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FDA recommends Takeda's drug for Chrohn's disease

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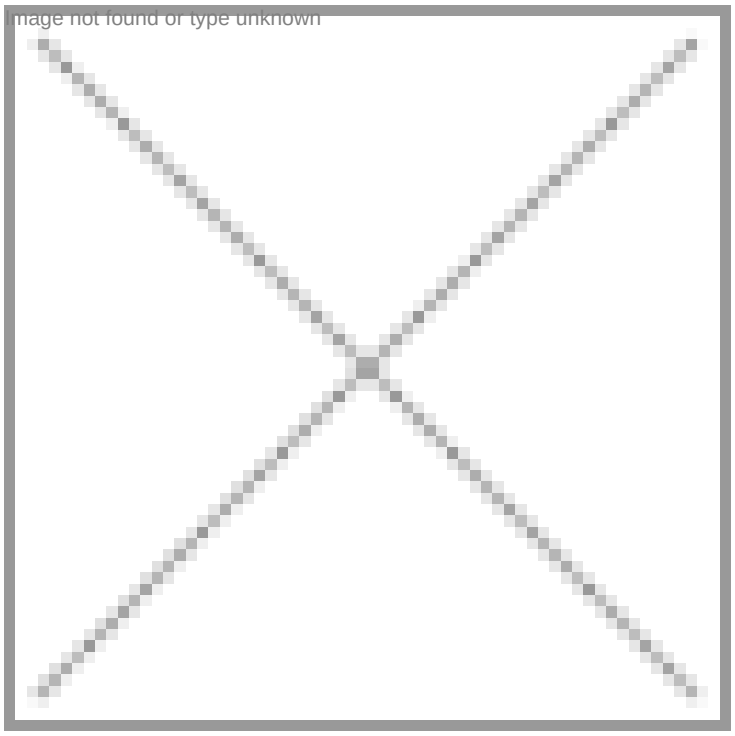

Singapore: A joint panel of members from the Gastrointestinal Drugs and Drug Safety and Risk Management Advisory Committees of the United States (U.S.) Food and Drug Administration (FDA) has voted to recommend approval of Takeda's vedolizumab for the treatment of adults with moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD).

All 21 committee members voted that based on currently available efficacy and safety data, the benefits outweigh the potential risks of vedolizumab to support approval for UC. Specifically, 13 committee members supported approval for UC patients who have failed steroids or immunosuppressants or TNF-alpha antagonists, while eight committee members supported approval for UC patients who have failed immunosuppressants or TNF-alpha antagonists (the indicated population would not include patients that failed steroids only).

"We are very pleased with the advisory committee's recommendation. People with ulcerative colitis or Crohn's disease are in need of additional treatment options, as many patients lose response to currently available treatments," said Mr. Asit Parikh, vice president, general medicine, Takeda. "Vedolizumab was designed to treat inflammation in the GI tract, and if approved, may offer an additional option for patients suffering from ulcerative colitis or Crohn's disease."

Without asking for a vote, the FDA also requested feedback from panel members about what post-market risk mitigation strategies beyond labeling, if any, would be needed to ensure that the benefits of vedolizumab outweigh its risks. Takeda will continue to work closely with the FDA on an appropriate Risk Evaluation Mitigation Strategy (REMS) for vedolizumab.

The outcome of the advisory committee meeting, which included five voting questions, is non-binding and will be taken into consideration by the FDA when making its decision on Takeda's Biologics License Application (BLA) for vedolizumab, which

was submitted in June 2013. The FDA granted vedolizumab Priority Review status for the proposed indication in UC in September 2013 and standard review for the indication of CD. Priority Review status is given to applications for investigational drugs that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness.