30 January 2025
EMA/CHMP/15109/2025
Committee for Medicinal Products for Human Use (CHMP)

Update as of 12 March 2025

The applicant withdrew the marketing authorisation application for Skojoy on 4 March 2025. The application was withdrawn after the Committee for Medicinal Products for Human Use (CHMP) had adopted a positive opinion recommending the granting of a marketing authorisation. At the time of withdrawal, the European Commission had not yet granted marketing authorisation for this product.

This application was a duplicate of the application for the medicine Pavblu, for which the CHMP adopted a positive opinion on 30 January 2025.

Summary of opinion[1] (initial authorisation)

Skojoy

aflibercept

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Skojoy, intended for the treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), and visual impairment due to myopic choroidal neovascularisation (myopic CNV).

The applicant for this medicinal product is Amgen Technology (Ireland) UC.

Skojoy will be available as 40 mg/ml solution for injection in pre-filled syringe and vial. The active substance of Skojoy is aflibercept, an antineovascularisation agent (ATC code: S01LA05). Aflibercept is a recombinant fusion protein consisting of the extracellular domains of human VEGF receptor 1 and 2 fused to the Fc portion of human IgG1. By acting as a soluble decoy for the natural VEGF receptors, aflibercept inhibits their activation, thereby reducing angiogenesis.

Skojoy is a biosimilar medicinal product. It is highly similar to the reference product Eylea (aflibercept), which was authorised in the EU on 22 November 2012. Data show that Skojoy has comparable quality, safety and efficacy to Eylea. More information on biosimilar medicines can be found here.

[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

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The full indication is:

> SKOJOY is indicated for adults for the treatment of
>
> - neovascular (wet) age-related macular degeneration (AMD) (see section 5.1),
> - visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) (see section 5.1),
> - visual impairment due to myopic choroidal neovascularisation (myopic CNV) (see section 5.1).

Skojoy must only be administered by a qualified physician experienced in administering intravitreal injections.

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.