Press Release
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Xspray announces positive preliminary results from the study for its lead product candidate HyNap-Dasa

Xspray Pharma AB (Nasdaq Stockholm: XSPRAY) today announces preliminary results from the second out of two bioequivalence studies in healthy volunteers with its lead product candidate HyNap-Dasa. The study fulfilled statistical and formal bioequivalence requirements for HyNap-Dasa compared to the reference product Sprycel. The study was conducted in healthy volunteers under fed conditions.

"I am very pleased that our HyNap-technology delivers the anticipated result. With this positive result we will now explore if the totality of data from the two studies will suffice for submittal of our ANDA-application, which will then be done during the fourth quarter this year. We are in parallel preparing for an additional study under fasting condition with the aim to demonstrate formal bioequivalence. In the case that the additional study is needed, our ANDA-application would be submitted during first quarter of 2021," says Per Andersson, CEO of Xspray Pharma.

This second pivotal bioequivalence study with HyNap-Dasa was performed in 35 healthy volunteers under fed conditions where each volunteer received two repeated single doses of HyNap-Dasa and Sprycel in a randomized cross-over design. The result shows that bioequivalence between HyNap-Dasa and Sprycel was achieved. Both Cmax and AUC were within the statistical bioequivalence requirement of 80-125% compared to Sprycel®.

"The positive results from this study furthermore support our business development efforts around HyNap-Dasa which are progressing according to plan. Xspray now has a validated product manufacturing capability of stable HyNap material and a technology platform that makes it possible to alter the formulation properties required to make either generic copies or improved versions of different PKI products. The preparations of the next products in our portfolio, an improved version of HyNap-Dasa and HyNap-Nilo, which both will follow the 505 (b)(2) regulatory pathway, are proceeding as planned," Per Andersson concludes.

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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 2020-09-25 09:40 CEST.

Attachments

Xspray announces positive preliminary results from the study for its lead product candidate HyNap-Dasa