

Brand Name: Ocrevus

Generic: ocrelizumab

Type: monoclonal antibody

Year Accepted/Phase: 2017

Mechanism:

Ocrevus targets CD20-positive B-cells, leading to their depletion. B-cells play a role in the immune response believed to contribute to the damage seen in MS.

Chemical Structure: N/A

Indication:

Ocrevus is indicated for the treatment of relapsing forms of multiple sclerosis MS and primary progressive MS.

Clinical trials:

Phase III Trials in Relapsing-Relmitting Multiple Sclerosis (RRMS)

Pubmed: <https://pubmed.ncbi.nlm.nih.gov/30844611/>

Purpose: Evaluate the efficacy and safety of Ocrevus in patients with RRMS.

Dates: Trials conducted from 2011 onwards.

Results: Ocrevus significantly reduced the annualized relapse rate (ARR) compared to interferon beta-1a (Rebif) in two pivotal Phase III trials (OPERA I and OPERA II). It also reduced the risk of disability progression and the number of brain lesions observed on MRI scans.

Impact: These trials led to the FDA approval of Ocrevus for the treatment of RRMS in March 2017, making it the first FDA-approved treatment for both relapsing and primary progressive forms of MS.

Phase III Trials in Primary Progressive Multiple Sclerosis (PPMS)

Pubmed: <https://pubmed.ncbi.nlm.nih.gov/28002688/>

Purpose: Evaluate the efficacy and safety of Ocrevus in patients with PPMS.

Dates: Trials conducted from 2012 onwards.

Results: Ocrevus significantly slowed the progression of disability compared to placebo in two Phase III trials (ORATORIO I and ORATORIO II) in PPMS patients. It also reduced the risk of brain volume loss and other markers of disease activity.

Impact: These trials led to the FDA approval of Ocrevus for the treatment of PPMS in March 2017, making it the first FDA-approved treatment for this form of MS.

Long-Term Extension Studies

Purpose: Assess the long-term safety and efficacy of Ocrevus in patients with MS.

Dates: Ongoing since the initial approval.

Results: Long-term extension studies have shown that Ocrevus maintains its efficacy in reducing disease activity and progression in both RRMS and PPMS patients. The safety profile remains consistent with the findings from the initial trials.

Impact: These studies provide important data on the long-term use of Ocrevus and support its continued use as a treatment for MS.