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Multiple sclerosis is estimated to affect more than 2.3 million people globally.

The FDA approval of Lemtrada is based on two pivotal randomized Phase III open-label rater-blinded studies comparing treatment with Lemtrada to Rebif (high-dose subcutaneous interferon beta-1a) in patients with relapsing remitting MS who were either new to treatment (CARE-MS I) or who had relapsed while on prior therapy (CARE-MS II).

"The approval is the culmination of more than a decade of work by Genzyme to develop Lemtrada," said C's president and CEO, Mr David Meeker.

Lemtrada has a unique dosing and administration schedule of two annual treatment courses.

The first treatment course is administered via intravenous infusion on five consecutive days, and the second course is administered on three consecutive days, 12 months later.

First approved in September 2013 in the European Union, Lemtrada is approved in more than 40 countries.

Additional marketing applications for Lemtrada are under review by regulatory agencies around the world.

The FDA approval of Lemtrada marks Genzyme's second MS treatment approval in the United States.

Genzyme received FDA approval of its once-daily, oral Aubagio (teriflunomide) for the treatment of relapsing forms of MS in September 2012.

Aubagio is approved in more than 50 countries, and is under review by additional regulatory agencies.

Between clinical trials and commercial use, approximately 30,000 patients have been treated with Aubagio.