23 February 2023
EMA/CHMP/55479/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Hyftor

sirolimus

On 23 February 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Hyftor[2], intended for the treatment of angiofibroma. The applicant for this medicinal product is Plusultra pharma GmbH.

Hyftor will be available as a 2 mg/g gel. The active substance of Hyftor is sirolimus, an immunosuppressant (ATC code: L04AA). Sirolimus binds to the immunophilin FKBP-12 to generate an immunosuppressive complex. This complex, in turn, binds to and inhibits the activation of the serine/threonine protein kinase mTOR which regulates cellular metabolism, growth and proliferation.

The benefit of Hyftor is a clinically relevant improvement over placebo in angiofibroma size, extension and redness, as observed in a randomised, double blind, Phase III study in patients with tuberous sclerosis complex who had facial angiofibromas. The most common side effects are skin irritation events, including application site irritation, dry skin, acne and pruritus.

Hyftor is a hybrid medicine[3] of Rapamune, which has been authorised in the EU since 13 March 2001. Hyftor contains the same active substance as Rapamune, but Hyftor is available as a gel intended for local administration.

The full indication is:

> Hyftor is indicated for the treatment of facial angiofibroma associated with tuberous sclerosis complex in adults and paediatric patients aged 6 years and older.

Hyftor should be prescribed by physicians experienced in the treatment of facial angiofibroma.

Detailed recommendations for the use of this product will be described in the summary of product

[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
[3] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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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.