Press Release
Stockholm April 8, 2021

Xspray Pharma announces update of its improved version of dasatinib

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) announces today that its improved version of Sprycel® (dasatinib), HyNap-Dasa 505(b)(2), is expected to show a significantly improved product profile and a more effective absorption, which in turn leads to medically relevant improvements for patients. This version is based on the thoroughly tested "A" formulation and will be tested in a pivotal bioequivalent study during Q2.

The current formulation has undergone scale-up in the manufacturing process, stability testing, and has been tested in four clinical studies. External experienced pharmacokinetic experts have, with existing clinical data, calculated that with a 30 percent reduction in dose, the product should be bioequivalent to Sprycel®. Human bioequivalence studies confirms that the formulation:

- can be used simultaneous with omeprazole without affecting the absorption of dasatinib, which enables treatment of ulcer at the same time as the patient receives cancer treatment
- gives an even absorption of dasatinib without the number of low uptake outliers related to previous studies with Sprycel®
- can be administrated with a lower dose, which could lead to fewer side effects

"Our product is designed to improve the quality of life for patients with acute lymphocytic leukemia (ALL) and chronic myeloid leukemia (CML). I am convinced that our version, which is more soluble, bioavailable, gastric pH independent, and has a lower variability will lead to oncology physicians seeing improvements to both safety and efficacy. The application for market approval for our product will be submitted in accordance with the 505(b)(2) regulatory pathway", says Per Andersson, CEO of Xspray Pharma.

HyNap-Dasa 505(b)(2) will be tested against Sprycel® at a 30% lower dose in a pivotal bioequivalence study. If results are positive, a 505(b)(2) NDA submission is expected during H2 2021.

In 2020 Sprycel® sold worldwide for USD 2.14 billion, of which USD 1.295 billion in the US. Xspray Pharma is working to obtain market approval for the improved version of dasatinib in the US, Europe, and all other major markets.

For further information, please contact:

Per Andersson, CEO, Xspray Pharma AB
Phone: +46 (0) 706 88 23 48
E-mail: per.andersson@xspray.com

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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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