Xspray receives FDA clearance of IND for HyNap-Dasa

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STOCKHOLM – October 31, 2019. Xspray Pharma (Nasdaq First North Growth Market: XSPRAY) announces that the US Food and Drug Administration (FDA) has cleared the company's IND application for the product candidate HyNap-Dasa.

Xspray Pharma's Investigational New Drug (IND) application, for permission to produce materials for and conduct clinical trials with the product candidate HyNap-Dasa, was accepted for review on September 30, 2019 by the US FDA. The application has now been given clearance by the FDA's Division of Hematology Products (DHP).

“We are very pleased that the FDA has cleared our IND application. This is yet an important milestone that validates both our clinical data and the development of our production method. The commercial production of amorphous material is already up and running in Milan and preparations for our upcoming ANDA application are proceeding as planned. This sends clear signals to potential commercial partners for HyNap-Dasa. With the IND-clearance at hand, we now look forward to being able to start our pivotal study with HyNap-Dasa shortly,” says Per Andersson, CEO of Xspray.

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About Xspray Pharma

Xspray Pharma AB (publ) is a product development company with multiple product candidates in clinical development. Xspray 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 47 in 2019. The company’s leading product candidates, HyNap-Dasa, HyNap-Sora and HyNap-Nilo, are stable amorphous versions of the three blockbuster cancer drugs Sprycel® (dasatinib), Nexavar® (sorafenib) and Tasigna® (nilotinib), respectively. The launch of the first product candidate, HyNap-Dasa, is planned to take place in 2021. The substance patent for the original drug Sprycel® (dasatinib) expires at the end of 2020, and the secondary patents in 2026, which offers Xspray’s HyNap-Dasa a period of five years of semi-exclusivity before other competitors gain access to the market.

The company has patented manufacturing technology, equipment and the resulting products. The shares in Xspray Pharma are traded on Nasdaq First North Growth Market Stockholm.

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