EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 September 2012
EMA/CHMP/611096/2012
Press Office

Press release

European Medicines Agency recommends authorisation of first medicine specifically for irritable bowel syndrome

Constella shown to improve symptoms in patients with constipation

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the authorisation of the first medicine specifically for the symptomatic treatment of irritable bowel syndrome (IBS) in the European Union (EU).

The Agency is recommending that Constella (linaclotide) be authorised for adults with moderate to severe IBS with constipation (IBS-C), a common subtype of the disease. Linaclotide is a new, synthetic 14-amino-acid peptide, which works by increasing the secretion of fluid in the intestine and accelerating the movement of material through the gut. It is taken by mouth once a day at least 30 minutes before a meal.

IBS is a long-term disorder of the gut characterised by intestinal pain or discomfort together with altered bowel habit, abdominal distension, bloating, constipation or diarrhoea, often resulting in reduced quality of life and work productivity.

Despite affecting up to 20% of the Western population, no medicines have been authorised in the EU specifically for the treatment of IBS. Treatments are currently limited to lifestyle modifications such as reducing stress or altering diet, psychological interventions and general symptomatic treatments such as laxatives, antidiarrhoeals and antispasmodics, or unapproved medicines.

The Committee based its recommendation on the results of two main clinical studies showing superiority of linaclotide over placebo in terms of improving symptoms after 12 weeks. These effects were sustained for at least six months. However, it noted that around half of the patients in the main studies did not respond to linaclotide sufficiently, leading to the recommendation that prescribers should assess patients regularly and reconsider treatment if there is no improvement in symptoms after four weeks.

The most common side effect in clinical trials was diarrhoea, which was reported in a fifth of the patients taking the medicine. The Agency is recommending that patients with severe or prolonged diarrhoea should be monitored closely when taking linaclotide and that it should be used with caution in patients prone to water or electrolyte-balance disturbances.

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Since diarrhoea appeared to be more common in the elderly and only 5% of the study subjects were over 65 years of age, the Agency has also requested that the marketing-authorisation holder carry out a post-authorisation safety study that specifically includes elderly patients.

The CHMP's opinion on Constella will now be sent to the European Commission for the adoption of a marketing authorisation.

Notes

1. This press release, together with all related documents and more information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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