Press Release
Stockholm July 3, 2020

First study group has been dosed in Xspray Pharma's ongoing pivotal registration studies with HyNap-Dasa

Xspray Pharma AB (Nasdaq Stockholm: XSPRAY) today announces that all healthy volunteers now have been dosed in the first of the two studies to demonstrate that HyNap-Dasa is bioequivalent to the original drug Sprycel® (dasatinib). The first group is conducted under fasting conditions and the second group is conducted under fed conditions.

The two bioequivalence studies are performed in healthy volunteers under fasting and fed conditions, respectively. All subjects in the first study group have now been fully dosed. The second study, under fed conditions, has been initiated and is expected to be fully dosed in the coming weeks. In both studies, HyNap-Dasa bioequivalence is compared to that of the original drug Sprycel®. The preliminary results from the first study are expected in August 2020.

The results of the two clinical trials, together with the results of the ongoing stability studies on the final tablets on HyNap-Dasa, will form the basis of the Company's first market approval application in the USA.

"This means that we, in spite of the Covid-19 situation, are one step closer to the date of filing for market approval in the US with our first product candidate and we will now initiate our search for commercial partners or purchasers for HyNap-Dasa. We are currently preparing for this process together with our legal and financial advisors and I feel confident that we will be well prepared for a more intensified process following the release of the clinical results," says Per Andersson, CEO Xspray. "Completing the trials with HyNap-Dasa will free up capacity for us to work more intensively with the next products in our portfolio, an improved version of HyNap-Dasa and HyNap-Nilo, which both will follow the 505(b)(2) regulatory pathway."

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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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