EXPAND

Important Safety Information

TECFIDERA Warnings and Precautions include: Anaphylaxis and Angioedema, Progressive Multifocal Leukoencephalopathy, Lymphopenia, Liver Injury, and Flushing.

Tecfidera (dimethyl fumarate) delayed-release capsules 240 mg

TECFIDERA Clinical Trials

THE DEFINE* TRIAL

The DEFINE trial included patients who were new to MS treatment and patients who were MS treatment-experienced[1]

A 2-year, randomized, double-blind, placebo-controlled study in 1234 patients with relapsing-remitting multiple sclerosis (RRMS)[2]

Previous therapy experience[1]

59%
NEW TO TREATMENT

41%
TREATMENT-EXPERIENCED

Median time since diagnosis[2]	Median EDSS score at baseline[2]
4 years	2

Randomization[2†]

TECFIDERA (dimethyl fumarate)
PO 240 mg n=410

One 120 mg capsule twice a day for the first 7 days, followed by an increase to one 240 mg capsule twice a day

Placebo n=408

Endpoints[2]

Primary

Proportion of patients relapsed (PPR)

Additional

- Annualized relapse rate (ARR)
- Time to confirmed disability progression
- Number of new or newly enlarging T2 hyperintense lesions
- Number of Gd+ lesions
- Number of new T1 hypointense lesions

Key inclusion criteria[2]

Experienced at least 1 relapse over the year preceding the trial

OR

Had a brain magnetic resonance imaging (MRI) scan demonstrating at least 1 gadolinium-enhancing (Gd+) lesion within 6 weeks of randomization

AND

An Expanded Disability Status Scale (EDSS) score ranging from 0 to 5

Key exclusion criteria[1]

- Interferon-beta or glatiramer acetate within 3 months of randomization
- An infusion disease-modifying therapy (DMT) within 6 months of randomization
- Primary progressive multiple sclerosis or secondary progressive multiple sclerosis
- Any major disease that would preclude participation in a clinical trial

Evaluations[2]

Neurological evaluations
Performed at baseline, every 3 months, and at time of suspected relapse

MRI evaluations
Performed in 44% of patients at baseline, month 6, and years 1 and 2

69% of patients treated with TECFIDERA BID completed 96 weeks of treatment (compared to 65% of patients taking placebo)[2]

THE CONFIRM‡ TRIAL

The CONFIRM trial included patients who were new to MS treatment and patients who were MS treatment-experienced[3]

A 2-year, multicenter, randomized, double-blind, placebo-controlled study that evaluated the efficacy and safety of TECFIDERA compared to oral placebo in 1417 patients with RRMS. CONFIRM included an open-label comparator arm[2]

Previous therapy experience[3]

71% NEW TO TREATMENT

29% TREATMENT-EXPERIENCED

Median time since diagnosis[2]	Median EDSS score at baseline[2]
3 years	2.5

Randomization[2§]

TECFIDERA (dimethyl fumarate) PO 240 mg n=359	Placebo n=363	Open-label Comparator n=350

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