22 June 2012
EMA/CHMP/409283/2012
Press Office

Press release

European Medicines Agency recommends first medical treatment for patients with short bowel syndrome

Novel peptide analogue expected to reduce the need for parenteral nutrition

The European Medicines Agency has recommended approval of Revestive (teduglutide) for the treatment of adult patients with short bowel syndrome. This is the first medical treatment recommended for approval in Europe in this rare but seriously debilitating condition.

Short bowel syndrome is a condition in which nutrients are not properly absorbed, due to severe intestinal disease or the surgical removal of a large portion of the small intestine. There are currently no medical treatments available. Most patients with the syndrome rely on full or supplemental parenteral nutrition (receiving food intravenously) to help them get the nutrients they need. However, parenteral nutrition has a significant impact on the quality of life of the concerned patients and is often associated with serious complications, e.g. infection of the catheter used to administer nutrition, bacterial overgrowth in the small intestine, liver toxicity or biliary disease.

Revestive was designated as an orphan medicine in 2001. The Agency gave free scientific advice to the applicant during the development of the medicine. Orphan designation and the associated incentives such as free scientific advice or 'protocol assistance' are among the Agency's most important instruments to encourage the development of medicines for patients suffering from rare diseases.

In clinical trials, Revestive has demonstrated that it can additionally reduce parenteral nutrition requirements in patients with short bowel syndrome.

The review by the Agency's Committee for Medicinal Products for Human Use (CHMP) showed that most adverse events under treatment with Revestive were mild or moderate in severity, mainly affecting the gastrointestinal system. However, about one third of the adverse events were considered to be severe, most of them related to hepatobiliary and pancreatic events.

The Committee considered that the safety profile was manageable and, given the benefits of Revestive in the treatment of a patient population in need of alternative therapeutic options, the Committee recommended granting a marketing authorisation.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

The Agency's recommendation is being sent to the European Commission for the adoption of a decision.

Notes

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

Contact our press officers

Monika Benstetter or Martin Harvey Allchurch

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu