Press Release
Stockholm January 14, 2021

Xspray Pharma announces results from additional bioequivalence study and provides update regarding upcoming regulatory applications for ANDA and 505(b)(2)

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) today announces results from the extra bioequivalence study in fasting healthy volunteers conducted with the Company's leading product candidate HyNap-Dasa. The results are in line with previous bioequivalence studies, but the results show that the study design is robust. Xspray Pharma will already next week start the previously communicated bioequivalence studies with modified formulations. Xspray Pharma has recently received positive results for an improved version of Sprycel, based on HyNap-Dasa, and will initiate registration studies for that product during Q1 2021 with the aim to submit for marketing approval according to the 505(b)(2) procedure during Q2 2021.

The recently conducted bioequivalence study in fasting healthy volunteers was of the same size and design as the study reported under Q3 2020. The results show that the study was well conducted and included a sufficient number of subjects, but that formal bioequivalence was not achieved. In both studies, markedly poor absorption of dasatinib was observed in a few subjects given the reference product Sprycel which was not seen in subjects given the HyNap-Dasa formulation. While the EMA finalized guidance on dasatinib bioequivalence allows the exclusion of the data for these poorly absorbing subjects, US FDA does not.

“This confirms the results of the previous study and our primary focus is now on the two modified formulations of HyNap-Dasa. These are optimized to achieve bioequivalence and enable an ANDA submission. I am glad that we, as promised, can start the first of these studies already next week. At the same time, we are now expanding our product portfolio with an improved product based on the results of the successful study with omeprazole,” says Per Andersson, CEO of Xspray Pharma. "We continue to work on commercial partnerships according to plan and can now offer both an improved and a generic version, which strengthens the value of our HyNap-Dasa product portfolio."

Xspray Pharma's program for registration studies during H1 2021

Improved version of Sprycel - HyNap-Dasa 505(b)(2)
The study with the improved version of HyNap-Dasa, reported on December 30, 2020, proved that HyNap-Dasa can be taken concomitantly with omeprazole, which is not possible with Sprycel. Based on these positive results showing a clinically relevant improvement potential, Xspray Pharma will initiate a registration study during Q1 2021. The results will form the basis for submission for the improved product in accordance with the 505(b)(2) procedure planned during Q2 2021. Xspray Pharma has also begun work on an application for Orphan Drug Designation (ODD) for this product candidate.

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Generic version of Sprycel - HyNap-Dasa ANDA
The work to achieve bioequivalence between HyNap-Dasa and Sprycel continues with two modified formulations of HyNap-Dasa developed together with an expert group of reputable external advisors.

The first formulation involves a minor modification, and a bioequivalence study is planned to start next week. No further stability studies are required for this formulation which, provided positive results, makes the ANDA submission during Q2 2021 possible.

The second formulation is slightly more modified for which reason some stability studies will need to be conducted. The Company expects to start bioequivalence studies with this formulation during Q2 2021 and provided positive results, submit an ANDA in Q3 2021 at the earliest.

Improved version of Nilotinib - HyNap-Nilo 505(b)(2)
As announced in December 2020, Xspray Pharma's product candidate HyNap-Nilo has received Orphan Drug Designation (ODD) from the FDA for the treatment of chronic myeloid leukemia (CML). A clinical trial program with two different formulations has been initiated.

For further information, please contact:

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About Xspray Pharma

Xspray Pharma AB (publ) is a pharma company with several product candidates in clinical development. Xspray Pharma 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 55 in December 2020. The company's leading product candidates, HyNap-Dasa, HyNap-Nilo and HyNap-Sora, are stable amorphous versions of the three blockbuster cancer drugs Sprycel® (dasatinib), Tasigna® (nilotinib) and Nexavar® (sorafenib), respectively.

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 2021-01-14 12:10 CET.

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Attachments

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