11 November 2021
EMA/625434/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Uplizna

inebilizumab

On 11 November 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Uplizna[2], intended for the treatment of adult patients with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin 4 immunoglobulin G (AQP4-IgG) seropositive

The applicant for this medicinal product is Viela Bio.

Uplizna will be available as a 100 mg concentrate for solution for infusion. The active substance of Uplizna is inebilizumab, an immunosuppressant (ATC code: L04AA). Inebilizumab binds to the B cell-specific surface antigen CD19, resulting in a profound depletion of B cells, which are believed to play a central role in the pathogenesis of NMOSD.

The benefit of Uplizna is a reduced risk of attacks in AQP4-IgG seropositive NMOSD. The most common side effects are urinary tract infections, joint pain and reduction of immunoglobulins levels.

The full indication is:

> Uplizna is indicated as monotherapy for the treatment of adult patients with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin 4 immunoglobulin G (AQP4-IgG) seropositive see section 5.1).

Uplizna should be prescribed by physicians experienced in the treatment of NMOSD and with access to appropriate medical support to manage potential severe reactions such as serious infusion-related reactions.

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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