



CORPORATE PRESS RELEASE

NORGINE AND TAKEDA ANNOUNCE THE NEW DRUG APPLICATION APPROVAL OF OBLEAN[®] (cetilistat) TABLETS 120MG IN JAPAN FOR THE TREATMENT OF OBESITY WITH COMPLICATIONS

London, 20 September, 2013. Norgine and Takeda Pharmaceutical Company Limited announced today that the Japanese Ministry of Health, Labour and Welfare has approved the New Drug Application (NDA) of OBLEAN[®] Tablets 120mg 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 commercialisation 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 3 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. The results of the 52-week placebo-controlled, double-blind study demonstrate that 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 ($p=0.0020$).¹ Greater reductions in HbA1c and low-density lipoprotein cholesterol were also observed in patients treated with OBLEAN[®]¹, compared to placebo. In all these three studies, OBLEAN[®] showed a good safety profile and was well tolerated.^{1, 2, 3}

In filing for this approval, Takeda utilised the Preliminary Assessment of the Pharmaceuticals and Medical Devices Agency (PMDA).*

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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 **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 2 diabetes and dyslipidaemia in Japan.”

* A type of PMDA consultation that is conducted at the development stage before NDA submission based on the available quality, non-clinical and clinical data and that is primarily intended to identify the issues anticipated during the NDA review as much as possible.

Notes to Editors

Type 2 Diabetes

Type 2 diabetes develops when the body can’t produce enough insulin, or when the insulin that is produced doesn’t work properly. If untreated, it can cause very serious health problems.

HbA1c

HbA1c is a term often used in relation to diabetes. HbA1c occurs when haemoglobin joins with glucose in the blood. Haemoglobin molecules make up the red blood cells in the blood stream. When glucose sticks to these molecules it forms a glycosylated haemoglobin molecule, also known as A1c and HbA1c. The more glucose found in the blood the more glycated haemoglobin (HbA1c) will be present.

Low-density lipoprotein (LDL) cholesterol

LDL collects in the walls of blood vessels, causing the blockages of atherosclerosis. Higher LDL levels put people at greater risk for a heart attack from a sudden blood clot in an artery narrowed by atherosclerosis.

References

1. A Phase 3, Multicentre, Randomized, Stratified, Placebo-controlled, Double-blind, Parallel-group Study to Investigate the Efficacy and Safety of ATL-962 in Obese Patients with Type 2 Diabetes

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and Dyslipidemia. Protocol No. ATL-962/CCT-002. Takeda Pharmaceutical Company Limited, Osaka, Japan

2. A Phase 3, Open-Label Study to Investigate the Efficacy and Safety of ATL-962 in Obese Patients with Type 2 Diabetes and Dyslipidemia. Protocol No. ATL-962/OCT-001. Takeda Pharmaceutical Company Limited, Osaka, Japan
3. A Phase 3, Open-Label, Multicenter Study to Evaluate the Safety and Efficacy of Long-term Treatment with ATL-962 in Obese Patients with Type 2 Diabetes Mellitus and Dyslipidemia. Protocol No. ATL-962/OCT-002. Takeda Pharmaceutical Company Limited, Osaka, Japan

Japanese Brand Name	OBLEAN® Tablets 120mg
Generic Name	cetilistat
Dosage and Administration	Usually, for adults, a dose of 120 mg is orally administered, three times a day, immediately after each meal.
Indication	Obesity (limited to patients with both type 2 diabetes mellitus and dyslipidemia, and with a BMI \geq 25 kg/m ² in spite of dietary treatment and/or exercise therapy)

About Norgine

Norgine is a successful, independent European specialty pharmaceutical company that has been established for over 100 years and has a presence in all major European markets. In 2012, Norgine's net product sales were c€250 million and the company employs over 1,000 people.

Norgine's focus is the development and marketing of pharmaceutical products that address significant unmet clinical needs in therapeutic areas such as gastroenterology, hepatology, critical and supportive care.

Norgine owns a manufacturing and development site in Hengoed, UK and a manufacturing site in Dreux, France. For more information: www.norgine.com.

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About Takeda Pharmaceuticals Company Limited

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, <http://www.takeda.com>.

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