20 March 2014
EMA/CHMP/134524/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Entyvio

vedolizumab

On 20 March 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Entyvio, 300 mg powder for concentrate for solution for infusion intended for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist and adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.

The applicant for this medicinal product is Takeda Pharma A/S. 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 Entyvio is vedolizumab, a selective immunosuppressant (L04AA33). Vedolizumab is a humanised immunoglobulin G1 (IgG1) monoclonal antibody directed against the human lymphocyte integrin α4β7. The α4β7 integrin is expressed on the surface of a discrete subset of memory T lymphocytes that preferentially migrate into the gastrointestinal tract and cause the inflammation that is characteristic of ulcerative colitis and Crohn's disease. By binding to the α4β7 integrin, vedolizumab selectively inhibits adhesion of these cells to mucosal addressin cell adhesion molecule-1 (MAdCAM-1), thereby preventing their transmigration into inflamed parenchymal tissue.

The benefits of Entyvio in ulcerative colitis are its ability to induce clinical response, remission and mucosal healing in patients with no prior TNFα antagonist exposure as well as in those who have failed prior TNFα antagonist therapy.

The benefits of Entyvio in Crohn's disease are its ability to induce clinical remission, enhanced clinical response and corticosteroid-free clinical remission (at Week 52) in patients with no prior TNFα antagonist exposure as well as in those who had failed prior TNFα antagonist therapy.

[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.

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The most common side effects are nausea, nasopharyngitis, upper respiratory tract infection, arthralgia, pyrexia, fatigue, headache, cough and Infusion-related reactions.

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

The approved indications are:

- treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.
- the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.

It is proposed that Entyvio be prescribed by specialist healthcare professionals experienced in the diagnosis and treatment of ulcerative colitis or Crohn's disease.

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 Entyvio and therefore recommends the granting of the marketing authorisation.