

First patient included in Xdivane pivotal clinical trial

Xbrane Biopharma AB (publ) ("Xbrane") (Nasdaq Stockholm: XBRANE) today announce that the first patient has been included in the pivotal clinical trial for Xdivane (nivolumab biosimilar candidate).

As previously communicated, Xbrane and Intas Pharmaceuticals Ltd (Intas) entered into a Global license agreement around Xdivane on November 19th 2024. According to the agreement Intas is the sponsor for the clinical trial and is set to commercialize the product post approval. The first patient has now been included in the pivotal clinical trial that will support the approval process by regulatory authorities including US FDA and EMA. Xdivane is being developed according to a timeline that enables launch in close connection with Loss of Exclusivity in respective territory. Initiation of the clinical trial triggered a milestone payment of €2 million from Intas to Xbrane, that was received during the third quarter of 2025.

About Xdivane

Xdivane™ is a biosimilar candidate to Opdivo®, a so called immune-oncology drug (PD1 inhibitor) used in treatment of different cancers, with sales of approx. 8 billion USD globally during 2023, expected to grow to 14 billion USD by 2028.

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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 23 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

Press Release
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Attachments

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