19 June 2025
EMA/CHMP/82619/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Imreplys

sargramostim

On 19 June 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Imreplys, intended for the treatment of people with haematopoietic acute radiation syndrome (H-ARS) following acute exposure to myelosuppressive doses of radiation. The applicant for this medicinal product is Partner Therapeutics Ltd.

Imreplys will be available as a 250 µg powder for solution for injection. The active substance of Imreplys, sargramostim, is a colony-stimulating factor (ATC code: L03AA09). Sargramostim is a granulocyte-macrophage colony-stimulating factor which induces the bone marrow to produce certain types of white blood cells, such as granulocytes, macrophages and monocytes, as well as red blood cells and platelets.

The benefits of Imreplys are increased 60-day survival rates in Rhesus monkeys who received H-ARS-inducing total body irradiation, compared with placebo, as shown in 3 randomised, blinded, placebo-controlled studies. All studies have also shown faster recovery of absolute neutrophil counts and platelets, reduced infection rates and fewer signs of sepsis. The most common side effects with Imreplys include fever, diarrhoea, vomiting, skin reactions, rash, asthenia, metabolic laboratory abnormalities, malaise, high glucose, abdominal pain, weight loss, low albumin, pruritus, gastrointestinal haemorrhage, chills, pharyngitis, bone pain, chest pain, hypomagnesaemia, haematemesis, arthralgia, anxiety, and eye haemorrhage.

The full indication is:

> Imreplys is indicated for treatment of patients of all ages acutely exposed to myelosuppressive doses of radiation with Haematopoietic Sub-syndrome of Acute Radiation Syndrome [H-ARS].
>
> Imreplys should be used in accordance with official radiological/nuclear emergency recommendations.

[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] In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.

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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 on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.