

## Ocrevus™ (ocrelizumab) – New drug approval

- On March 28, 2017, the [FDA approved Genentech's Ocrevus \(ocrelizumab\)](#) for the treatment of adult patients with relapsing or primary progressive forms of multiple sclerosis (MS).
- MS is a chronic disease where the immune system attacks the area around nerve cells causing inflammation and damage. Symptoms that occur include muscle weakness, fatigue and difficulty seeing, and may eventually lead to disability. In the U.S., MS affects approximately 400,000 people.
  - Relapsing-remitting MS (RRMS) occurs in about 85% of people with MS and is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery.
  - Primary progressive MS (PPMS) occurs in about 15% of people with MS and is a debilitating form of the disease marked by steadily worsening symptoms but typically without distinct relapses or periods of remission.
- Ocrevus is the first treatment approved for PPMS. Ocrevus is a monoclonal antibody that selectively targets CD20-positive B cells, a specific type of immune cell thought to be a key contributor to myelin and axonal damage.
- The safety and efficacy of Ocrevus were based on 2 RRMS studies, OPERA I and OPERA II, and 1 PPMS study, ORATORIO. In OPERA I and II, 821 and 835 patients, respectively, were randomized to Ocrevus 600 mg every 24 weeks or [Rebif® \(interferon beta-1a\)](#) 44 mcg 3 times per week for 96 weeks. The primary outcome of both studies was the annualized relapse rate (ARR). In ORATORIO, 732 patients were randomized to Ocrevus 600 mg every 24 weeks or placebo for 120 weeks. The primary outcome was 12-week confirmed disability progression (CDP).
  - In OPERA I, the ARR for Ocrevus-treated and Rebif-treated patients was 0.156 and 0.292, respectively (relative reduction = 46%;  $p < 0.0001$ ).
  - In OPERA II, the ARR for Ocrevus-treated and Rebif-treated patients was 0.155 and 0.290, respectively (risk reduction = 47%;  $p < 0.0001$ ).
  - In addition, for both OPERA I and II, Ocrevus showed a 40% relative risk reduction in CDP vs. Rebif ( $p = 0.0006$ ).
  - In ORATORIO, the proportion of patients with CDP was 32.9% for the Ocrevus-treated patients and 39.3% for the placebo-treated patients (risk reduction = 24%;  $p = 0.0321$ ).
- Ocrevus is contraindicated in patients with active hepatitis B virus (HBV) infection and a history of life-threatening infusion reaction to Ocrevus.
- Warnings and precautions of Ocrevus include infusion reactions, infections and malignancies.
- The most common adverse reactions ( $\geq 10\%$  and  $>$  Rebif) with Ocrevus use in RRMS were upper respiratory tract infections and infusion reactions.
- The most common adverse reactions ( $\geq 10\%$  and  $>$  placebo) with Ocrevus use in PPMS were upper respiratory tract infections, infusion reactions, skin infections, and lower respiratory tract infections.
- The recommended initial dose of Ocrevus is 300 mg by intravenous (IV) infusion, followed 2 weeks later by a second 300 mg IV infusion. Subsequent doses are single 600 mg IV infusions every 6 months.

- Before each infusion, patients should be pre-medicated with 100 mg of [methylprednisolone](#) (or an equivalent corticosteroid) and an antihistamine (eg, [diphenhydramine](#)). An antipyretic (eg, [acetaminophen](#)) may also be considered.
  - Before the first dose of Ocrevus, screening for active infections and HBV infection is warranted. Additionally, all necessary immunizations must be administered at least 6 weeks prior to the start of therapy.
- Through [Genentech Access Solutions](#)<sup>®</sup>, patients may receive assistance with insurance coverage, financial assistance and medication delivery.
  - The wholesale acquisition cost of Ocrevus is \$65,000 annually.
  - Genentech plans to launch Ocrevus within the next 2 weeks. Ocrevus will be available as a 300 mg/10 mL (30 mg/mL) single-dose vial.



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