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# Withdrawal of application to change the marketing authorisation for Imcivree (setmelanotide)

Rhythm Pharmaceuticals Netherlands B.V. withdrew its application for the use of Imcivree to treat obesity and control hunger associated with genetically confirmed Alström syndrome.

The company withdrew the application on 22 April 2022.

## What is Imcivree and what is it used for?

Imcivree is a medicine used to treat obesity and help control hunger in people with certain genetic conditions that affect how the brain controls feelings of hunger. It is used in adults and children aged 6 years and older who have conditions known as pro-opiomelanocortin (POMC) deficiency or leptin receptor (LEPR) deficiency.

The medicine has been authorised in the EU since July 2021.

Imcivree contains the active substance setmelanotide.

Further information on Imcivree's current uses can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/imcivree

## What change had the company applied for?

The company applied to extend the use of Imcivree to treat obesity and control hunger associated with genetically confirmed Alström syndrome. Alström syndrome is a rare genetic disease that causes a variety of problems in several organs across the body.

Imcivree was designated an 'orphan medicine' (a medicine used in rare diseases) on 9 January 2020 for treatment in people with Alström syndrome. Further information on the orphan designation can be found on the Agency's website: ema.europa.eu/medicines/human/orphan-designations/eu-3-19-2245.

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## How does Imcivree work?

The active substance in Imcivree, setmelanotide, attaches to a receptor in the brain called melanocortin receptor 4, which promotes a feeling of fullness after eating. By attaching to this receptor, Imcivree is expected to reduce excessive food intake and obesity.

In patients with Alström syndrome, the signals that control appetite and how the body produces energy are disrupted. In these patients, Imcivree is expected to work in the same way as it does in its existing indications.

## What did the company present to support its application?

The company presented the results of a study which included 6 patients with Alström syndrome. The study compared Imcivree with placebo (a dummy treatment) and looked at the proportion of patients who achieved a clinically meaningful reduction in body weight.

## How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

## What did the Agency recommend at that time?

Based on the review of the information, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Imcivree could not have been authorised for treating obesity and controlling hunger in people with genetically confirmed Alström syndrome.

The Agency's opinion was that the company had not provided enough information to support the application for a change to the marketing authorisation of Imcivree. The small number of patients with Alström syndrome included in the trial and the lack of adequate data did not allow the Agency to establish the benefits of the medicine in the proposed indication.

## What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that its withdrawal was based on the Agency's consideration that the data submitted were insufficient to conclude on a positive benefit-risk balance in the proposed indication.

## Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials with Imcivree.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

## What is happening with Imcivree for the treatment of other diseases?

There are no consequences on the use of Imcivree in its authorised uses.