Press Release
Stockholm January 13, 2022

FDA allows review of application for market approval for Xspray Pharma's Dasynoc™

Xspray Pharma (publ) (Nasdaq Stockholm: XSPRAY) announced today that the US Food and Drug Administration (FDA) has agreed to review the company's application for market approval for Xspray Pharma's product candidate, Dasynoc™ (dasatinib) in the US under the 505(b)(2) process.

In November 2021, Xspray Pharma submitted an application for market approval in the US of the product candidate Dasynoc™ to the FDA under the Section 505(b)(2) NDA process, the registration pathway that applies to improved drugs. After an initial review, the FDA has now agreed to conduct a comprehensive review of Xspray Pharma's application.

"This gratifying news marks an important milestone for Xspray Pharma. We are ready to develop a portfolio of improved PKI drugs that could enable a better quality of life for patients while creating value for the company. This news is entirely in line with our expectations, since the amorphous structure of Dasynoc means that the product is an improvement over the current market leader," says Xspray Pharma's CEO Per Andersson.

The FDA's review of Dasynoc™ will be completed within ten months, but the time span could be altered depending on potential questions during the review process. The application will also be supplemented with lower dosages, at a time to be determined in consultation with the FDA. As previously communicated, Xspray Pharma estimates that a launch in the market, assuming approval from the FDA, could take place in 2023.

"We see a number of key advantages with Dasynoc for patients, physicians and payers. Xspray Pharma's product can be administered at a lower dosage than the reference product, which is expected to yield fewer side effects in patients. Studies have also shown that the product is not affected by the pH value in the stomach, which is why in comparison to the reference product it can be used in combination with proton-pump inhibitors in the concurrent treatment of peptic ulcers – a commonly occurring need in patients. Xspray Pharma's product has also displayed significantly lower variability, which means that uptake of the active substance into the body is even," Per Andersson says.

Xspray Pharma's application consists of the results from the registrational studies on healthy volunteers, where bioequivalence was achieved at an approximately 30 percent lower dosage than the reference product Sprycel®. The application includes Dasynoc™ for the treatment of acute lymphoblastic leukemia (ALL) and chronic myeloid leukemia (CML), which are blood cancer illnesses in an area where only one new drug has been registered over a ten-year period.

For further information, please contact:

Christina Malmberg Hägerstrand, VP Investor Relations & Communications, Xspray Pharma AB
Mob: +46 (8) 730 37 00
E-mail: christina.malmberg.hagerstrand@xspray.com

About Xspray Pharma

Xspray Pharma AB (publ) is a pharmaceutical company with several product candidates in clinical development. Xspray Pharma uses its innovative, patented RightSize™ technology to develop improved 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 72 in the end of 2021. The company's leading product candidates, Dasynoc (former 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 as 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

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 2022-01-13 08:15 CET.

Attachments

FDA allows review of application for market approval for Xspray Pharma's Dasynoc™