Press Release
Stockholm August 30, 2021

All participants in Xspray Pharma studies have received their dose of generic version of dasatinib, HyNap-Dasa ANDA

Xspray Pharma (publ) (Nasdaq Stockholm: XSPRAY) announces today that all participants have received their dose in the two bioequivalence studies with the generic product candidate of dasatinib, HyNap-Dasa ANDA.

The bioequivalence studies were conducted on fed and fasting healthy volunteers. The aim of the studies is to achieve bioequivalence for HyNap-Dasa ANDA compared with the reference product, Sprycel® (dasatinib). The studies used a modified formulation of dasatinib, called HyNap-Dasa ANDA formulation C. The results from both studies are expected in H2 2021.

“Our technology makes it possible for us to manufacture improved and generic versions of the PKI substances being marketed. Our improved version of dasatinib has already achieved bioequivalence and is ready to apply for market approval in the US. We are now looking forward to the results from our generic version. Due to Covid-19, the possible closure of facilities where the analyses are being conducted, may mean it takes longer to obtain the results compared with previous studies,” says Per Andersson, CEO of Xspray Pharma.

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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

All participants in Xspray Pharma studies have received their dose of generic version of dasatinib, HyNap-Dasa ANDA