21 June 2012
EMA/CHMP/390445/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Revestive

teduglutide

On 21 June 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 Revestive, 5 mg, powder and solution for solution for injection intended for the treatment of adult patients with Short Bowel Syndrome. Revestive was designated as an orphan medicinal product on 11 December 2001. The applicant for this medicinal product is Nycomed Danmark ApS. 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 Revestive is teduglutide, an alimentary tract and metabolism product (ATC code A16AX08) which, in several nonclinical studies, has been shown to preserve mucosal integrity by promoting repair and normal growth of the intestine through an increase of villus height and crypt depth.

The benefits with Revestive are its ability to reduce parenteral nutrition requirements in patients with Short Bowel Syndrome. In the pivotal study the proportion of teduglutide treated subjects achieving a 20% to 100% reduction of parenteral nutrition at Week 20 and 24 was statistically significantly different from placebo. Treatment with teduglutide resulted in a 4.4 l/week reduction in parenteral nutrition requirements (from a pre-treatment baseline of 12.9 litres) *versus* 2.3 l/week (from a pre-treatment baseline of 13.2 litres) for placebo at 24 weeks.

The most common side effects are abdominal pain and distension (49%), respiratory tract infections (28%), nausea (27%), injection site reactions (21%), headache (17%), vomiting (14%) and oedema peripheral (10%). Approximately 38% of the treated patients with a stoma experienced gastrointestinal stoma complications. The majority of these reactions are mild or moderate.

A pharmacovigilance plan for Revestive will be implemented as part of the marketing authorisation.

The approved indication is: "Revestive is indicated for the treatment of adult patients with Short Bowel Syndrome. Patients should be stable following a period of intestinal adaptation after surgery."

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Treatment should be initiated under the supervision of a medical professional with experience in the treatment of Short Bowel Syndrome (SBS).

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, considers there to be a favourable benefit-to-risk balance for Revestive and therefore recommends the granting of the marketing authorisation.