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Takeda Gemini II trial shows positive results

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Singapore:Ã?Â Positive results were reported from Takeda Pharmaceutical'sÃ?Â international, randomized, placebo-controlled, double-blind GEMINI II pivotal phase III trial. The trial evaluated vedolizumab in 1,115 patients with moderately to severely active Crohn's disease who have failed at least one conventional therapy, including TNFÃ?Å½Ã?Â± antagonists.

Many of the patients included in the study have failed two or more TNFÃ?Å½Ã?Â± antagonists. Patients received a year of vedolizumab (MLN0002) or placebo treatment, starting with six weeks of induction therapy. In both phases of the trial, induction and maintenance, vedolizumab demonstrated statistically significant improvement in the primary endpoint of clinical remission compared to placebo. Additionally, vedolizumab provided a numerically higher rate of enhanced response, the other primary end point in the induction phase, although not statistically significant.

The most common adverse events (>10 percent) reported in both the vedolizumab arm and the placebo arm were Crohn's disease, arthralgia(joint pain), pyrexia(fever), nasopharyngitis(upper respiratory inflammation), headache, nausea, and abdominal pain.

"People living with moderately to severely active Crohn's disease currently have few treatment options to help them manage their disease," said Dr Asit Parikh, vice president, general medicine (gastrointestinal and genitourinary), Takeda. "We are very excited about the results of this pivotal study and the potential it may hold for patients."