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Press release

New medicine for multiple sclerosis

Ocrevus is first medicine to receive positive opinion for treatment of patients with early stage of primary progressive multiple sclerosis

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for Ocrevus (ocrelizumab) for the treatment of adult patients with relapsing multiple sclerosis (RMS) and early primary progressive multiple sclerosis (PPMS).

Multiple sclerosis (MS) is a condition which affects the brain and/or spinal cord, causing a wide range of potential symptoms, including problems with vision, arm or leg movement, sensation or balance. It occurs more frequently in women than men and is among the most common causes of neurological disability in young adults. In the majority of patients (around 85%), MS begins as a relapsing, episodic disorder with gradual complete or incomplete recovery. For the approximately 10% of patients with PPMS the disease is characterised by worsening neurologic function from the onset of symptoms, without early relapses or remissions.

The positive opinion by EMA's Committee for Medicinal Products for Human Use (CHMP) provides an additional treatment option for patients with RMS and is the first medicine in the EU intended to treat some patients with PPMS. There are currently no disease-modifying therapies available for this particular form of MS so there is a great medical need for treatment of such a relentless, seriously debilitating disease.

The recommendation from EMA's CHMP is based on data from three pivotal Phase III clinical trials in 1,423 patients with MS (two in RMS and one in PPMS patients). Treatment with Ocrevus significantly reduced the annualised relapse rate by 46.4% at 96 weeks compared with interferon beta-1a treatment in patients with RMS. For patients with PPMS, treatment with Ocrevus led to a 24% reduction in the risk of 12-week confirmed disability progression compared with placebo. Data from the clinical trial in PPMS indicate that patients in the early stage of disease benefit more from the medicine. More investigation is needed to better understand how beneficial Ocrevus might be in the more advanced stages of the disease.

The most common adverse reactions observed with Ocrevus are infusion-related reactions and infections. The CHMP therefore recommended that Ocrevus treatment should be initiated and supervised by an experienced healthcare professional with access to appropriate medical support to manage severe reactions.

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The opinion adopted by the CHMP at its November 2017 meeting is an intermediary step on Ocrevus' 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 Ocrevus is Roche Registration 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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