Xbrane Accelerates Development of Xdivane – A Nivolumab (Opdivo®) Biosimilar

Xbrane Biopharma AB (Nasdaq Stockholm First North: XBRANE) announces today that the Company has successfully established a mammalian cell based technological platform and accelerate the development of Xdivane, a biosimilar of the PD-1 inhibitor Nivolumab (Opdivo®) as the first product of this platform. Xbrane remains committed to expand its innovative technology platforms to further address the unmet needs in the market and help provide patients with better treatment options.

"With this announcement we continue to broaden our technology platforms to improve the quality and production of our mammalian cell based products, further confirming our goal of becoming a leading innovative biosimilar development company," stated Martin Årmark, CEO of Xbrane.

Establishing a Mammalian Cell Based Biosimilar Development Platform

Xbrane continues to focus on innovation in development and production efficiency. For its *E. coli* based biosimilars, this is ensured by Xbrane's patented production technology, which provides up to a 12 times yield advantage compared to the current standard systems in the market. Xbrane has now secured the required competence and technology for mammalian cell based biosimilars, with the ambition of providing a similar yield advantage. Xbrane has recruited key experts with deep experience in the development of mammalian cell based biosimilars primarily within cell line development, process development and analytics. Additionally, Xbrane has entered into strategic partnerships with selected key technology providers regarding cell line development and expression vectors. This, in combination with Xbrane's deep knowledge in all aspects of biosimilar development, gives Xbrane a strong foundation for its mammalian cell based biosimilar programs.

Accelerating Development of Xdivane

Xbrane is now, based on the established technological platform, accelerating development of Xdivane, a biosimilar to Nivolumab (Opdivo®). Opdivo® is a leading immunoncology product for the treatment of cancer with annual sales of SEK 54 billion[1] in 2018, in a total oncology pharmaceutical market that generated sales of SEK 1200 billion[2] in 2018.

Xbrane expects to be able to launch Xdivane at patent expiration of Opdivo® occurring 2026-2030 depedent on country. Opdivo® is a revolutionary product that has provided significant benefits to patients. However, Opdivo® is also, as most biologics, an expensive treatment with annual per patient costs often above SEK 1 million. Developing a cost efficient biosimilar to Opdivo® is therefore of great importance in order to increase accessibility globally of the treatment. Xbrane's clear ambition with Xdivane is to become the leading biosimilars to Opdivo®, both in terms of cost efficiency and time for launch.

[1] BMS Year end report
[2] IQVIA

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About Us

Xbrane is a commercial phase Swedish biopharmaceutical company specialized in biosimilars. Xbrane has a patented protein production platform for development of biosimilars and world leading expertise in biosimilars. Xbrane's headquarter is located in Solna outside of Stockholm and the company's in-house research and development facilities are in Sweden and Italy. Xbrane is listed at Nasdaq First North since February 3rd, 2016 under the name XBRANE and Avanza Bank AB is Xbrane's certified adviser (corp@avanza.se, +46 (0)8 409 421 20).
For more information see www.xbrane.com.

This information is information that Xbrane Biopharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2019-04-24 08:00 CEST.

Attachments

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