FDA approves new MS therapy

A new medication for use by people with relapsing forms of multiple sclerosis was approved in November by the U.S. Food and Drug Administration.

by Marcella Durand

A new therapy for use by people with relapsing forms of multiple sclerosis was approved in November 2014 by the U.S. Food and Drug Administration. Because of certain safety risks, Lemtrada™ is recommended only after a person with MS has first tried two or more disease-modifying therapies (DMTs) without successful results.

Lemtrada (alemtuzumab) works by targeting immune cells that are implicated in MS. It is administered via intravenous infusions for five consecutive days initially and for three consecutive days one year later. Two large phase 3 clinical trials, known as CARE-MS I and II, which together studied more than 1,100 people with MS, demonstrated that Lemtrada could better reduce relapse rates over two years compared with another approved treatment (in this case, Rebif). One study also suggested that Lemtrada may reduce worsening of disability. The full results of both studies were published in The Lancet (November 2012).

“The approval of Lemtrada provides an important and immunologically powerful new therapeutic option for people with relapsing MS,” says Dr. Bruce A. Cohen, professor, Davee Department of Neurology and Clinical Neurosciences at Northwestern University’s Feinberg School of Medicine, and chair of the National MS Society’s National Medical Advisory Committee. “Its long-lasting effects may profoundly influence the course of relapsing MS but will require careful and sustained monitoring for side effects, which people receiving the

medicine must follow.”

Prescribing information for Lemtrada includes a boxed warning about serious infusion reactions, increased risk for malignancies, and the potential for serious and sometimes fatal autoimmune conditions such as thrombocytopenia, a rare bleeding disorder. Other adverse reactions include rash, headache, fever, nausea and fatigue.

The FDA requires that individuals and their healthcare providers take several steps before and during treatment with Lemtrada. These include being vaccinated against shingles (varicella zoster virus), testing thyroid function, and having regular skin exams, monthly blood counts and more. Regular monthly testing continues at least four years after the last infusion. People taking Lemtrada, as well as prescribers, infusion centers and pharmacies, will be enrolled in a Risk Evaluation and Mitigation Strategy (REMS) program to ensure that any potential problems are detected early.

Marcella Durand is a frequent contributor to Momentum.

Visit nationalMSsociety.org/LemtradaFDA to learn more.

To learn about other disease-modifying therapies for MS, read “The medication map” and visit nationalMSsociety.org/Treating-MS/Medications.