Press Release
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Xspray Pharma provides an update on how the Covid-19 pandemic affects the company's planned clinical studies

STOCKHOLM – April 15, 2020. Xspray Pharma AB (Nasdaq Stockholm: XSPRAY) announces that the start of the pivotal clinical bioequivalence studies with HyNap-Dasa are expected to be postponed by two to three months due to the Covid-19 pandemic.

Xspray Pharma's planned clinical trials are, like the trials of many other drug developing companies, affected by the ongoing COVID-19 pandemic. The clinical bioequivalence studies in healthy volunteers with HyNap-Dasa that were planned to commence in the beginning of Q2 2020 are now expected to be postponed to begin by the end of Q2 2020.

"The results of the clinical studies, together with the results from the ongoing stability studies, which are continuing without delays, will form the basis of our ANDA application to the FDA. We have now postponed the start of the clinical studies as we want to feel confident that the studies can be completed without interruptions or drop-offs. This will lead to that the ANDA the application may be submitted later than planned as the results of the clinical trial are now time critical," says Per Andersson, CEO of Xspray.

The clinical bioequivalence studies are conducted on healthy volunteers and the objective is to demonstrate that the company's first product candidate HyNap-Dasa is bioequivalent to Sprycel® (dasatinib). Together with the results of the ongoing stability studies, the data will form the basis of the company's ANDA application for market approval in the USA.

"In all other aspects, the HyNap-Dasa project is going according to plan. And I am very pleased that all our partners around the world can continue to work actively on our projects. As the clinical material for HyNap-Dasa is completed, we focus on getting results for the upcoming products in the pipeline, such as HyNap-Nilo," concludes Per Andersson, CEO of Xspray.

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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 2020-04-15 17:20 CEST.

Attachments

Xspray Pharma provides an update on how the Covid-19 pandemic affects the company's planned clinical studies