



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 June 2024  
EMA/CHMP/277218/2024  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

### Imcivree

setmelanotide

On 27 June 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 Imcivree. The marketing authorisation holder for this medicinal product is Rhythm Pharmaceuticals Netherlands B.V.

The CHMP adopted an extension to the existing indications to include treatment of children from 2 years of age. For information, the full indication will therefore be as follows:<sup>2</sup>

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~~2 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.

<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in bold, removed text as strikethrough

