION † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	1/351 (0.28%)
APPENDICITIS † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
BORRELIA INFECTION † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
ENDOCARDITIS BACTERIAL † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
INFLUENZA † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
PNEUMONIA † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	2/351 (0.57%)
PYOTHORAX † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
SEPSIS † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
TRACHEITIS † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
Injury, poisoning and procedural complications					
FEMUR FRACTURE † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	1/344 (0.29%)	2/703 (0.28%)	1/351 (0.28%)
MUSCLE STRAIN † 1					
# participants affected /	0/363 (0.00%)	0/359 (0.00%)	2/344 (0.58%)	2/703 (0.28%)	0/351 (0.00%)

at risk					
ALCOHOL POISONING † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
FACIAL BONES FRACTURE † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
FALL † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
FOOT FRACTURE † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
LIGAMENT RUPTURE † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
OVERDOSE † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
ROAD TRAFFIC ACCIDENT † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	1/351 (0.28%)
TRAUMATIC HAEMATOMA † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
WRIST FRACTURE † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
EYE INJURY † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
HAND FRACTURE † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
LIGAMENT INJURY † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
MENISCUS LESION † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
RADIUS FRACTURE † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
TENDON RUPTURE † 1					
# participants affected /	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)

at risk					
THERAPEUTIC AGENT TOXICITY † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
WHIPLASH INJURY † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
Investigations					
BETA 2 MICROGLOBULIN URINE INCREASED † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
HEPATIC ENZYME INCREASED † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
Metabolism and nutrition disorders					
DEHYDRATION † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
DIABETIC KETOACIDOSIS † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
Musculoskeletal and connective tissue disorders					
BACK PAIN † 1					
# participants affected / at risk	0/363 (0.00%)	2/359 (0.56%)	0/344 (0.00%)	2/703 (0.28%)	0/351 (0.00%)
ARTHRALGIA † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
BURSITIS † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
OSTEOARTHRITIS † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
SPINAL OSTEOARTHRITIS † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
UTERINE LEIOMYOMA † 1					

# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	1/351 (0.28%)
BASAL CELL CARCINOMA † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
BREAST NEOPLASM † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
CERVIX CARCINOMA † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
ENDOMETRIAL CANCER † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
FIBROMA † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
THYROID CANCER METASTATIC † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
Nervous system disorders					
MULTIPLE SCLEROSIS RELAPSE † 1					
# participants affected / at risk	51/363 (14.05%)	39/359 (10.86%)	30/344 (8.72%)	69/703 (9.82%)	36/351 (10.26%)
BENIGN INTRACRANIAL HYPERTENSION † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
DYSARTHRIA † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
GRAND MAL CONVULSION † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	1/351 (0.28%)
HEADACHE † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
MIGRAINE † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
OCCIPITAL NEURALGIA † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
PARTIAL SEIZURES † 1					

# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	1/351 (0.28%)
RESTLESS LEGS SYNDROME † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
APHASIA † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
CEREBROVASCULAR ACCIDENT † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
CEREBROVASCULAR DISORDER † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
CONVULSION † 1					
# participants affected / at risk	2/363 (0.55%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
EPILEPSY † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
LOSS OF CONSCIOUSNESS † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
MULTIPLE SCLEROSIS † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
Pregnancy, puerperium and perinatal conditions					
ABORTION SPONTANEOUS † 1					
# participants affected / at risk	2/363 (0.55%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
GESTATIONAL OEDEMA † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
Psychiatric disorders					
BIPOLAR I DISORDER † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
DEPRESSION † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	2/351 (0.57%)
SUICIDE ATTEMPT † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	1/351 (0.28%)

ANXIETY † [1]					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
COMPLETED SUICIDE † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
SUICIDAL IDEATION † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
Renal and urinary disorders					
BLADDER DYSFUNCTION † [1]					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
BLADDER PERFORATION † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
URINARY INCONTINENCE † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
BLADDER DIVERTICULUM † [1]					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
NEPHROPTOSIS † [1]					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
Reproductive system and breast disorders					
MENORRHAGIA † [1]					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
METRORRHAGIA † [1]					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	1/351 (0.28%)
BARTHOLIN'S CYST † [1]					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
UTERINE HAEMORRHAGE † [1]					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
Respiratory, thoracic and mediastinal disorders					
ASTHMA † [1]					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)

NASAL POLYPS † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
Social circumstances					
SOCIAL PROBLEM † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
Surgical and medical procedures					
BREAST LUMP REMOVAL † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
INTERVERTEBRAL DISC OPERATION † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	1/344 (0.29%)	1/703 (0.14%)	0/351 (0.00%)
MEDICAL DIET † 1					
# participants affected / at risk	0/363 (0.00%)	1/359 (0.28%)	0/344 (0.00%)	1/703 (0.14%)	0/351 (0.00%)
CERVICAL CONISATION † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
STERILISATION † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)
TURBINECTOMY † 1					
# participants affected / at risk	1/363 (0.28%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	0/351 (0.00%)
Vascular disorders					
DEEP VEIN THROMBOSIS † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	1/351 (0.28%)

† 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. One patient randomly assigned to the BG00012 TID group & included in the group of the ITT population took GA throughout the study and was therefore counted in the GA group of the safety population.

