Press Release
Stockholm December 11, 2020

Xspray Pharma has decided to await the result of two ongoing clinical studies before submitting its ANDA application

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) today announces that the last subject in the additional bioequivalence (BE) study has been dosed faster than expected and that it has also obtained preliminary positive data from a study on improved HyNap-Dasa. Xspray Pharma has therefore made the strategic decision to submit its ANDA application for HyNap-Dasa in early 2021. This decision allows Xspray Pharma to optimize its strategic commercial opportunities for the HyNap-Dasa product portfolio.

Despite the ongoing Covid-19 pandemic, the recruitment and dosing in the additional BE study has progressed surprisingly swiftly and the last subject has today been dosed with HyNap-Dasa. The preliminary data is expected February 2021. The study is similar to the former study where bioequivalence was unexpectedly not obtained, mainly as a consequence of the reference drug Sprycel® showing low or no absorption in a few subjects.

In a separate study with an improved HyNap-Dasa version of the reference drug Sprycel® the dosing has already been completed, and Xspray Pharma has received positive preliminary data for a sub-group of the subjects. The aim of this study is to demonstrate that absorption of HyNap-Dasa is not dependent on the gastric pH level. Preliminary data for all subjects is expected during the second half of December 2020.

Xspray Pharma has decided to await the results from the two studies before submitting the ANDA application. The decision is based on the possibility that the additional BE study shows formal bioequivalence between HyNap-Dasa and Sprycel® to achieve ANDA approval. Together with the upcoming data from the study of the improved HyNap-Dasa version, this would furthermore increase the strategic alternatives for the ongoing business development of the HyNap-Dasa product portfolio. Xspray Pharma is also advancing its back-up formulations where the first is now ready to enter clinic and the study start is expected in early Q1 2021.

“It is very encouraging that we managed to run the additional study so fast, which proves that our process and supply chain is in place and delivers the required quality. This, together with the received positive preliminary data for the improved HyNap-Dasa version, are decisive factors for our strategic decision to temporarily await submitting the ANDA. Our top priority is to maximize the value and finding the best commercial partner for our HyNap-Dasa products,” says Per Andersson, CEO of Xspray Pharma.

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About Xspray Pharma

Xspray Pharma AB (publ) is a product development company with multiple product candidates in clinical development. Xspray uses its innovative, patented RightSize technology to develop improved and generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. The segment is the second largest in oncology, and drug prices are very high.

The company´s innovative technology allows Xspray Pharma to gain entry as the first competitor to today's original drugs before the secondary patents expire. Xspray's goal is to become the leader in the development of improved drugs or generic versions of PKIs already marketed for the treatment of cancer, which numbered to 54 in December 2019. The company's leading product candidates, HyNap-Dasa, HyNap-Sora and HyNap-Nilo, are stable amorphous versions of the three blockbuster cancer drugs Sprycel® (dasatinib), Nexavar® (sorafenib) and Tasigna® (nilotinib), respectively. The launch of the first product candidate, HyNap-Dasa, is planned to take place in 2021. The substance patent for the original drug Sprycel® (dasatinib) expires at the end of 2020, and the secondary patents in 2026, which offers Xspray's HyNap-Dasa a period of five years of semi-exclusivity before other competitors gain access to the market.

The company has patented manufacturing technology, equipment and the resulting products. The shares in Xspray Pharma are traded on Nasdaq Stockholm.
www.xspraypharma.com

This information is information that Xspray Pharma AB 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 2020-12-11 13:10 CET.

Attachments

Xspray Pharma has decided to await the result of two ongoing clinical studies before submitting its ANDA application