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ASIA EDITION

Takeda seeks bowel drug marketing nod from EU

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Singapore: Takeda Pharmaceutical submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for vedolizumab, an investigational, gut-selective humanized monoclonal antibody for the treatment of adults with moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD). If approved, vedolizumab would be the first and only gut-selective biologic agent for UC and CD, which are the two most common types of inflammatory bowel disease (IBD).

The MAA submission was supported by phase III clinical studies, Gemini I, Gemini II, Gemini III and Gemini LTS (long-term safety), which are part of the Gemini studies, a four-study clinical research program to investigate the efficacy and safety of vedolizumab on clinical response and remission in moderately to severely active CD and UC patients, who had failed at least one conventional or anti-TNFÃ?Å½Ã?Â± therapy.

Dr Asit Parikh, vice president, general medicine, Takeda, said that, "Ulcerative colitis and Crohn's disease are chronic debilitating diseases with important unmet medical needs, often affecting young people in the prime of their lives. We are encouraged by the findings of Gemini, the vedolizumab phase III clinical development program, which studied approximately 3,000 patients in nearly 40 countries, making it the largest IBD clinical trial program conducted to date."

Dr Paul Rutgeerts, professor of medicine, Catholic University of Leuven, Belgium, said that, "With a targeted mechanism of action, vedolizumab has clinical promise as a potential treatment option for people with moderate to severely active CD and UC. While there is no known cure, there is a need for new CD and UC treatment options, in an effort to provide patients with additional choices for managing their disease, reducing symptoms and achieving remission."

Nearly four million people worldwide are affected by IBD, with UC affecting more than 500,000 people and CD affecting approximately 230,000 people in the EU.Crohn's disease and ulcerative colitis are chronic diseases that cause inflammation of the lining of the digestive tract. Inflammation caused by CD can involve varying areas of the digestive tract, while UC impacts the colon only.CD and UC can be both painful and debilitating, which may sometimes lead to serious complications and can significantly impact the quality of life for patients.