

Ravulizumab: Adis Evaluation

Clinical Considerations

- **First approved long-acting complement C5 inhibitor, administered intravenously every 8 weeks**
- **Provides improvements in activities of daily living that were sustained over the longer term compared with placebo**
- **Generally well tolerated**

Plain Language Summary

Background and rationale

- Generalised myasthenia gravis (gMG) is a rare chronic condition that affects the muscles, making them become abnormally tired and weak after use. Prevalence can vary (5.3–35 per 100,000 people) and is steadily rising.
- Management of gMG can involve modifying or suppressing the immune system, symptom management and/or surgical removal of the thymus gland. Complement C5 inhibitors are another treatment option for patients with gMG.
- Ravulizumab (ULTOMIRIS®) is the first long-acting complement C5 inhibitor (administered intravenously every 8 weeks) to be approved in several countries globally for the treatment of adults with gMG who are anti-acetylcholine receptor antibody-positive (AChR Ab+).

Clinical findings

- Ravulizumab is associated with long-lasting improvements in activities of daily living and disease status in adults with AChR Ab+ gMG, as demonstrated in a phase III clinical trial.
- In this trial, ravulizumab was generally well tolerated; headache, diarrhoea and nausea were the most common adverse events.
- Although there is a potential risk for adverse reactions with ravulizumab treatment, including serious meningococcal infections, other infections and infusion-related reactions, no meningococcal infections occurred and the incidence of infusion-related reactions was low in patients with gMG.
- The efficacy and tolerability of ravulizumab were sustained for up to 1 year of treatment; further results are awaited with interest.

Conclusion

Ravulizumab is an efficacious, generally well tolerated and convenient treatment option in adults with AChR Ab+ gMG, expanding the options available for gMG management.

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