Press Release
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Xspray Pharma aims to submit its improved version of dasatinib for market approval application in second half of 2021

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) announces today an update on the upcoming pivotal study with its improved version of Sprycel® (dasatinib), based on the company's HyNap-Dasa formulation. The study has been initiated and the dosing for the bioequivalence study will start in the second quarter with the aim to submit an application for market approval in accordance with the 505(b)(2) procedure in the second half of 2021.

In parallel with its development of generic protein kinase inhibitors (PKIs) based on the company's amorphous technology platform, Xspray Pharma also develops improved versions of the original pharmaceutical agents. The overall strategy for HyNap-Dasa is unchanged and based on fastest possible route to market for;

- a generic (ANDA) HyNap-Dasa version of Sprycel® during the patent window
- an improved (505(b)(2)) HyNap-Dasa version of Sprycel® with relevant medical benefits

The improved version of Sprycel® is designed to offer patients suffering from acute lymphocytic leukemia (ALL) and chronic myeloid leukemia (CML) an improved quality of life by enabling treatment with protein pump inhibitors, PPIs (omeprazole), together with the life-saving treatment with dasatinib. This improved version is also designed to overcome the issue with patients with low or no uptake as demonstrated for Sprycel® in earlier bioequivalence studies. The improved version will also be administrated at a significantly lower strength compared to Sprycel® and reduce variability. With these improvements HyNap-Dasa will offer meaningful medical benefits for patients and caregivers.

"Almost a third of the patient population has a need for PPIs. I hope that this improved version will offer them a treatment where you can treat cancer and for example ulcer at the same time. We will use the same formulation of HyNap-Dasa as was used in the bioequivalence studies that we ran in 2020 but giving a lower strength of HyNap-Dasa compared to Sprycel®. Since we have already tested the formulation in healthy volunteers it is a de-risked study without significantly affecting our financial situation. We have a very robust set of pharmacokinetic data supporting the design of this study which reduces the risk considerably.", says Per Andersson, CEO Xspray Pharma.

The pivotal bioequivalence study aims to demonstrate that Xspray Pharma's improved version can be administrated using significantly lower strength compared to the original drug and still obtain the same bioavailability. Previous studies with this formulation have already showed no food interaction and no drug-drug interaction with PPI, omeprazole.

"With our multiple pathway strategy, we are now in parallel developing both an improved and a generic version. Thereby we will be able to challenge the original product's market position and create substantial value for the company and its shareholders. Our clinical work on the generic version of dasatinib continues according to plan. We are currently running a bioequivalence

study with a slightly modified formulation and we expect data from this study in April. As a risk mitigating strategy, we are prepared to start studies with an additional formulation that has shown encouraging data in laboratory tests," concludes Per Andersson.

In 2020 Sprycel® sold worldwide for USD 2,140 million of which USD 1,295 million was in the US. Xspray Pharma is aiming for market approval for the improved version of dasatinib in US, Europe, and all other major markets.

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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

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