18 September 2025
EMA/CHMP/292567/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Imaavy

nipocalimab

On 18 September 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Imaavy, intended for the treatment of generalised myasthenia gravis.

The applicant for this medicinal product is Janssen-Cilag International NV.

Imaavy will be available as a 300 mg/1.62 ml and 1200 mg/6.5 ml concentrate for solution for infusion. The active substance of Imaavy is nipocalimab, a selective immunosuppressant (ATC code: L04AL03). Nipocalimab is a human IgG1 monoclonal antibody that binds to the neonatal Fc receptor (FcRn), thereby decreasing the levels of circulating IgG, including pathogenic IgG autoantibodies.

In clinical trials, the benefits of Imaavy plus standard of care include reduced functional disability as rated by patients, and decreased disease severity as assessed by qualified physicians, compared with placebo plus standard of care. The most common side effects with Imaavy include increased lipids, decreased serum albumin, muscle spasms and peripheral oedema.

The full indication is:

> Imaavy is indicated as an add-on to standard therapy for the treatment of generalised Myasthenia Gravis (gMG) in adult and adolescent patients aged 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

Treatment with Imaavy should be supervised by a physician experienced in the management of patients with neuromuscular disorders and must be administered by a healthcare professional.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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