25 July 2019
EMA/CHMP/410407/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Soliris

eculizumab

On 25 July 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Soliris. The marketing authorisation holder for this medicinal product is Alexion Europe SAS.

The CHMP adopted a new indication as follows:[2]

"Soliris is indicated in adults and children for the treatment of:

- Paroxysmal nocturnal haemoglobinuria (PNH).

  Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history (see section 5.1).

- Atypical haemolytic uremic syndrome (aHUS) (see section 5.1).

Soliris is indicated in adults for the treatment of:

- Refractory generalized myasthenia gravis (gMG) in patients who are anti-acetylcholine receptor (AChR) antibody-positive (see section 5.1).

- **Neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody-positive with a relapsing course of the disease (see section 5.1)**."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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] New text in **bold**

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