22 February 2024
EMA/518075/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Filspari

sparsentan

On 22 February 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 Filspari[3], intended for the treatment of adults with primary immunoglobulin A nephropathy (IgAN). The applicant for this medicinal product is Vifor France.

Filspari will be available as 200 mg and 400 mg film-coated tablets. The active substance of Filspari is sparsentan, a dual endothelin angiotensin receptor antagonist (agents acting on the renin-angiotensin system, ATC code: C09XX01). Endothelin 1 and Angiotensin II are central actors in the pathological cycle of IgAN and by inhibiting their receptors sparsentan can help decrease disease progression.

The benefit of Filspari is its ability to reduce proteinuria and slow down the progression of kidney disease, as seen in a phase 3, randomised, active-control (irbesartan) study in adults with IgAN. The most common side effects are low blood pressure, increase blood potassium levels, dizziness, swelling. The most common serious side effect is acute kidney injury.

The full indication is:

> Filspari is indicated for the treatment of adults with primary immunoglobulin A nephropathy (IgAN) with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ≥0.75 g/g).

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.

[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.
[3] 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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