Press Release
Stockholm December 29, 2020

Xspray Pharma's HyNap-Nilo receives FDA Orphan Drug Designation for the treatment of Chronic Myeloid Leukemia

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) today announces that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for its product candidate, HyNap-Nilo, for the treatment of chronic myeloid leukemia (CML). HyNap-Nilo is under development as an improved version of TasignaTM (nilotinib), a leading drug for CML.

The FDA's Orphan Drug Designation (ODD) has been granted to Xspray Pharma for nilotinib oral formulation intended for the treatment of chronic myeloid leukemia. The ODD program provides orphan status to drugs intended for the treatment of rare disorders that affect fewer than 200,000 people in the United States. This designation allows developers benefits such as the waiver of filling fees under Prescription Drug User Fee Act (PDUFA), as well as potential marketing exclusivity in the U.S for a period of 7 years, should clinical superiority over the originator drug be demonstrated upon approval of the product.

"We are pleased to have received the orphan designation from the FDA based on the potential clinical benefit of HyNap-Nilo. In this case, the reference product has a food effect on drug exposure that is clearly described in a black box safety warning," says Per Anderson, CEO of Xspray Pharma.

A black box warning appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks associated with the treatment. In an earlier reported study in healthy volunteers, the results showed that HyNap-Nilo can eliminate the clinically relevant food effect.

"This is also a strong confirmation of our strategy, showing that products developed based on our unique technology platform can play a key role in improving established cancer drugs for the clinical benefit of the patients," continues Per Andersson.

About HyNap-Nilo
HyNap-Nilo is being developed as an improved version of the originator drug TasignaTM (nilotinib) with potential to significantly reduce food effect on the plasma concentration and absorption, increase bioavailability as demonstrated in a previous pilot clinical trial, and decrease the drug-drug interactions with gastric pH modulating drugs. According to the drug label for the marketed PKI nilotinib, patients need to refrain from food intake for two hours before and one hour after administration of the drug which is given twice daily. In a completed cross-over Phase I clinical trial, Xspray Pharma measured the exposure of its proprietary HyNap-Nilo formulation in healthy individuals. When administered in the fasted state, a HyNap-Nilo dose of 150 mg produced the same area under the curve values as those reported for a dose of 400 mg of the marketed product. After a high-fat meal the study showed an increase

in drug exposure of 25% for HyNap-Nilo, measured both as peak concentration (Cmax) and AUC. For the marketed product, the corresponding increases after a high-fat meal are reported to be 112% and 82%, respectively. In 2019 sales of TasignaTM amounted to USD 804 million in the U.S.

Chronic myeloid leukemia - CML
CML is a type of blood cancer where the body produces malignant white blood cells. Almost all patients with CML have an abnormality known as the "Philadelphia chromosome," which produces a protein called BCR-ABL. This protein aids the proliferation of malignant white blood cells in affected patients. About 15% of all leukemia is CML. In 2020 it is projected that 8,450 people in the US will be diagnosed with CML and in 2017, there were an estimated 58,000 people living with the disease in the US.

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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

This information is information that Xspray Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2020-12-29 18:05 CET.

Attachments

Xspray Pharma's HyNap-Nilo receives FDA Orphan Drug Designation for the treatment of Chronic Myeloid Leukemia