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Media and Public Relations

Press release

First monoclonal antibody therapy for prevention of migraine

Aimovig recommended for marketing authorisation

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended granting a marketing authorisation for Aimovig (erenumab), the first human monoclonal antibody therapy for prevention of migraine. Aimovig belongs to a new class of medicines that work by blocking the activity of calcitonin gene-related peptide (CGRP), a molecule that is involved in migraine attacks.

It is estimated that approximately 15% of the European population suffers from migraine. Patients experience recurrent episodes of intense, throbbing headache, most often only on one side of the head. Sometimes, the pain is preceded by visual or sensory disturbances known as an 'aura'. Many people also experience nausea, vomiting and increased sensitivity to light or sound. Migraine can substantially impair a patient's ability to function physically, at work or school, and socially.

The exact cause of migraine is unknown, but it is believed to be a neurovascular disorder with disease mechanisms both within the brain and the blood vessels of the head. It is most frequent in women and has a strong genetic component.

There is no cure for migraine, but there are a number of treatments available both to tackle the symptoms and reduce the frequency of migraine days. However, existing prophylactic treatments are frequently associated with variable efficacy and poor safety and tolerability. There is therefore an unmet medical need for new treatment options.

The benefits and safety of Aimovig were studied in two pivotal trials involving 667 patients with chronic migraine and 955 with episodic migraine. After three months of treatment, patients with chronic migraine showed a reduction of 2.5 monthly migraine days on average compared to placebo. For patients with episodic migraine the reduction was either 1.3 or 1.8 days, depending on the dose taken. The most common adverse events observed were injection site reactions, constipation, muscle spasms and pruritus.

Aimovig should only be taken by patients who have at least 4 migraine days a month. It is a solution for injection that is administered once a month. Patients can inject themselves after appropriate training.

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The opinion adopted by the CHMP is an intermediary step on Aimovig's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Aimovig is Novartis Europharm Limited.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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