Norgine, Takeda Receive NDA Approval For OBLEAN Tablets 120mg In Japan

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AsianScientist (Sep. 23, 2013) - Norgine BV and Takeda Pharmaceutical Company Limited announced on Friday that the Japanese Ministry of Health, Labor and Welfare has approved the New Drug Application (NDA) of OBLEAN® Tablets 120mg (generic name: cetilistat, "OBLEAN") for the treatment of obesity with complications.

OBLEAN is a lipase inhibitor discovered by UK-based Alizyme Therapeutics Limited. 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 II 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.

According to the 52-week placebo-controlled, double-blind study, OBLEAN 120mg three times daily is superior to placebo in the primary endpoint, with a mean reduction in body weight from baseline of -2.776% with OBLEAN versus -1.103% with placebo (p=0.0020). Greater reductions in HbA1c and low-density lipoprotein cholesterol were also observed in patients treated with OBLEAN compared to placebo. In all these three studies, OBLEAN showed a good safety profile and was well tolerated. In filing for this approval, Takeda utilized the Preliminary Assessment of the Pharmaceuticals and Medical Devices Agency (PMDA).

> "Obesity is an increasingly important issue in Japan with limited treatment options," said Nancy Joseph-Ridge M.D., General Manager of 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 II diabetes and dyslipidemia in Japan."

Source: Takeda.