12 December 2024
EMA/CHMP/563904/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Welireg

belzutifan

On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Welireg, intended for the treatment of advanced clear cell renal cell carcinoma and von Hippel-Lindau disease-associated tumours.

The applicant for this medicinal product is Merck Sharp & Dohme B.V.

Welireg will be available as 40 mg film-coated tablets. The active substance of Welireg is belzutifan, an antineoplastic agent (ATC code: L01XX74). Belzutifan inhibits the transcription factor hypoxia-inducible factor 2 alpha (HIF-2α), which regulates cellular proliferation, angiogenesis and tumour growth.

The benefits of Welireg are its objective response rate and duration of response in patients with VHL disease-associated localised tumours and, compared with Everolimus, its improved progression-free survival in patients with renal cell carcinoma. The most common side effects are anaemia, fatigue, nausea, dyspnoea, dizziness and hypoxia.

The full indications are:

> Renal cell carcinoma (RCC)
>
> WELIREG is indicated as monotherapy for the treatment of adult patients with advanced clear cell renal cell carcinoma that progressed following two or more lines of therapy that included a PD-(L)1 inhibitor and at least two VEGF-targeted therapies.
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> von Hippel-Lindau (VHL) disease-associated tumours
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> WELIREG is indicated as monotherapy for the treatment of adult patients with von Hippel-Lindau disease who require therapy for associated, localised renal cell carcinoma (RCC), central nervous

[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] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.

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system (CNS) haemangioblastomas, or pancreatic neuroendocrine tumours (pNET), and for whom localised procedures are unsuitable.

Treatment with Welireg should be prescribed and supervised by physicians experienced in the treatment of cancer.

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.