Xbrane receives GMP authorization from the Swedish Medical Products Agency, strengthening commercial supply capabilities

Xbrane Biopharma AB (publ) ("Xbrane") announces today that the Swedish Medical Products Agency (Läkemedelsverket) has granted Xbrane authorization to import medicinal products from countries outside the EU/EEA and perform batch certification and release for supply within the EU. The authorization represents an important expansion of Xbrane's pharmaceutical and commercial supply capabilities and is expected to simplify the supply chain for Ximluci®/Lucamzi including supply of final goods to the USA.

The authorization enables Xbrane to take a more active role in the pharmaceutical supply chain, including the import into the EU of medicinal products manufactured in third countries and their subsequent Qualified Person (QP) certification and release in accordance with applicable EU Good Manufacturing Practice requirements.

For Ximluci®, Xbrane's ranibizumab biosimilar, the authorization provides the opportunity to simplify the existing commercial supply chain and increase Xbrane's control over import and release activities.

The authorization also establishes infrastructure that can support Xdarzane, Xbrane's biosimilar candidate to daratumumab, as well as additional future biosimilar products. Xbrane can thereby offer partners a broader set of capabilities covering not only development of biosimilars and establishment of commercial manufacturing processes, but also EU import, QP certification and batch release.

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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 Hagastaden, Stockholm. Xbrane is listed on Nasdaq Stockholm under the ticker XBRANE. For more information, visit www.xbrane.com

Attachments

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