16 February 2012
EMA/109002/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Riluzole Zentiva

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On 16 February 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Riluzole Zentiva 50 mg film-coated tablet, intended to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS). The applicant for this medicinal product is Aventis Pharma S.A. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Riluzole Zentiva is riluzole, pharmaco-therapeutic group: other nervous system drugs (N07XX02). Riluzole is proposed to act by inhibiting glutamate processes. The mode of action is unclear.

The benefits with Riluzole Zentiva are its ability to extend survival, defined as patients who were alive, not intubated for mechanical ventilation and tracheotomy-free. In a trial with 155 patients randomised to riluzole or placebo, the median survival time was 17.7 months versus 14.9 months, respectively. The most common side effects are nausea, abnormal liver function tests, asthenia, diarrhoea, abdominal pain, vomiting, headache, dizziness, oral paraesthesia, somnolence and tachycardia.

The approved indication is: "Riluzole Zentiva is indicated to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS).

Clinical trials have demonstrated that Riluzole Zentiva extends survival for patients with ALS (see section 5.1). Survival was defined as patients who were alive, not intubated for mechanical ventilation and tracheotomy-free.

There is no evidence that Riluzole Zentiva exerts a therapeutic effect on motor function, lung function, fasciculations, muscle strength and motor symptoms. Riluzole Zentiva has not been shown to be effective in the late stages of ALS.

Safety and efficacy of Riluzole Zentiva has only been studied in ALS. Therefore, Riluzole Zentiva should not be used in patients with any other form of motor neurone disease."

[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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Treatment with Riluzole Zentiva should only be initiated by specialist physicians with experience in the management of motor neurone diseases.

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.

The CHMP, on the basis of quality, safety and efficacy data submitted for the reference product Rilutek, considers there to be a favourable benefit-to-risk balance for Riluzole Zentiva and therefore recommends the granting of the marketing authorisation.