20 September 2012
EMA/CHMP/604998/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Constella

linaclotide

On 20 September 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 Constella, 290 micrograms, hard capsules intended for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults.

The applicant for this medicinal product is Almirall, 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 Constella is linaclotide. The ATC code is not yet assigned.

Linaclotide is a Guanylate Cyclase-C receptor agonist (GCCA) with visceral analgesic and secretory activities. The benefits with Constella are its ability to reduce visceral pain and relieve constipation. The most common side effect is diarrhoea. A pharmacovigilance plan for Constella will be implemented as part of the marketing authorisation.

The approved indication is: "Constella is indicated for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults". It is proposed that Constella be prescribed by physicians.

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 Constella and therefore recommends the granting of the marketing authorisation.

[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 8545
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union