20 July 2023
EMA/CHMP/268353/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tyruko

natalizumab

On 20 July 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 Tyruko, intended for the treatment of multiple sclerosis. The applicant for this medicinal product is Sandoz GmbH.

Tyruko will be available as 300 mg concentrate for solution for infusion. The active substance of Tyruko is natalizumab, a selective immunosuppressive medicinal product (ATC code: L04AA23). It acts mainly by preventing transmigration of mononuclear leukocytes into inflamed parenchymal tissue, reducing the inflammatory activity present in the central nervous system in patients with multiple sclerosis.

Tyruko is a biosimilar medicinal product. It is highly similar to the reference product Tysabri (natalizumab), which was authorised in the EU on 27 June 2006. Data show that Tyruko has comparable quality, safety and efficacy to Tysabri. More information on biosimilar medicines can be found here.

The full indication is:

> Tyruko is indicated as single disease modifying therapy in adults with highly active relapsing remitting multiple sclerosis (RRMS) for the following patient groups:
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> - Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy (DMT) (for exceptions and information about washout periods see sections 4.4 and 5.1)
>
> or
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> - Patients with rapidly evolving severe RRMS defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain Magnetic Resonance Imaging (MRI) or a significant increase in T2 lesion load as compared to a previous recent MRI.

Tyruko should be prescribed by specialised physicians experienced in the diagnosis and treatment of neurological conditions, in centres with timely access to MRI.

[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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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.