Press Release
Stockholm June 10, 2021

Xspray Pharma commences study with improved version of dasatinib

Xspray Pharma (Nasdaq Stockholm: XSPRAY) announced today that a bioequivalence study with the improved version of dasatinib has commenced. The objective of the study is to demonstrate that a lower dose strength of Xspray Pharma's improved version of dasatinib is bioequivalent to a higher dose strength of the original drug Sprycel®. The study is being conducted with a previously used formulation of Xspray Pharma's amorphous version of dasatinib. The findings will form the basis of an application for market approval in the US under the 505(b)(2) regulatory pathway. The preliminary findings from this study are expected in the third quarter of 2021.

"I am pleased that we are initiating this bioequivalence study as planned. This product candidate that has the potential to improve the therapy for a cohort of cancer patients in a high-value field where no new or improved drugs have been registered for many years. In addition, we have tested this formulation A in previous studies and can better predict the findings compared to the studies that have been based on completely new untested formulations," says Per Andersson, CEO of Xspray Pharma.

Xspray Pharma's improved version of dasatinib for the treatment of acute lymphoblastic leukemia (ALL) and chronic myeloid leukemia (CML) and is designed to enable therapy with proton-pump inhibitors (PPIs) such as omeprazol which should be avoided with the original product. Xspray Pharma's product will be administered at a lower dose strength compared with Sprycel® but with the same availability.

Bioequivalence studies with Xspray Pharma generic product candidate, formulation C, where the objective is to demonstrate bioequivalence with Sprycel®, will be initiated this summer. The findings will form the basis of an application for market approval in the US under the ANDA regulatory pathway.

For further information, please contact:

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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

Image Attachments

Per Andersson_CEO Xspray Pharma AB

Attachments

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