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
Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)	Participants received glatiramer acetate (GA) 20 mg subcutaneous injection once daily (QD)

Other Adverse Events

	Placebo	BG00012 240 mg Twice Daily (BID)	BG00012 240 mg 3 Times Daily (TID)	Total BG00012	Glatiramer Acetate (GA) 20 mg Injection Once Daily (QD)
Total, other (not including serious) adverse events					
# participants affected / at risk	332/363 (91.46%)	336/359 (93.59%)	316/344 (91.86%)	652/703 (92.75%)	303/351 (86.32%)
Ear and labyrinth disorders					
VERTIGO † 1					
# participants affected / at risk	22/363 (6.06%)	9/359 (2.51%)	13/344 (3.78%)	22/703 (3.13%)	15/351 (4.27%)
Gastrointestinal disorders					
DIARRHEA † 1					
# participants affected / at risk	28/363 (7.71%)	45/359 (12.53%)	50/344 (14.53%)	95/703 (13.51%)	14/351 (3.99%)
NAUSEA † 1					
# participants affected / at risk	29/363 (7.99%)	40/359 (11.14%)	51/344 (14.83%)	91/703 (12.94%)	15/351 (4.27%)
ABDOMINAL PAIN UPPER † 1					
# participants affected / at risk	17/363 (4.68%)	36/359 (10.03%)	33/344 (9.59%)	69/703 (9.82%)	4/351 (1.14%)
ABDOMINAL PAIN † 1					
# participants affected / at risk	15/363 (4.13%)	25/359 (6.96%)	26/344 (7.56%)	51/703 (7.25%)	4/351 (1.14%)
VOMITING † 1					
# participants affected / at risk	12/363 (3.31%)	25/359 (6.96%)	23/344 (6.69%)	48/703 (6.83%)	8/351 (2.28%)

DYSPEPSIA † 1					
# participants affected / at risk	8/363 (2.20%)	12/359 (3.34%)	16/344 (4.65%)	28/703 (3.98%)	6/351 (1.71%)
General disorders					
FATIGUE † 1					
# participants affected / at risk	33/363 (9.09%)	37/359 (10.31%)	33/344 (9.59%)	70/703 (9.96%)	30/351 (8.55%)
PYREXIA † 1					
# participants affected / at risk	19/363 (5.23%)	11/359 (3.06%)	24/344 (6.98%)	35/703 (4.98%)	17/351 (4.84%)
INJECTION SITE ERYTHEMA † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	31/351 (8.83%)
INJECTION SITE PAIN † 1					
# participants affected / at risk	0/363 (0.00%)	0/359 (0.00%)	0/344 (0.00%)	0/703 (0.00%)	29/351 (8.26%)
Infections and infestations					
NASOPHARYNGITIS † 1					
# participants affected / at risk	58/363 (15.98%)	62/359 (17.27%)	63/344 (18.31%)	125/703 (17.78%)	51/351 (14.53%)
URINARY TRACT INFECTION † 1					
# participants affected / at risk	42/363 (11.57%)	51/359 (14.21%)	40/344 (11.63%)	91/703 (12.94%)	46/351 (13.11%)
UPPER RESPIRATORY TRACT INFECTION † 1					
# participants affected / at risk	34/363 (9.37%)	36/359 (10.03%)	47/344 (13.66%)	83/703 (11.81%)	27/351 (7.69%)
INFLUENZA † 1					
# participants affected / at risk	22/363 (6.06%)	20/359 (5.57%)	25/344 (7.27%)	45/703 (6.40%)	15/351 (4.27%)
BRONCHITIS † 1					
# participants affected / at risk	14/363 (3.86%)	14/359 (3.90%)	22/344 (6.40%)	36/703 (5.12%)	16/351 (4.56%)
SINUSITIS † 1					
# participants affected / at risk	11/363 (3.03%)	18/359 (5.01%)	18/344 (5.23%)	36/703 (5.12%)	11/351 (3.13%)
Investigations					
ALANINE AMINOTRANSFERASE INCREASED † 1					
# participants affected / at risk	25/363 (6.89%)	16/359 (4.46%)	22/344 (6.40%)	38/703 (5.41%)	20/351 (5.70%)
ALBUMIN URINE PRESENT † 1					
# participants					

