25 July 2019
EMA/CHMP/85932/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Trogarzo

ibalizumab

On 25 July 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trogarzo, intended for the treatment of HIV infection. The applicant for this medicinal product is Theratechnologies International Limited.

Trogarzo will be available as 200 mg concentrate for solution for infusion. The active substance of Trogarzo is ibalizumab, a monoclonal antibody (ATC code: J05AX23) that binds to a conformational epitope located primarily on domain 2 of the CD4 receptor, inhibiting HIV entry into target cells.

The benefits with Trogarzo are that it can be used as part of a suppressive antiretroviral regimen for patients who cannot be adequately treated with other approved medicines due to extensive viral resistance. The most common side effects are diarrhoea, vomiting, rash, and dizziness. Some cases of immune reconstitution inflammatory syndrome have been reported.

The full indication is: “Trogarzo, in combination with other antiretroviral(s), is indicated for the treatment of adults infected with multidrug-resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen.”

It is proposed that Trogarzo should be prescribed by physicians experienced in the treatment of HIV disease.

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

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