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CLINICAL UPDATE

Brand Name	Kesimpta Pen
Generic Name	ofatumumab
Drug Manufacturer	Novartis

Clinical Update

FDA Approves Kesimpta (ofatumumab) subcutaneous injection Targeted B-cell Therapy for Patients with Relapsing Multiple Sclerosis

FDA approval date: August 20, 2020

Overview

Kesimpta (ofatumumab, formerly OMB157) is an injection for subcutaneous used for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Kesimpta is a targeted, precisely dosed and delivered B-cell therapy that has shown superior efficacy with a similar safety profile compared with teriflunomide and is a first-choice treatment option for RMS patients. Kesimpta is the first B-cell therapy that can be self-administered once monthly at home via the Sensoready® autoinjector pen.

The U.S. Food and Drug Administration (FDA) has approved Kesimpta (ofatumumab), a CD20-directed cytolytic IgG1 antibody used to treat relapsing forms of multiple sclerosis (MS) in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. The approval is based on the Phase 3 ASCLEPIOS studies. The ASCLEPIOS I and II studies are twin, identical design, flexible duration (up to 30 months), double-blind, randomized, multi-center Phase III studies evaluating the safety and efficacy of Kesimpta 20 mg monthly subcutaneous injections versus teriflunomide 14 mg oral tablets taken once daily in adults with RMS. The ASCLEPIOS I and II studies enrolled 1,882 patients with MS, between the ages of 18 and 55 years, with an Expanded Disability Status Scale (EDSS) score between 0 and 5.51. The studies were conducted in over 350 sites in 37 countries10. Kesimpta demonstrated a significant reduction in ARR by 51% (0.11 vs 0.22) and 59% (0.10 vs 0.25) compared with teriflunomide (P<.001 in both studies) in ASCLEPIOS I and II, respectively (primary endpoint). Kesimpta also showed a relative risk reduction of 34.4% (P=.002) in 3-month CDP compared with teriflunomide in pre-specified meta-analysis, as defined in ASCLEPIOS.

Moreover, it showed significant reduction of both Gd+ T1 lesions and new or enlarging T2 lesions. It significantly reduced the mean number of both Gd+ T1 lesions (98% and 94% relative reduction in ASCLEPIOS I and II, respectively, both P<.001) and new or enlarging T2 lesions (82% and 85% relative reduction in ASCLEPIOS I and II, respectively, both P<.001) vs teriflunomide. Kesimpta had a similar safety profile to teriflunomide, with the frequency of serious infections and malignancies also being similar across both treatment groups1. Upper respiratory tract infection, headache, injection-related reactions, and local injection site reactions were the most commonly observed adverse reactions with Kesimpta (incidence greater than 10%).

A separate post hoc analysis demonstrated Kesimpta may halt new disease activity in RMS patients. It showed the odds of achieving no evidence of disease activity (NEDA-3; no relapses, no MRI lesions, and no disability worsening combined) with ofatumumab versus teriflunomide were >3-fold higher at Months 0–12 (47.0% vs 24.5% of patients; P<.001) and >8-fold higher at Months 12–24 (87.8% vs 48.2% of patients; P<.001). Overall Kesimpta, an antibody targeting CD20 positive B-cells, delivered superior efficacy and demonstrated a safety profile with infection rates similar to teriflunomide.