Press Release
Stockholm December 30, 2020

Xspray Pharma reports positive results from a study with dasatinib during omeprazole treatment

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) announces today that it has received positive preliminary results from a bioavailability study in healthy volunteers with an improved HyNap-Dasa version of the reference drug Sprycel™, demonstrating that absorption of HyNap-Dasa is not dependent on the gastric pH level. HyNap-Dasa is being developed both as a generic and improved version of the marketed drug Sprycel® (dasatinib).

The preliminary results from the bioavailability study demonstrates that solubility and absorption of Xspray Pharma's amorphous version of dasatinib, HyNap-Dasa, is not dependent on the gastric acidity (pH level). Xspray Pharma has earlier announced positive preliminary data for a sub-group of the subjects in the study.

As disclosed in Sprycel® US labelling, the uptake is dependent on the patient's gastric acidity. Increased pH dramatically decreases dasatinib´s solubility and absorption. The results from Xspray Pharma's clinical study show that HyNap-Dasa is not affected during omeprazol treatment which increases the gastric pH. The results from the current conducted study shows a minor absorbtion increase of 8%, measured as area under the curve (AUC) after treatment with 40 mg of omeprazole (proton pump inhibitor) daily for five days. This can be compared to publiced data for Sprycel® where AUC was reduced by 43% in combination with omeprazole. In 2019, Sprycel® was the leading drug for the treatment of chronic myeloid leukaemia (CML) in sales, with global and US sales of 2,11 and 1,19 billion dollar, respectively.

"We have now demonstrated that our amorphous HyNap-Dasa formulation, produced in our commercial supply chain, can eliminate the pH dependent absorption seen in the crystalline reference product. This will allow for long-lasting acid suppressing medication also for CML patients treated with dasatinib. There are also patients with no production of hydrochloric acid in the stomach (achlorhydria) resulting in high gastric pH. These patients will have the chance to get a better dasatinib product for their cancer therapy," says Per Andersson, CEO of Xspray Pharma. "For many of the amorphous drug candidates we decide to develop, we will have the possibility to develop either a generic or an improved version, or both where we see a clinical and commercial rationale. This makes multiple registration pathways also for our lead product candidate possible and will not only increase Xspray Pharma's value proposition to potential partners, but also broaden the commercial possibilities for Xspray Pharma as a company".

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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), respectively.

The company has patented manufacturing technology, equipment and the resulting products. The shares in Xspray Pharma are traded on Nasdaq Stockholm.
www.xspraypharma.com

Attachments

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