22 June 2023
EMA/CHMP/257716/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Aquipta

atogepant

On 22 June 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 Aquipta, intended for the prophylaxis of migraine. The applicant for this medicinal product is AbbVie Deutschland GmbH & Co. KG.

Aquipta will be available as 10 mg and 60 mg tablets. The active substance of Aquipta is atogepant, an analgesic (ATC code: N02CD07) which works as a calcitonin gene-related peptide (CGRP) antagonist. The benefit of Aquipta is that it reduces the number of migraine days per month, as observed in two phase 3, randomised, placebo-controlled clinical trials in patients with episodic or chronic migraine The most common side effects are nausea, constipation and fatigue/somnolence.

The full indication is:

> AQUIPTA is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month.

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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