Xbrane and Intas enter into a Global Licensing agreement to jointly develop Nivolumab biosimilar referencing Opdivo®

Intas secures exclusive global commercialization rights for Xbrane´s Nivolumab biosimilar candidate, (referencing Opdivo®). Opdivo® achieved global sales of USD 9 billion in 2023. This partnership with Xbrane strengthens Intas's global biosimilar portfolio, emphasizing its commitment to expanding its pipeline through collaborations and enhancing access to high-quality medicines worldwide.

Xbrane Biopharma AB (publ) ("**Xbrane**" or the "**Company**") (Nasdaq Stockholm: XBRANE) and Intas Pharmaceuticals Ltd. ("**Intas**") are pleased to announce an exclusive Global Licensing and Co-Development Agreement for Xbrane´s Nivolumab Biosimilar candidate (referencing Opdivo®). The Nivolumab biosimilar will be commercialized by Intas, through its subsidiary Accord Healthcare, which plays a significant role in the global biosimilar market. With a strong focus on oncology, Accord has extensive commercial expertise and currently supplies about one-third of injectable oncology medicines in Europe.

Under the exclusive Global Licensing and Co-Development Agreement, Intas will finance and oversee the clinical and regulatory development activities, as well as the global commercialization of the Nivolumab biosimilar candidate. As part of the agreement, Xbrane will receive an upfront payment of EUR 10 millions from Intas, in addition to development milestone payments of EUR 3 million. After the product is launched, Xbrane will also be entitled to receive double-digit royalties on profits.

"We are now, with this partnership, very well positioned to bring our Nivolumab biosimilar candidate to launch at the time of patent expiration of Opdivo® in the US in December 2028 and June 2030 in Europe and generate significant income from profit sharing from that point and onwards. Opdivo® will be the first PD1 inhibitor to go off patent and has reported global sales of USD 9 billion in 2023 with 9% growth. We are convinced that Intas, given its vast capabilities in biosimilar development, is the perfect partner to finalize the development in a timely manner. We are also convinced that Intas' commercialization arm Accord, given its previous achievements and track record with oncology biosimilars such as Pelgraz, Accofil and Zercepac will do a phenomenal job in commercializing our Nivolumab biosimilar in global markets. We believe that introducing biosimilars for core oncology treatments, particularly PD-1 inhibitors, plays a critical role in advancing cancer care. By making these foundational therapies more accessible, biosimilars enable healthcare systems to allocate more resources towards innovative combination treatments, which have the potential to improve overall treatment outcomes."* says **Martin Åmark**, CEO of Xbrane.

"Our partnership with Xbrane marks a significant milestone in Intas' global biosimilar strategy. Developing Nivolumab as a high-quality, next-generation biosimilar to Opdivo® aligns with our 'Patient First' philosophy, paving the way for innovative and combinatory treatments that improve patient safety, treatment outcomes, and to expand access worldwide. By leveraging our strong leadership and commercialization capabilities, we are committed to our shared mission of transforming oncology care with accessible and groundbreaking solutions," stated Mr. **Binish Chudgar**, Executive Chairman and Managing Director of Intas Pharmaceuticals Ltd.

Paul Tredwell, Executive Vice President of EMENA, Accord, said, "*I am delighted that Accord Healthcare has strengthened its position as a leader in specialty medicines, particularly in oncology, through its collaboration with Xbrane on developing and commercializing Nivolumab. This partnership complements Accord's existing platform, which supplies up to 25% of chemotherapy medicines in the region and further solidifies Accord's commitment to our mission to improve access to value-based medicines for patients."*

About Xbrane Nivolumab Biosimilar
Xbrane´s Nivolumab biosimilar candidate, (referencing Opdivo®), is a monoclonal antibody used in cancer immunotherapy. It is a PD-1 (programmed death-1) inhibitor that works by blocking the PD-1 protein on immune cells, which normally suppresses the immune response against cancer cells. By inhibiting PD-1, nivolumab helps the immune system recognize and attack cancer cells more effectively. It has been approved for use in treating various types of cancers and can be used alone or in combination with other treatments depending on the cancer type and stage. Opdivo® reported sales of approx. USD 9 billion globally during 2023 *with 9% growth.** Xbrane Nivolumab biosimilar candidate is currently under development and has achieved alignment on a streamlined clinical development plan with both EMA (European Medicines Agency) and the US FDA (Food and Drug Administration). The parties intend to launch the product in the US upon loss of exclusivity by December 2028. Launch in Europe could take place after June 2030, after expiry of relevant patents in Europe.

About Intas
Intas Pharmaceuticals Ltd. is a leading vertically integrated pharmaceutical company based in Ahmedabad, India, having end-to-end capabilities of formulation development, manufacturing, and marketing along with backward integration of APIs. Intas also has strong in-house biosimilar development and marketing capabilities, with more than 15 products being marketed. Intas is committed to expanding global healthcare access by providing affordable, high-quality medications through strategic partnerships and extensive R&D investment to meet the diverse needs of healthcare systems around the world.

Intas has set up a network of subsidiaries, under the umbrella name of Accord Healthcare to operate in global markets. Over the years, Intas has grown both organically and via acquisition, expanding its product portfolio and operations year on year. It is currently present in more than 85 countries worldwide with robust sales, marketing and distribution infrastructure in markets like North America, Europe, Central & Latin America, Asia-Pacific as well as CIS and MENA countries. Intas' remarkable success in North America and European operations have helped us emerge as a global brand in the world's largest pharmaceutical markets.

*) BMS 2023 Annual Report

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About Us

Xbrane Biopharma AB develops biological drugs based on a patented platform technology that provides significantly lower production costs compared to competing systems. Xbrane has a portfolio of biosimilar candidates targeting EUR 26 billion in estimated annual peak sales of the respective reference product. The lead candidate Ximluci® is granted market authorization approval in Europe and was launched during 2023. Xbrane's head office is in Solna, just outside Stockholm. Xbrane is listed on Nasdaq Stockholm under the ticker XBRANE. For more information, visit 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 2024-11-19 12:20 CET.

Attachments

Xbrane and Intas enter into a Global Licensing agreement to jointly develop Nivolumab biosimilar referencing Opdivo®