



News Release

Takeda Submits a New Drug Application for Cetilistat (Development Code: ATL-962) in Japan for the Treatment of Obesity with Complications

The Netherlands, Amsterdam and Osaka, Japan, October 30, 2012— Norgine BV (“Norgine”) (Headquarters: Amsterdam, the Netherlands) and Takeda Pharmaceutical Company Limited (“Takeda”) (Headquarters: Osaka, Japan) announced today that Takeda has submitted a New Drug Application (NDA) to the Ministry of Health, Labour and Welfare for cetilistat (generic name, development code: ATL-962) for the treatment of obesity with complications, in Japan.

Cetilistat is a lipase inhibitor discovered by UK-based Alizyme Therapeutics Limited (“Alizyme”). 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. Norgine acquired all rights to the product from Alizyme in October 2009.

The NDA submission is based on the results of three phase 3 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. The result of the efficacy study demonstrate that cetilistat 120mg three times daily was superior to placebo in the primary endpoint , reduction of average body weight, with -2.776% versus -1.103% with placebo.¹ Greater reductions in HbA1c and LDL cholesterol were also observed in patients treated with cetilistat¹. All clinical trials demonstrated that cetilistat has a good safety profile and is well tolerated^{1,2,3}.

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 Nancy Joseph-Ridge M.D., 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.”

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 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

About Norgine

Norgine is an independent, successful European specialty pharmaceutical company that has been established for over 100 years and has a presence in all major European markets. In 2011, Norgine's net product sales were €246 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 and supportive care.

The Company currently markets a range of products in various markets in its key therapeutic areas e.g. MOVICOL[®] for the treatment of constipation and faecal impaction, MOVIPREP[®] a bowel cleansing preparation, KLEAN-PREP[®] for large bowel preparation prior to colonoscopy or surgery, XIFAXAN^{™*} for the treatment of traveller's diarrhoea and ORAMORPH[®] for the treatment of moderate to severe pain associated with cancer.

Norgine is active in research and development and currently has products in various stages of clinical development. Norgine manufactures most of its own products in Hengoed, UK and 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 patients worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, <http://www.takeda.com>.

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