Inebilizumab: Adis Evaluation

Clinical Considerations

- Monoclonal antibody that depletes a broad range of B cells, including plasmablasts and some plasma cells
- Effectively prevents NMOSD relapses, including in AQP4-antibody seropositive patients
- Clinical benefit is sustained over long-term treatment (≥ 4 years)
- Generally well tolerated; the most common adverse events were urinary tract infection and arthralgia

Plain Language Summary

Background and rationale

- Neuromyelitis optica spectrum disorder (NMOSD) is a chronic condition denoted by relapsing autoimmune attacks affecting the central nervous system, which may lead to accruing disability or death
- It is frequently associated with anti-aquaporin-4 (AQP4) autoantibodies
- In recent years, three new monoclonal antibody therapies have gained regulatory approval for the treatment of NMOSD
- Inebilizumab (Uplizna®), a monoclonal antibody that targets B cells, is approved for use in AQP4-antibody seropositive adults as an intravenous infusion

Clinical findings

- Inebilizumab was effective at preventing NMOSD relapse compared with placebo in a pivotal phase 2/3 trial
- It also prevented worsening of disability scores, and decreased the number of NMOSD-related hospitalisations and MRI lesions, but did not significantly improve low-contrast binocular vision
- The clinical benefit of inebilizumab was maintained long-term (≥ 4 years in the open-label extension)
- Inebilizumab was generally well tolerated, with most adverse events being mild to moderate in severity. The most common adverse events were urinary tract infection and joint pain

Conclusion

Inebilizumab provides an effective option for preventing NMOSD attacks in adults who are AQP4-antibody seropositive