Press Release
Stockholm November 18, 2021

Xspray Pharma submits application for market approval to FDA for its product candidate Dasynoc

Xspray Pharma (publ) (Nasdaq Stockholm: XSPRAY) announces today that the application for US market approval of its first product candidate Dasynoc (dasatinib) has been submitted, in accordance with plans, to the Food and Drug Administration (FDA) under the 505(b)(2) NDA procedure, which is the registration path that applies to improved drugs.

The application consists of the results from the registrational studies on healthy volunteers, where bioequivalence was achieved at about 30 percent lower dosage than the original drug, Sprycel®. The studies confirms that:

- Dasynoc™ is unaffected by the pH value of the stomach, and can thus be used in combination with proton-pump inhibitors such as omeprazole for treatment of peptic ulcers
- Dasynoc™ has significantly lower variability than Sprycel, and did not demonstrate cases where there was no uptake of dasatinib at all in the subjects
- the uptake of Dasynoc is not affected by food intake
- Dasynoc™ can be administered at a lower dosage than the reference product, which is expected to yield fewer side effects

Under the application procedure, the FDA has up to 60 days to conduct an initial review of the company's application, and afterward will announce whether the application is ready to continue to a complete review or if additional information is needed. If the application moves on to a full review, approval will take ten months but may also take longer depending on the questions from the FDA during the review process. The application will be supplemented with stability data for lower dosages of Dasynoc™. The point in time at which this is to be done will be determined in consultation with the FDA.

The application includes Dasynoc for the treatment of acute lymphoblastic leukemia (ALL) and chronic myeloid leukemia (CML), which are blood cancer indications in an area where only one new drug has been registered for a number of years. The leading product, Sprycel®, sold globally for USD 2.1 billion in 2020, of which USD 1.3 billion was in the US.

"This is our first application for market approval, and it marks a major milestone for Xspray Pharma. Our unique technology is especially suited to overcoming many of the shortcomings that PKI substances generally possess, and the technology is applicable to a majority of the 72 PKIs being marketed today. In this way, we are now developing a portfolio of improved PKI drugs that create value for the company and make better quality of life possible for patients," says CEO Per Andersson.

Press Release
Stockholm November 18, 2021

For further information, please contact:

Per Andersson, CEO, Xspray Pharma AB
Phone: +46 (0) 706 88 23 48
E-mail: per.andersson@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 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 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

Attachments

Xspray Pharma submits application for market approval to FDA for its product candidate Dasynoc