EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2015
EMA/CHMP/94647/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Soliris

eculizumab

On 26 February 2015, 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 change to an existing indication as follows:

Soliris is indicated in adults and children for the treatment of patients with
- Paroxysmal nocturnal haemoglobinuria (PNH).
Evidence of clinical benefit ~~of Soliris in the treatment of patients with PNH~~ is ~~limited~~ **demonstrated** ~~to~~ **in** patients with ~~history of transfusions~~ **haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history (see section 5.1)**.

For information, the full indications for Soliris will be as follows:

Soliris is indicated in adults and children for the treatment of patients with
- 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).

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact