Press Release
Stockholm August 6, 2021

Xspray Pharma has initiated studies with generic version of dasatinib, HyNap-Dasa ANDA

Xspray Pharma (publ) (Nasdaq Stockholm: XSPRAY) announced today that the pivotal bioequivalence studies have been initiated with the modified tablet formulation of the generic product candidate with dasatinib, HyNap-Dasa ANDA "C".

The bioequivalence studies are being conducted in fed and fasting healthy volunteers. The purpose of the studies is to achieve bioequivalence for HyNap-Dasa ANDA "C" compared with the reference product, Sprycel® (dasatinib). The results from both studies are expected in H2 2021.

"It is extremely gratifying to have initiated the bioequivalence studies with the generic product candidate with dasatinib, HyNap-Dasa ANDA "C". We have modified the formulation to compensate for Sprycel's low absorption in the body under fasting conditions, where our previous formulations had too high absorption in comparison to the reference product," says Per Andersson, CEO of Xspray Pharma.

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 in two versions, a generic and 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

Attachments

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