EMA/12438/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Aspaveli

pegcetacoplan

On 25 January 2024 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 Aspaveli. The marketing authorisation holder for this medicinal product is Swedish Orphan Biovitrum AB (publ).

The CHMP adopted an extension to the existing indication to include patients with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia and have not had previous treatment with a C5 inhibitor. For information, the full indication will therefore be as follows:[2]

> Aspaveli is indicated **as monotherapy** in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who ~~are anaemic after treatment with a C5 inhibitor for at least 3 months~~ **have haemolytic anaemia**.

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, removed text as strikethrough

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union