20 May 2021
EMA/CHMP/270677/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Imcivree

setmelanotide

On 20 May 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Imcivree[2], intended for the treatment of obesity and the control of hunger associated with genetic deficiencies of the melanocortin 4 receptor (MC4R) pathway.

The applicant for this medicinal product is Rhythm Pharmaceuticals Limited.

Imcivree will be available as 10 mg/ml solution for injection. The active substance of Imcivree is setmelanotide (ATC code: A08AA12), an 8-amino acid cyclic peptide analogue of naturally occurring alpha-melanocyte stimulating hormone (α-MSH). Setmelanotide is a selective MC4 receptor agonist and is claimed to re-establish MC4 receptor pathway activity to reduce hunger and promote weight loss.

The benefits of Imcivree are its ability to achieve a weight loss equal or greater than 10% after 1 year of treatment and demonstrate clinically meaningful improvement in hunger management in patients with pro-opiomelanocortin (POMC) deficiency obesity and in patients with leptin receptor (LEPR) deficiency obesity. The most common side effects are hyperpigmentation, injection site reaction, nausea and headache.

The full indication is:

> Imcivree is indicated for the treatment of obesity and the control of hunger associated with genetically confirmed 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.

Imcivree should be prescribed and supervised by physicians with expertise in obesity with underlying genetic aetiology.

[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

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.