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Takeda submits plea for cetilistat approval in Japan

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Takeda submits new drug application for lipase inhibitor cetilistat in Japan

Singapore: Takeda Pharmaceutical has submitted a new drug application (NDA) to the Ministry of Health, Labor and Welfare for cetilistat (ATL-962) for the treatment of obesity with complications, in Japan.

Cetilistat is a lipase inhibitor discovered by UK-based Alizyme Therapeutics. The product 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 reduced body weight. Amsterdam-based Norgine acquired all rights to the product from Alizyme in October 2009.

The NDA submission is based on the results of three phase III clinical trials, a 52-week placebo-controlled to evaluate the efficacy and safety study, a 24-week and 52-week open-label safety study in obese patients with type 2 diabetes and dyslipidemia. Mr Peter Stein, CEO of Norgine, said, "We are excited that this important new medicine may soon be available in Japan for patients who suffer from obesity, and its complications such as type 2 diabetes mellitus and dyslipidaemia. Norgine is looking forward to building on our excellent working relationship with our partners, Takeda."

"Obesity is a disease with limited treatment options and thus has remarkable unmet medical need," said Dr Nancy Joseph-Ridge, general manager of Takeda's Pharmaceutical Development Division. "If approved, cetilistat, with its novel mechanism of action, is expected to provide a welcomed new treatment option for physicians treating patients with obesity, with complications of both type 2 diabetes and dyslipidaemia in Japan."