Press Release
Stockholm January 22, 2021

Xspray Pharmas study with modified formulation of HyNap-Dasa has now started

Xspray Pharma (Nasdaq Stockholm: XSPRAY) announces today that the new bioequivalence studies with a slightly modified formulation of HyNap-Dasa has started. The studies are conducted on healthy volunteers with the objective to demonstrate that HyNap-Dasa is bioequivalent to the original drug Sprycel® (dasatinib) in order to then be able to submit an application for market approval in the USA, so called ANDA. The preliminary result from this study is expected at the beginning of the second quarter.

The bioequivalence studies consist of two studies, where the first one that has started now, is conducted on fasted healthy volunteers. The second study, starting in early February, is conducted on non-fasted healthy volunteers. In both studies, HyNap-Dasa bioavailability is compared to the original drug Sprycel®.

“Immediately after we received the results from the studies this autumn, we decided to develop new formulations of HyNap-Dasa to achieve bioequivalence. With this large market potential, we want to enter the market as soon as possible. The study with the first formulation, which is slightly modified, has now started. We have a second formulation which is more modified, with study start in the second quarter,” says CEO Per Andersson. “We expect to achieve a lower general absorption for this modified formulation than the results we received last autumn. This is to compensate for the fact that the original drug showed very low absorption in some subjects where our formulation did not.

For further information, please contact:

Per Andersson, CEO, Xspray Pharma AB
Phone: +46 (0) 706 88 23 48
E-mail: per.andersson@xspray.com

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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 and HyNap-Nilo, are stable amorphous versions of the three blockbuster cancer drugs Sprycel® (dasatinib) and Tasigna® (nilotinib). HyNap-Dasa is being developed in two versions, a generic and an improved version. HyNap-Nilo is being developed as an improved version and has has received orphan drug status from the US FDA.

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

Attachments

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