Press Release
Stockholm October 13, 2021

Xspray Pharma has obtained results from bioequivalence studies with HyNap-Dasa ANDA and decides to focus on its improved dasatinib product, Dasynoc™

Xspray Pharma (publ) (Nasdaq Stockholm: XSPRAY) announces today that the Company has obtained results from the bioequivalence studies with the generic product candidate HyNap-Dasa ANDA C. The results show that the bioequivalence with the reference product Sprycel® was achieved in fed but not in fasting subjects due to the high variability of Sprycel®. The Company now chooses to focus entirely on the improved version, Dasynoc, which has achieved bioequivalence with a 30 percent lower dose than Sprycel®, and decides to end development of the generic version of dasatinib.

“We have been developing the generic and the improved versions of dasatinib, Dasynoc, in parallel, but now we choose to focus on Dasynoc since the market value is high not only during, but also after the end of the patent window. A shorter time in the patent window decreases the importance of the generic version in our product portfolio. An important consequence of this decision is to free up the capacity to accelerate the development of our current product candidates in the pipeline with longer patent window. The development of Dasynoc has been rapid and we can take advantage of the clinical improvements that amorphous formulations of protein kinase inhibitors (PKIs) provide for patients, doctors and payers", says Per Andersson, CEO of Xspray Pharma.

Submission for the market approval for Dasynoc in the USA is scheduled as planned for the fourth quarter this year, in accordance with the 505(b)(2) procedure.

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 68 in the beginning of 2021. 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). HyNap-Dasa is being developed as an improved version of Sprycel. HyNap-Nilo is being developed as an improved version of Tasigna and has has received orphan drug status from the US FDA. HyNap-Sora is being developed as an improved version of Nexavar®.

The company has patented manufacturing technology, equipment, and the resulting products. The shares in Xspray Pharma are traded on Nasdaq Stockholm (Nasdaq Stockholm: XSPRAY). 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 2021-10-13 08:10 CEST.

Attachments

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