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NDA approval for obesity drug Oblean in Japan

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Singapore: Netherlands-based Norgine BV and Japanese drugmaker Takeda Pharmaceutical have announced the approval of the New Drug Application (NDA) for Oblean (cetilistat) Tablets 120mg for the treatment of obesity with complications.

Oblean is a lipase inhibitor discovered by UK-based Alizyme Therapeutics. Norgine acquired all rights to the product from Alizyme in October 2009. In 2003, Takeda acquired the rights for development and commercialization for Japan.

Oblean inhibits the activity of lipase, a lipolytic enzyme, secreted by the digestive tract and pancreas, and blocks the absorption of fat from the gut, resulting in not only reduced body weight, but also reduced visceral fat and improved parameters related to lifestyle diseases. Oblean is the first therapy that controls lipid absorption approved in Japan for the treatment of obesity with complications.

The NDA submission is based on the results of three phase III clinical trials in obese patients with type 2 diabetes and dyslipidemia: a 52-week placebo-controlled, double-blind study to evaluate the efficacy and safety, and two open-label studies to evaluate safety, 24-week and 52-week respectively.

Mr Paul Pay, VP corporate and business development at Norgine, said, "Being overweight or obese is a major risk factor in the development of many chronic diseases and we are pleased that Takeda has obtained manufacturing and marketing approval by the regulatory authorities in Japan."

"Obesity is an increasingly important issue in Japan with limited treatment options," said Ms Nancy Joseph-Ridge, general manager, Takeda's Pharmaceutical Development Division. "The approval of Oblean, with its novel mechanism of action, provides options for this unmet medical need to patients with obesity, with complications of both type 2 diabetes and dyslipidemia in Japan," she added.