Press Release
Stockholm March 5, 2021

Both groups in the two ongoing bioequivalence studies with Xspray Pharma's product candidate HyNap-Dasa have been dosed

Xspray Pharma (publ) (Nasdaq Stockholm: XSPRAY) announces today that all healthy volunteers in the bioequivalence studies with an adjusted tablet formulation of the generic HyNap-Dasa ANDA have been dosed. The studies have been conducted in two groups of healthy volunteers under fasting and non-fasting conditions. The purpose of the studies is to achieve bioequivalence for HyNap-Dasa to the reference product Sprycel® (dasatinib). The preliminary results are expected in April.

“The development work for these adjusted formulations began immediately after we received the final results from the bioequivalence studies conducted during the second quarter 2020. This first formulation can be viewed as slightly riskier than the latter, but if bioequivalence is reached a little earlier, we believe it is worth the risk. In case bioequivalence is not achieved with the first formulation, we will be able to start studies with the other formulation in the second quarter,” says Per Andersson, CEO of Xspray Pharma. “Multiple studies are common in the development of generics and I note that our studies are fairly quick to carry out. We are now in the third month of the patent window's expected timeframe of 45 - 60 months, where Sprycel® today sells for over USD 100 million every month in the U.S. The high value of the product candidate is partly time dependent which motivates this study”.

About HyNap-Dasa
Xspray Pharma's leading product candidate HyNap-Dasa is being developed both as a generic and an improved version of BMS's Sprycel® (dasatinib) for the treatment of chronic myeloid leukemia (CML) and acute lymphocytic leukemia (ALL). The primary patent for Sprycel® expired in December 2020 and the secondary patent in 2026, giving HyNap-Dasa a patent window of several years before other competitors gain access to the market. In 2020, the global market for Sprycel® amounted to approximately USD 2.1 billion, of which the US market accounted for approximately
USD 1.3 billion.

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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). 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

Both groups in the two ongoing bioequivalence studies with Xspray Pharma's product candidate HyNap-Dasa have been dosed