

All participants in Xspray Pharma's study have received their dose of the improved version of dasatinib

Xspray Pharma (Nasdaq Stockholm: XSPRAY) announces today that all participants have received their dose of the company's improved amorphous version of dasatinib for the bioequivalence study. The study is being conducted on fasting healthy volunteers with the objective to demonstrate that a lower dose strength of Xspray Pharma's improved version of dasatinib will have the same uptake as a higher dose strength of the original marketapproved drug. Previous studies have shown that Xspray Pharma's formulation has demonstrated lower variability, that it is not affected by the pH value in the stomach and therefore enables simultaneous therapy with proton-pump inhibitors (PPIs) such as omeprazole. The preliminary results are expected during the third quarter and will form the basis of an application for market approval in the US under the 505(b)(2) regulatory pathway.

"A major advantage of our amorphous formulations is that they are easier to be absorbed by the body, which enables us to lower the strength of the dose while still improving therapy for patients, in particular the large patient group that is also affected by, for example, peptic ulcers, and therefore requires PPI therapy, something that should be avoided with the original drug," says Per Andersson, CEO of Xspray Pharma.

Xspray Pharma's improved version of dasatinib is developed for the treatment of acute lymphoblastic leukemia (ALL) and chronic myeloid leukemia (CML), an area in which no new or improved drugs have been registered for several years.

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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

Attachments

All participants in Xspray Pharma's study have received their dose of the improved version of dasatinib