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US FDA's Priority Review Status for Takeda's IND

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Singapore: Takeda Pharmaceutical and its wholly-owned subsidiary, Takeda Pharmaceuticals USA, have announced that the US Food and Drug Administration (FDA) has granted Priority Review status for the Biologics License Application (BLA) for its investigational new drug vedolizumab for the treatment of adults with moderately to severely active ulcerative colitis.

A BLA was submitted in June 2013 seeking approval for vedolizumab for the treatment of adults with moderately to severely active Crohn's disease (CD) or ulcerative colitis (UC).

The application submitted for vedolizumab for the treatment of adults with moderately to severely active CD will be reviewed by the FDA under the standard review timeline.

An application can receive Priority Review designation if it is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. Priority Review status allows for an eight month review period from the date of submission, compared to the standard review period of 12 months.

"Additional treatment options are needed for ulcerative colitis, and the acceptance for Priority Review of vedolizumab underscores this need," said Karen Lasch, medical director - GI, Medical Affairs, US Region, Takeda.

CD and UC are the two most common types of inflammatory bowel disease (IBD), and can be both painful and debilitating, sometimes leading to serious complications. While CD and UC treatment options are available, many patients may not achieve or maintain remission of their disease.

The BLA filings were supported by the GEMINI Studies, a four-study clinical program investigating vedolizumab in 2,700 patients in nearly 40 countries, making it the largest phase III clinical trial program conducted to date simultaneously evaluating both CD and UC. Enrolled patients had failed at least one conventional therapy, including glucocorticoids, immunomodulators and/or a tumor necrosis factor-alpha (TNF-alpha) antagonists. TNF-alpha antagonist and conventional therapy failure patients included those with inadequate response (primary non-responders), loss of response (secondary non-responders) or those who were intolerant.

Phase III study results for vedolizumab were published recently in the *New England Journal of Medicine.*