

ORIGINAL ARTICLE

A Correction Has Been Published

Placebo-Controlled Phase 3 Study of Oral BG-12 or Glatiramer in Multiple Sclerosis

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N Engl J Med 2012; 367:1087-1097 September 20, 2012 DOI: 10.1056/NEJMoa1206328

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Abstract Article References Citing Articles (14)

BACKGROUND

BG-12 (dimethyl fumarate) is in development as an oral treatment for relapsing–remitting multiple sclerosis, which is commonly treated with parenteral agents (interferon or glatiramer acetate).

Full Text of Background...

METHODS

In this phase 3, randomized study, we investigated the efficacy and safety of oral BG-12, at a dose of 240 mg two or three times daily, as compared with placebo in patients with relapsing–remitting multiple sclerosis. An active agent, glatiramer acetate, was also included as a reference comparator. The primary end point was the annualized relapse rate over a period of 2 years. The study was not designed to test the superiority or noninferiority of BG-12 versus glatiramer acetate.

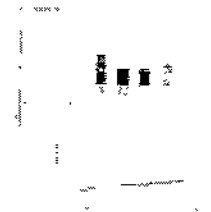
Full Text of Methods...

RESULTS

At 2 years, the annualized relapse rate was significantly lower with twice-daily BG-12 (0.22), thrice-daily BG-12 (0.20), and glatiramer

MEDIA IN THIS ARTICLE

FIGURE 1



Clinical Outcomes at 2 Years in the Intention-to-Treat Population.

TABLE 1

Characteristic	Twice-daily BG-12	Thrice-daily BG-12	Glatiramer acetate
Age (mean, years)	38.5	38.5	38.5
Female (%)	75	75	75
EDSS (mean)	3.5	3.5	3.5
Annualized relapse rate (%)	22	20	30

Baseline Demographic and Disease Characteristics (ITT Population).

acetate (0.29) than with placebo (0.40) (relative reductions: twice-daily BG-12, 44%, $P < 0.001$; thrice-daily BG-12, 51%, $P < 0.001$; glatiramer acetate, 29%, $P = 0.01$). Reductions in disability progression with twice-daily BG-12, thrice-daily BG-12, and glatiramer acetate versus placebo (21%, 24%, and 7%, respectively) were not significant. As compared with placebo, twice-daily BG-12, thrice-daily BG-12, and glatiramer acetate significantly reduced the numbers of new or enlarging T₂-weighted hyperintense lesions (all $P < 0.001$) and new T₁-weighted hypointense lesions ($P < 0.001$, $P < 0.001$, and $P = 0.002$, respectively). In post hoc comparisons of BG-12 versus glatiramer acetate, differences were not significant except for the annualized relapse rate (thrice-daily BG-12), new or enlarging T₂-weighted hyperintense lesions (both BG-12 doses), and new T₁-weighted hypointense lesions (thrice-daily BG-12) (nominal $P < 0.05$ for each comparison). Adverse events occurring at a higher incidence with an active treatment than with placebo included flushing and gastrointestinal events (with BG-12) and injection-related events (with glatiramer acetate). There were no malignant neoplasms or opportunistic infections reported with BG-12. Lymphocyte counts decreased with BG-12.

ARTICLE ACTIVITY

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CONCLUSIONS

In patients with relapsing–remitting multiple sclerosis, BG-12 (at both doses) and glatiramer acetate significantly reduced relapse rates and improved neuroradiologic outcomes relative to placebo. (Funded by Biogen Idec; CONFIRM ClinicalTrials.gov number, NCT00451451.)

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BG-12 240 mg

Generic Name: dimethyl fumarate

Pill imprint BG-12 240 mg has been identified as **Tecfidera 240 mg**.

Risk cannot be ruled out during pregnancy.

Tecfidera 240 mg Unknown

See also [related documents](#).

Images & Information

Tecfidera

Generic Name:
dimethyl fumarate

Imprint:
BG-12 240 mg

Strength:
240 mg

Color:
Green

Shape:
Capsule-shape

Availability:
Prescription only

Pregnancy Category:
C - Risk cannot be ruled out

CSA Schedule:
U - Unknown

Manufacturer:
Biogen Idec Inc.

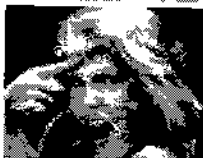
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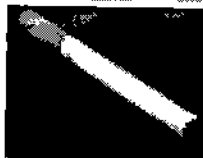
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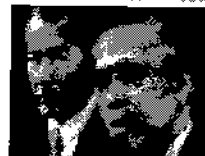
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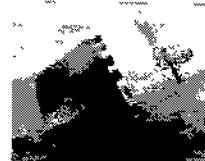
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