Press Release
Stockholm May 29, 2020

Xspray Pharma initiates pivotal registration studies with HyNap-Dasa for the market approval application in the United States

Xspray Pharma AB (Nasdaq Stockholm: XSPRAY) today announces the start of the pivotal clinical bioequivalence studies with HyNap-Dasa. The studies are conducted on healthy volunteers with the objective to demonstrate that HyNap-Dasa is bioequivalent to the original drug Sprycel® (dasatinib).

The bioequivalence studies consist of two studies, where the first one, starting today, is conducted on fasted healthy volunteers. The second study, starting next month, is conducted on non-fasted healthy volunteers. In both studies, HyNap-Dasa bioavailability is compared to the original drug Sprycel®. The preliminary results from the two studies are expected during the third quarter 2020.

"The initiation of the pivotal clinical trials marks a major milestone for Xspray and for our HyNap-Dasa product candidate," says Per Andersson, CEO Xspray. “HyNap-Dasa has in previous clinical studies shown positive results and we now look forward to see the clinical outcome this time as well, and take a big step closer to submitting our first application for market approval in the US."

The results of the two clinical trials together with the results of the ongoing stability studies will form the basis of the company’s ANDA application for market approval in the USA.

For further information, please contact:

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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 2020-05-29 16:00 CEST.

Attachments

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