18 May 2017
EMA/CHMP/714138/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kyntheum

brodalumab

On 18 May 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Kyntheum, intended for the treatment of psoriasis. The applicant for this medicinal product is LEO Pharma A/S.

Kyntheum will be available as a 210 mg solution for injection. The active substance of Kyntheum is brodalumab, an interleukin inhibitor (ATC code: L04AC12). Brodalumab is a recombinant fully human monoclonal immunoglobulin IgG2 antibody that binds with high affinity to human IL-17RA and blocks the biological activities of the pro-inflammatory cytokines IL-17A, IL-17F, IL-17A/F heterodimer and IL-25.

The benefits with Kyntheum are its ability to inhibit the inflammation and clinical symptoms associated with psoriasis. The most common side effects are arthralgia, headache, fatigue, diarrhoea, and oropharyngeal pain.

The full indication is: "Kyntheum is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy."

Kyntheum is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

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