Ocrevus Zunovo™ (ocrelizumab/hyaluronidase-ocsq) – New subcutaneous formulation approval

- On September 13, 2024, Halozyme announced that Roche received FDA approval of Ocrevus Zunovo (ocrelizumab/hyaluronidase-ocsq), for the treatment of:
  - Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
  - Primary progressive MS (PPMS), in adults
- Ocrelizumab was previously available as an intravenous formulation (Ocrevus®) for the same indications.
- The approval of Ocrevus Zunovo was supported by a randomized, open-label study evaluating the comparative bioavailability, pharmacokinetics, pharmacodynamics, safety, and immunogenicity of Ocrevus Zunovo vs. IV Ocrevus in 236 patients with either RMS or PPMS.
  - The study demonstrated comparable exposure of Ocrevus Zunovo relative to the Ocrevus IV formulation.
- Ocrevus Zunovo is contraindicated in patients with:
  - Active hepatitis B virus infection
  - A history of life-threatening administration reaction to ocrelizumab
  - A history of hypersensitivity to ocrelizumab, hyaluronidase, or any component of Ocrevus Zunovo.
- Warnings and precautions for Ocrevus Zunovo include injection reactions; infections; progressive multifocal leukoencephalopathy; reduction in immunoglobulins; malignancies; and immune-mediated colitis.
- The safety profile of Ocrevus Zunovo is based on IV Ocrevus. The most common adverse reactions in patients treated with IV Ocrevus were:
  - RMS (incidence ≥ 10% and > Rebif® [interferon beta-1a]): upper respiratory tract infections and infusion reactions
  - PPMS (incidence ≥ 10% and > placebo): upper respiratory tract infections, infusion reactions, skin infections, and lower respiratory tract infections.
- The recommended dosage of Ocrevus Zunovo is 920 mg/23,000 units (920 mg ocrelizumab and 23,000 units of hyaluronidase) administered as a single 23 mL SC injection in the abdomen over approximately 10 minutes every 6 months.
  - Ocrevus Zunovo should be administered by a healthcare professional.
- Roche's launch plans for Ocrevus Zunovo are pending. Ocrevus Zunovo will be available as a solution in a single-dose vial containing 20 mg ocrelizumab and 23,000 units hyaluronidase per 23 mL (40 mg and 1,000 units per mL).