Press release
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Xbrane Biopharma announces results of in-vivo study showing equivalent tolerability and pharmacokinetic profile of Xlucane compared to Lucentis®

In an in-vivo study involving 16 New Zeeland White rabbits Xlucane (ranibizumab (Lucentis®) biosimilar) demonstrated equivalent tolerability and pharmacokinetic profile in the serum and in the vitreous body compared to the reference product Lucentis®.

Design of the study

The objective of the study was to compare the pharmacokinetic profile and tolerability between Xlucane and the reference product Lucentis®. The study involved 16 New Zeeland White rabbits, divided in two equally sized groups, where each rabbit received a single bilateral intravitreal injection of Xlucane and Lucentis® respectively. Tolerability was monitored via ophthalmologic examinations on all animals throughout the study as well as via histopathology at selected timepoints to observe potential inflammations at microscopical level. The pharmacokinetic profile, i.e. the concentration of the active substance ranibizumab over time, was measured in the serum of the animals throughout the study as well as in the vitreous body.

Main results

An equivalent pharmacokinetic profile was observed in the Xlucane group compared to the Lucentis® group both measured in the serum as in the vitreous body. Eyes treated with Xlucane did not develop any ocular inflammation and the product was well tolerated.

"We are very pleased with the result of this study as it demonstrates an equivalent tolerability and pharmacokinetic profile of Xlucane compared to the reference product. This, combined with the excellent comparable in-vitro analytical data previously announced, gives us full confidence ahead of the upcoming pivotal clinical equivalence trial." says Martin Åmark, CEO Xbrane.

The study was performed by Charles River Laboratories.

This information is information that Xbrane Biopharma AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 4 October at 08.00, 2018.

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About Xbrane

Xbrane is a commercial phase Swedish biopharmaceutical company that develop and produces 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. For more information see www.xbrane.com.