23 June 2022
EMA/CHMP/604677/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vyvgart

efgartigimod alfa

On 23 June 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vyvgart[2], intended for the treatment of anti-acetylcholine receptor (AChR) antibody positive generalised Myasthenia Gravis. The applicant for this medicinal product is Argenx.

Vyvgart will be available as 20mg/ml concentrate for solution for infusion. The active substance of Vyvgart is efgartigimod alfa, an immunosuppressant (ATC code: L04AA58). Efgartigimod alfa is a fragment of human IgG1 antibody that binds to the neonatal Fc Receptor (FcRn), thereby decreasing the levels of circulating IgG, including pathogenic IgG autoantibodies.

Benefits of Vyvgart include a decrease in functional disability as rated by patients, and less disease severity as assessed by qualified physicians, as compared with placebo in clinical trials. The most common side effects are upper respiratory tract infections and urinary tract infections.

The full indication is:

> Vyvgart is indicated as an add-on to standard therapy for the treatment of adult patients with generalised Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

Efgartigimod alfa must be administered by a healthcare professional and under the supervision of a physician experienced in the management of patients with neuromuscular disorders.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available 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
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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