20 September 2018
EMA/CHMP/621470/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Emgality

galcanezumab

On 20 September 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Emgality, intended for prophylaxis of migraine. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Emgality will be available as a 120-mg solution for injection. The active substance of Emgality is galcanezumab, an analgesic (ATC code: N02CX07) that works by binding to calcitonin gene-related peptide (CGRP).

The benefits with Emgality are its ability to reduce the number of monthly migraine days. The most common side effects are pain and reactions at the injection site, vertigo and constipation.

The full indication is: "Emgality is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month". It is proposed that Emgality be prescribed by physicians experienced in the treatment of migraine.

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