Press Release
Stockholm July 28, 2021

Xspray Pharma announces achievement of bioequivalence compared with reference product from bioequivalence study with HyNap-Dasa 505(b)(2)

Xspray Pharma (publ) (Nasdaq Stockholm: XSPRAY) announced today that positive results have been obtained from the pivotal bioequivalence study with the company's improved product dasatinib, known as HyNap-Dasa 505(b)(2). The study fulfilled the bioequivalence requirements compared with the reference product, Sprycel®. The results demonstrate that Xspray Pharma can reduce the dose strength by 30% but still yield the same uptake in the body as the reference product. These findings will form the basis of the application for market approval in the US under the 505(b)(2) procedure.

The bioequivalence study was conducted in fasting healthy volunteers. The dose strength used by HyNap-Dasa was 30% lower than that for the reference drug. The results show that bioequivalence (confidence intervals for Cmax and AUC in the range of 80–125% of the reference drug) was achieved with healthy margins for this formulation.

"We have now demonstrated that we can significantly reduce the dose of dasatinib in a tablet and still achieve the same bioavailability as in the reference product, which is one of the major advantages of our amorphous formulation. Our previous studies have shown that uptake is not affected by the pH value of the stomach, and thus simultaneously allows treatment with, for example, drugs for peptic ulcers – known as proton-pump inhibitors (PPIs) – such as omeprazole, which we know that many in this patient group utilize. Since this is not recommended with the reference product, HyNap-Dasa can offer important clinical advantages for both patients and care providers. Together with a favourable patent landscape, these findings give us great hopes for this product in the US market," says Per Andersson, CEO of Xspray Pharma.

An application for market approval in the US under the 505(b)(2) procedure based on data from this study is expected to be ready for submission in H2 2021. Supplementary data pertaining to dose strength will be sent to the US Food & Drug Administration in H1 2022.

"These findings mark a major milestone for Xspray Pharma. Our unique technology platform makes it possible to develop amorphous versions of protein kinase inhibitors, or PKIs. With this and previous studies, we have demonstrated that we can scale up the process and modify formulations to change the uptake of the drug and achieve bioequivalence. This will also be of crucial value for Xspray Pharma over the long term, since our platform was developed to create improved products of many of today's PKI drugs," says CEO Per Andersson.

Xspray Pharma's improved version of dasatinib was developed for the treatment of acute lymphoblastic leukemia (ALL) and chronic myeloid leukemia (CML), both of which are blood cancer illnesses in an area in which no new or improved drugs have been registered for a number of years. The reference drug Sprycel® sold globally for USD 2,140 million in 2020, of which USD 1,295 million in the US.

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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

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 2021-07-28 15:40 CEST.

Attachments

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