Press Release
Stockholm April 8, 2021

Xspray Pharma announces the results of two bioequivalence studies with adjusted tablet formulation of HyNap-Dasa (ANDA)

Xspray Pharma AB (publ), (Nasdaq Stockholm: XSPRAY) announces today the preliminary results of two bioequivalence study on fasting and non-fasting healthy volunteers using a slightly adjusted tablet formulation of the generic product candidate HyNap-Dasa "B". In the study on non-fasting subjects, bioequivalence with Sprycel was achieved. In the study on fasting subject's lower absorption was achieved, however the effect was not enough to achieve bioequivalence. The bioequivalence studies with a more modified version of HyNap-Dasa, the "C" formulation, is scheduled to commence in Q2 with preliminary results in Q3 2021. This formulation will further lower the absorption levels as displayed in laboratory testing.

The current HyNap-Dasa tablet formulations and bioequivalence studies are:

- HyNap-Dasa "A", the first formulation, where the results were announced in the second half of 2020 and in January 2021
- HyNap-Dasa "B", the minor modification of tablet formulation that is now being tested
- HyNap-Dasa "C", the larger modification of the tablet formulation; bioequivalence studies are scheduled to commence in Q2

"With this tablet formulation, HyNap-Dasa "B", we have succeeded in lowering absorption compared to the previous formulation, but not enough to achieve bioequivalence for the fasting group. The results confirm that we are working with the correct formulation tools but show that we need to make larger modifications to reduce the uptake of dasatinib in order to compensate for the low absorption of Sprycel. The next study will be conducted with HyNap-Dasa "C", which displayed positive results in laboratory testing. Our opinion is that we now have excellent chances of achieving bioequivalence," says Per Andersson, CEO of Xspray Pharma.

The bioequivalence studies were conducted using the HyNap-Dasa "B" tablet formulation. The results show that the formulation lowers absorption compared to "A", but that formal bioequivalence was not achieved in the study with fasting subjects. As previously, there was great variation in the uptake of dasatinib in the group that received Sprycel®, where several subjects also displayed low absorption of dasatinib. HyNap-Dasa "B" demonstrated a significantly more even uptake, and no subjects displayed low absorption. As previously, bioequivalence was achieved with subjects who received food, with good margins.

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About Xspray Pharma

Xspray Pharma AB (publ) is a pharma 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 55 in December 2020. 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 in two versions, a generic and 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

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 2021-04-08 22:30 CEST.

Attachments

Xspray Pharma announces the results of two bioequivalence studies with adjusted tablet formulation of HyNap-Dasa (ANDA)