Press Release
Stockholm August 31, 2020

Xspray announces positive stability data on HyNap-Dasa tablets

Xspray Pharma AB (Nasdaq Stockholm: XSPRAY) today announces six months data from its stability study with HyNap-Dasa tablets manufactured in commercial scale. Six months stability data on commercially manufactured HyNap-Dasa demonstrates that the tablets complies with specifications and that they can be used in an upcoming ANDA filing.

In February 2020 stability studies were initiated with HyNap-Dasa tablets manufactured in commercial scale according to GMP-standard. In accordance with regulatory requirements three batches were put on stability at accelerated conditions (40oC and 75% relative humidity) and normal conditions (25oC and 60% relative humidity). Xspray now announces that the six months data have been analyzed and show compliance with the specification.

“As expected, the stability study showed good results, which is necessary for the filing for market approval in the US. We continue to work intensively on the preparations to be able to file an application for market approval for HyNap-Dasa as soon as possible. In late September we are awaiting the results from the second bioequivalence study with HyNap-Dasa, thereafter we will decide on the best strategy for our upcoming ANDA filing,” comments Per Andersson.

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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 54 in December 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 Stockholm.
www.xspraypharma.com

Attachments

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