22 April 2021
EMA/CHMP/215160/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Enspryng

satralizumab

On 22 April 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 Enspryng[2], intended for the treatment of neuromyelitis optica spectrum disorders (NMOSD) in patients from 12 years of age who are anti-aquaporin-4 IgG (AQP4-IgG) seropositive.

The applicant for this medicinal product is Roche Registration GmbH.

Enspryng will be available as a solution for injection (120 mg/mL) in prefilled syringes. The active substance of Enspryng is satralizumab, an immunosuppressant (ATC code: L04AC19), a monoclonal antibody binding IL-6 receptor and thereby, preventing the pleiotropic pro-inflammatory effects involved in the pathogenesis of NMOSD.

Compared to placebo, Enspryng as a monotherapy or in combination with other immunosuppressants reduces the risk of relapses, the main driver of neurological disability in NMOSD. The most common side effects are infections, arthralgia, injection site reactions, leukopenia and elevation of transaminases.

The full indication is:

> Enspryng is indicated as a monotherapy or in combination with immunosuppressive therapy (IST) for the treatment of neuromyelitis optica spectrum disorders (NMOSD) in adult and adolescent patients from 12 years of age who are anti-aquaporin-4 IgG (AQP4-IgG) seropositive (see section 5.1).

Enspryng should be initiated under the supervision of a physician experienced in the treatment of neuromyelitis optica (NMO) or NMOSD.

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

[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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