

press release

Novo Nordisk expands its biopharm business with the acquisition of the US and Canadian rights to Macrilen™

Bagsværd, Denmark, 31 October 2018 – Novo Nordisk today announced the expansion of its biopharm business with an agreement to acquire the US and Canadian rights to Macrilen™ (macimorelin), an enhancer of growth hormone secretion and the first and only FDA-approved oral product indicated for the diagnosis of Adult Growth Hormone Deficiency (AGHD), a rare endocrine disorder, from Strongbridge Biopharma Plc.

Diagnosis of growth hormone deficiency is time consuming and a considerable burden for both patients and health care providers. By enabling a fast and deeper roll out of Macrilen™, Novo Nordisk can address a significant unmet medical need. Macrilen™ was approved by the US Food and Drug Administration (FDA) in December 2017 and FDA has granted Macrilen™ orphan drug exclusivity in the US. Macrilen™ was launched in the US in July 2018. With the acquisition of Macrilen™, Novo Nordisk can further leverage its long-standing scientific and commercial expertise and commitment to the growth disorders community. As a partner to the endocrinology community Novo Nordisk is committed to raising awareness of growth disorders and advancing patient care.

Novo Nordisk will pay USD 145 million to Strongbridge as well as tiered royalties related to sales of Macrilen™. In addition, Strongbridge's current field organisation will continue to promote Macrilen™ in the US for up to three-year agreement. Novo Nordisk's existing biopharm field force will also support the commercialisation of Macrilen™. As part of the partnership with Strongbridge, Novo Nordisk will acquire newly issued Strongbridge shares representing approximately 10% of the outstanding shares of Strongbridge at a share price of USD 7 per share, corresponding to an investment of approximately USD 37 million.

"The acquisition of Macrilen™ is in line with the strategy for our biopharm business with growth being driven by both organic and bolt-on initiatives. Macrilen™ is highly complementary to Norditropin® and will allow Novo Nordisk to assist physicians and patients in the diagnosis as well as treatment of patients with growth hormone deficiency," said Jesper Brandgaard, executive vice president and head of Biopharm.

The transaction is expected to close in December 2018 and is subject to US regulatory approval.

About Macrilen™

Macrilen™ (macimorelin) is a prescription oral test that has been granted orphan drug designation in the US, as the first and only FDA-approved oral growth hormone secretagogue receptor agonist indicated for the diagnosis of Adult Growth Hormone Deficiency (AGHD), a rare endocrine disorder. In an open-label, randomised, cross-over trial with 154 people, Macrilen™ was shown to diagnose AGHD accurately when comparing the diagnostic agreement between Macrilen™ and the benchmark, Insulin Tolerance Test (ITT)¹.

About Strongbridge Biopharma

Strongbridge Biopharma is a global commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs. Founded in 1996, Strongbridge is today based in Trevose, PA, USA and publicly listed on the US NASDAQ Global Market. Strongbridge's rare endocrine franchise includes Recorlev™ (levoketoconazole), a cortisol synthesis inhibitor currently being studied in Phase 3 clinical studies for the treatment of endogenous Cushing's syndrome, and veldoreotide extended release, a pre-clinical next-generation somatostatin analog being investigated for the treatment of acromegaly and potential additional applications in other conditions amenable to somatostatin receptor activation. Strongbridge's rare neuromuscular franchise includes Keveyis® (dichlorphenamide), the first and only FDA-approved treatment for hyperkalemic, hypokalemic, and related variants of primary periodic paralysis. Keveyis® has orphan drug exclusivity in the US.

Forward-looking statements

This press release contains forward-looking statements. Words such as 'believe', 'expect', 'may', 'would', 'will', 'plan', 'strategy', 'prospect', 'foresee', 'estimate', 'project', 'anticipate', 'can', 'intend', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance or plans or proposals including regarding Macrilen™ identify forward-looking statements.

Forward-looking statements are based on current plans, estimates and projections. By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific. Novo Nordisk cautions that a number of important factors could cause actual results or events to differ materially from those contemplated in any forward-looking statements. Unless required by law, Novo Nordisk is under no duty and undertakes no obligation to update or revise any forward-looking statement after the distribution of this press release, whether as a result of new information, future events or otherwise.

¹ Macrilen US FDA prescribing information. Strongbridge Biopharma Inc, Trevose, PA; 2018.

About Novo Nordisk

Novo Nordisk is a global healthcare company with 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 43,100 people in 79 countries and markets its products in more than 170 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

Further information

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