affected / at risk	15/363 (4.13%)	22/359 (6.13%)	14/344 (4.07%)	36/703 (5.12%)	18/351 (5.13%)
PROTEIN URINE PRESENT † 1					
# participants affected / at risk	10/363 (2.75%)	18/359 (5.01%)	7/344 (2.03%)	25/703 (3.56%)	15/351 (4.27%)
Musculoskeletal and connective tissue disorders					
BACK PAIN † 1					
# participants affected / at risk	33/363 (9.09%)	34/359 (9.47%)	36/344 (10.47%)	70/703 (9.96%)	32/351 (9.12%)
ARTHRALGIA † 1					
# participants affected / at risk	26/363 (7.16%)	20/359 (5.57%)	27/344 (7.85%)	47/703 (6.69%)	17/351 (4.84%)
PAIN IN EXTREMITY † 1					
# participants affected / at risk	29/363 (7.99%)	21/359 (5.85%)	26/344 (7.56%)	47/703 (6.69%)	21/351 (5.98%)
MUSCLE SPASMS † 1					
# participants affected / at risk	14/363 (3.86%)	13/359 (3.62%)	21/344 (6.10%)	34/703 (4.84%)	8/351 (2.28%)
Nervous system disorders					
MULTIPLE SCLEROSIS RELAPSE † 1					
# participants affected / at risk	147/363 (40.50%)	104/359 (28.97%)	81/344 (23.55%)	185/703 (26.32%)	115/351 (32.76%)
HEADACHE † 1					
# participants affected / at risk	49/363 (13.50%)	52/359 (14.48%)	46/344 (13.37%)	98/703 (13.94%)	46/351 (13.11%)
PARAESTHESIA † 1					
# participants affected / at risk	31/363 (8.54%)	21/359 (5.85%)	21/344 (6.10%)	42/703 (5.97%)	15/351 (4.27%)
HYPOAESTHESIA † 1					
# participants affected / at risk	21/363 (5.79%)	11/359 (3.06%)	19/344 (5.52%)	30/703 (4.27%)	16/351 (4.56%)
Psychiatric disorders					
DEPRESSION † 1					
# participants affected / at risk	35/363 (9.64%)	24/359 (6.69%)	15/344 (4.36%)	39/703 (5.55%)	28/351 (7.98%)
INSOMNIA † 1					
# participants affected / at risk	18/363 (4.96%)	15/359 (4.18%)	10/344 (2.91%)	25/703 (3.56%)	13/351 (3.70%)
Renal and urinary disorders					
PROTEINURIA † 1					
# participants affected / at risk	25/363 (6.89%)	29/359 (8.08%)	35/344 (10.17%)	64/703 (9.10%)	30/351 (8.55%)

MICROALBUMINURIA † 1					
# participants affected / at risk	13/363 (3.58%)	14/359 (3.90%)	19/344 (5.52%)	33/703 (4.69%)	15/351 (4.27%)
Respiratory, thoracic and mediastinal disorders					
COUGH † 1					
# participants affected / at risk	17/363 (4.68%)	16/359 (4.46%)	18/344 (5.23%)	34/703 (4.84%)	9/351 (2.56%)
OROPHARYNGEAL PAIN † 1					
# participants affected / at risk	14/363 (3.86%)	12/359 (3.34%)	21/344 (6.10%)	33/703 (4.69%)	15/351 (4.27%)
Skin and subcutaneous tissue disorders					
RASH † 1					
# participants affected / at risk	13/363 (3.58%)	24/359 (6.69%)	28/344 (8.14%)	52/703 (7.40%)	8/351 (2.28%)
PRURITIS † 1					
# participants affected / at risk	11/363 (3.03%)	20/359 (5.57%)	24/344 (6.98%)	44/703 (6.26%)	7/351 (1.99%)
ERYTHEMA † 1					
# participants affected / at risk	5/363 (1.38%)	16/359 (4.46%)	21/344 (6.10%)	37/703 (5.26%)	6/351 (1.71%)
Vascular disorders					
FLUSHING † 1					
# participants affected / at risk	13/363 (3.58%)	110/359 (30.64%)	83/344 (24.13%)	193/703 (27.45%)	6/351 (1.71%)
HOT FLUSH † 1					
# participants affected / at risk	8/363 (2.20%)	18/359 (5.01%)	19/344 (5.52%)	37/703 (5.26%)	4/351 (1.14%)

† 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 our agreement 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

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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.

Fox RJ, Miller DH, Phillips JT, Hutchinson M, Havrdova E, Kita M, Yang M, Raghupathi K, Novas M, Sweetser MT, Viglietta V, Dawson KT; CONFIRM Study Investigators. Placebo-controlled phase 3 study of oral BG-12 or glatiramer in multiple sclerosis. N Engl J Med. 2012 Sep 20;367(12):1087-97. Erratum in: N Engl J Med. 2012 Oct 25;367(17):1673.

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United States: Food and Drug Administration
Belgium: Federal Agency for Medicines and Health Products, FAMHP