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Media and Public Relations

Press release

New medicine for the prevention of migraine

Monoclonal antibody Emgality 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 Emgality (galcanezumab), a monoclonal antibody for the prevention of migraine. Emgality 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 population in the European Union 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.

Emgality will be available as a solution for injection intended only for patients who have at least 4 migraine days per month. The benefits and safety of Emgality were studied in three pivotal trials involving 1,780 patients with episodic migraine and 1,117 with chronic migraine. After six months of treatment, patients with episodic migraine showed a reduction of 1.9 monthly migraine days on average compared to placebo. For patients with chronic migraine the reduction was 2 days. The most common side effects are pain and reactions at the injection site, vertigo and constipation.

Emgality is the second monoclonal antibody therapy for the prevention of migraine to be recommended for authorisation, following the positive opinion for Aimovig (erenumab) in May 2018. There is no cure for migraine and these two medicines widen the therapeutic options for this disease. There are other available treatments to tackle the symptoms and reduce the frequency of migraine days. However, existing preventative treatments do not always work well and may have unpleasant side effects.

The opinion adopted by the CHMP is an intermediary step on Emgality'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.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Emgality is Eli Lilly Nederland B.V.
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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