Press Release
Stockholm August 12, 2020

Xspray announces preliminary results from the first study for its lead product candidate HyNap-Dasa

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) today announces preliminary data from the first out of two bioequivalence studies in healthy volunteers with its lead product candidate HyNap-Dasa. The primary aim was to demonstrate bioequivalence for HyNap-Dasa compared to the reference product Sprycel. The first study did not fulfil statistical bioequivalence requirements due to high variability in pharmacokinetic parameters for the reference product Sprycel. A few subjects had very low absorption from Sprycel which was not observed for HyNap-Dasa. As these data with negligible absorption from Sprycel do not represent a clinically relevant treatment drug exposure, Xspray intends to discuss the results with the FDA before submitting the ANDA application.

This first pivotal study with HyNap-Dasa was performed in 51 healthy volunteers under fasting conditions over a period of four weeks where each volunteer received two repeated single doses of HyNap-Dasa and Sprycel in a randomized cross-over design. Final results from full data analysis are expected in September. The second bioequivalence study, where the effect of food intake on the absorption is assessed, is ongoing and preliminary results are expected in the end of September. The totality of data from the two clinical studies will form the basis for the coming ANDA application.

“These first data indicate that formal bioequivalence criteria were not met which was mainly related to unusually poor absorption of dasatinib from the Sprycel formulation in a few subjects. We are now waiting for the final study report of this first study, as well as the preliminary data from the second study with food intake which is expected end of September. Both studies will form the basis for the ANDA application. Provided positive response from the FDA, we can still file at the end of the year.” says Per Andersson, CEO of Xspray Pharma.

In addition to Xspray’s continued work towards an ANDA application based on the current and the ongoing study, Xspray will in parallel prepare for an additional bioequivalence study as a back-up. The validated manufacturing process enables this study to be initiated within 4 - 6 months.

“Since we have achieved bioequivalence earlier in two smaller studies, the outcome of this study was unexpected. We have analysed the results and have a good understanding of the factors that contributed to this outcome. We are planning to adjust the formulation in case the FDA decides that an additional study is needed. Alongside our efforts of getting the ANDA for HyNap-Dasa approved we are proceeding with the preparation of the next products in our portfolio as planned, an improved version of HyNap-Dasa and HyNap-Nilo, which both will follow the 505(b)(2) regulatory pathway. Furthermore, our planned business development efforts around HyNap-Dasa will progress according to plan,” Per Andersson concludes.

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An audiocast with the possibility to ask questions on the results is scheduled at 08:00 CEST on August 13 (audiocast will be held in Swedish): https://financialhearings.com/event/13022

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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

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 2020-08-12 19:55 CEST.

Attachments

Xspray announces preliminary results from the first study for its lead product candidate HyNap-Dasa