

Grünenthal licenses exclusive Canadian rights to testosterone replacement therapy Nebido® to Apotex

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Aachen, Germany & Toronto, Canada - Grünenthal, a global leader in pain management and related diseases, and

Apotex Inc. ("Apotex"), the largest Canadian-based pharmaceutical company, today announced they have entered into a licensing agreement whereby Apotex will have the exclusive Canadian rights to Nebido® (testosterone undecanoate), a long-acting injectable therapy indicated for the treatment of male hypogonadism (testosterone deficiency).[1]

Under the agreement, Searchlight Pharma, Apotex's branded medicine division, will pursue marketing authorisation and will market and distribute the product in Canada upon regulatory approval. Grünenthal will receive an upfront payment, regulatory milestone payments, and a margin on the sales.

This agreement deepens the existing partnership between Grünenthal and Apotex and strengthens their shared commitment to expanding Canadian patients' access to important therapies.

"We are delighted to expand our partnership with Apotex and further strengthen the global presence of the brand," says Jan Adams, Chief Commercial Officer (CCO) at Grünenthal. "Through this agreement, we are providing a valuable and well-established brand that can benefit countless people living with testosterone deficiency in Canada."

"This marks an important step in Apotex's mission to broaden access to innovative medicines and advance our purpose as a Force for Health," says Mark Nawacki, President, Searchlight Pharma. "Nebido® addresses a recognised need in men's health and represents our first entry into testosterone therapy – opening a meaningful new therapeutic area for Apotex while strengthening our branded portfolio and expanding our presence in specialty care."

Grünenthal acquired the global rights for the brand in 2022 as part of its growth strategy. Since 2017, the company has invested over €2 billion in successful mergers and acquisitions (M&A) transactions, diversifying its portfolio, enhancing its profitability, and driving business growth. Grünenthal continues to expand the footprint of these brands and to create synergies throughout Grünenthal's infrastructure, including manufacturing, supply, logistics, and commercial activities.

About hypogonadism (testosterone deficiency)

Male hypogonadism due to a reduced or absent secretion of testosterone from the testes is characterised by clinical symptoms such as low libido, erectile dysfunction, asthenia, small testes and decreased muscle mass. These symptoms are sometimes misinterpreted as signs of stress and ageing. In addition to physical symptoms, there can also be psychological symptoms, including depression. One in six men over 50 live with symptomatic androgen deficiency[2]. Only one in ten men between the age of 30 to 79 with symptomatic androgen deficiency receives treatment[3].

About Nebido®

Nebido® is an injectable long-acting depot preparation of testosterone undecanoate. Nebido® is indicated for testosterone replacement therapy in adult men with confirmed hypogonadism, a condition caused by insufficient testosterone levels. The product is directly administered by a physician every 10 – 14 weeks.

About Apotex

Apotex is a Canadian-based global health company. We improve everyday access to affordable, innovative medicines and health products for millions of people around the world, with a broad portfolio of generic, biosimilar, and innovative branded pharmaceuticals, and consumer health products. Headquartered in Toronto, with regional offices globally, including in the United States, Mexico, and India, we are the largest Canadian-based pharmaceutical company and a health partner of choice for the Americas for pharmaceutical licensing and product acquisitions. Learn more about us at www.apotex.com.

About Grünenthal

Grünenthal is a global leader in pain management and related diseases. As a science-based, fully integrated pharmaceutical company, we have a long track record of bringing innovative treatments and state-of-the-art technologies to patients worldwide. Our purpose is to change lives for the better – and innovation is our passion. We focus all our activities and efforts on working towards our vision of a World Free of Pain.

Grünenthal is headquartered in Aachen, Germany, and has affiliates in 28 countries across Europe, Latin America, and the U.S. Our products are available in approx. 100 countries. In 2024, Grünenthal employed around 4,300 people and achieved revenues of €1.8 billion.

Learn more about us at: www.grunenthal.com

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[1] <https://www.medicines.org.uk/emc/product/14631/smpc>

[2] Araujo, A. B., Esche, G. R., Kupelian, V., O'Donnell, A. B., Travison, T. G., Williams, R. E., ... & McKinlay, J. B. (2007). Prevalence of symptomatic androgen deficiency in men. The Journal of Clinical Endocrinology & Metabolism, 92(11), 4241-4247.

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