9 November 2023
EMA/CHMP/488847/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rystiggo

rozanolixizumab

On 9 November 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rystiggo[2], intended for the treatment of Myasthenia Gravis (gMG). The applicant for this medicinal product is UCB Pharma.

Rystiggo will be available as a 140 mg/ml solution for injection. The active substance of Rystiggo is rozanolixizumab, an immunosuppressant (ATC code: L04AG16). Rozanolixizumab decreases the concentration of pathogenic IgG autoantibodies associated with gMG by inhibiting IgG binding to FcRn, thereby stimulating intracellular IgG degradation, and preventing IgG from being recycled to the cell surface.

The benefit of Rystiggo is an improvement in the severity of the disease compared with placebo, as measured by clinical scales in a phase 3, randomised clinical trial. The most common side effects are headache, diarrhoea and pyrexia.

The full indication is:

> Rystiggo is indicated as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

Rystiggo should be prescribed by physicians experienced in the treatment of patients with neuromuscular or neuro-inflammatory 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 has reviewed the information available to date and determined that the orphan designation can be maintained.

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