21 July 2022
EMA/639016/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Imcivree

setmelanotide

On 21 July 2022, 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 Imcivree[2]. The marketing authorisation holder for this medicinal product is Rhythm Pharmaceuticals Netherlands B.V.

The CHMP adopted a new indication to include treatment of obesity and hunger control in patients with Bardet-Biedl syndrome (BBS).

For information, the full indications for Imcivree will therefore be as follows[3]:

> IMCIVREE is indicated for the treatment of obesity and the control of hunger associated with genetically confirmed **Bardet-Biedl syndrome (BBS)**, loss-of-function biallelic pro-opiomelanocortin (POMC), including PCSK1, deficiency or biallelic leptin receptor (LEPR) deficiency in adults and children 6 years of age and above.

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] 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
[3] new text in **bold**

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