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Media and Public Relations

Press release

New medicine for rare inflammatory condition of the oesophagus

Jorveza approved under accelerated assessment

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for Jorveza (budesonide), a medicine for the treatment of eosinophilic oesophagitis, a rare inflammatory condition of the oesophagus.

Large numbers of white blood cells called eosinophils are found in the tissue of the oesophagus in patients with eosinophilic esophagitis. This chronic allergic/immune condition affects both children and adults, and men more than women. The symptoms vary with age and include swallowing difficulty or pain, and vomiting. In some patients with the disease the oesophagus can narrow to the point that food gets stuck. This is a medical emergency.

There is currently no authorised medicine available to treat the condition and EMA's Committee for Medicinal Products for Human Use (CHMP) reviewed the application for Jorveza under its accelerated assessment procedure, which is reserved for medicines of major public health interest.

The active substance in Jorveza, budesonide, is a well-known glucocorticosteroid that has been authorised for many years in the treatment of autoimmune disorders such as asthma and inflammatory bowel disease in different presentations. Budesonide as inhalation spray has been used off-label in the treatment of patients with eosinophilic esophagitis and its effects on the inflamed oesophageal mucosa of these patients have been extensively described in the scientific literature.

Jorveza will be available as orodispersible tablets (that dissolve in the mouth). The effects of the tablets were studied in a main phase III clinical trial involving 88 patients. The results confirmed the efficacy of the new formulation, with 90% of the patients treated with Jorveza showing histological remission (clearing of eosinophils from the oesophagus). The most common side effects observed in the studies include local fungal infections (mouth, pharynx and oesophagus), headache, nausea, dyspepsia, gastroesophageal reflux disease, decreased cortisol levels and lip oedema.

As always at time of approval, this orphan designation will now be reviewed by EMA's Committee for Orphan Medicinal Products to determine whether the information available to date allows maintaining Joverza's orphan status and granting this medicine ten years of market exclusivity.

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The opinion adopted by the CHMP at its November 2017 meeting is an intermediary step on Jorveza'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 Jorveza is Dr. Falk Pharma GmbH.
3. Following this positive CHMP opinion, the Committee for Orphan Medicinal Products (COMP) will assess whether the orphan designation should be maintained.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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