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Press Office

Press release

EMA recommends approval of a locally targeted treatment for ulcerative colitis and Crohn's disease

Entyvio (vedolizumab) offers a treatment option for patients who do not respond to standard therapies

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended granting a marketing authorisation for Entyvio (vedolizumab) for the treatment of adult patients with moderately to severely active ulcerative colitis or Crohn's disease, who have had an inadequate response to, or were intolerant to either conventional therapy or a tumour necrosis factor alpha (TNFα) antagonist therapy.

Ulcerative colitis and Crohn's disease are the two most common types of inflammatory bowel disease. They are chronic auto-immune diseases that cause considerable ill health and mortality in patients, and affect more than two million people across the European Union. Moreover, both ulcerative colitis and Crohn's disease patients have an increased risk of developing colon cancer.

Current therapies for ulcerative colitis and Crohn's disease have a broad mechanism of action, potentially leading to serious side effects including systemic immunosuppression, serious infection and certain types of cancer. Furthermore, some ulcerative colitis and Crohn's disease patients have an inadequate response to, or do not tolerate standard therapies. These patients have no other medical therapeutic option available and often require surgical treatment.

Entyvio is a monoclonal antibody whose mechanism of action is based upon its specific binding of the $\alpha 4 \beta 7$ integrin, a key mediator of gastrointestinal inflammation. It was developed to address the unmet medical need recognised in moderately to severely active ulcerative colitis and Crohn's disease patients. This novel mechanism of action allows for a more selective, intestinal-targeted anti-inflammatory activity and it may offer a significant additional treatment option for the management of ulcerative colitis and Crohn's disease patients who have failed standard available therapies.

The CHMP opinion on Entyvio will now be sent to the European Commission for adoption of a decision on an EU-wide marketing-authorisation.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Entyvio is Takeda Pharma A/S.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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