Press Release
Stockholm May 14, 2025

FDA sets PDUFA-date for Xspray Pharma's re-submitted application for Dasynoc®

The U.S. Food and Drug Administration (FDA) has acknowledged receipt of Xspray Pharma's re-submitted NDA (New Drug Application) for Dasynoc®. The re-submission is based on a CRL (Complete Response Letter) received from the FDA in July 2024 where additional information was requested. The FDA has now set the PDUFA date to 7 October 2025, which is the FDA's deadline for communicating its decision on the company's application. Xspray Pharma is now continuing to prepare for the US launch of Dasynoc® with the aim that it can begin as soon as possible if market approval is received in October.

“I am pleased that we now have a PDUFA date, and with that date now set we continue to prepare for a successful launch of Dasynoc® as soon as we receive market approval. At such point we will be ready to offer ALL and CML patients in the US Dasynoc, a dasatinib drug with important advantages compared to today's treatment options,” says Per Andersson, CEO of Xspray Pharma.

The acknowledgement from the FDA was received a week after the FDA was expected to communicate a PDUFA date, but the Authority did not specify a reason for the delay.

For further information, please contact:

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About Xspray Pharma

Xspray Pharma AB (publ) is a pharmaceutical company with several product candidates in clinical development utilizing its innovative, patented HyNap™ technology platform to create improved versions of marketed protein kinase inhibitors (PKI), the largest oncology market segment, often with high drug prices. The company’s goal is to become the market leader in improved PKI’s for cancer treatment. Xspray Pharma's lead drug candidate, Dasynoc®, is currently undergoing FDA review. It is an amorphous form of dasatinib, demonstrating bioequivalence at a 30% lower dose due to a better solubility profile. Its compatibility with proton pump inhibitors (PPIs), which are often co-prescribed to patients with CML and ALL, is a significant advantage. Xspray Pharma is building a robust product portfolio, including XS003-nilotinib (an optimized version of Tasigna®) and XS008-axitinib (an optimized version of Inlyta®) and XS025-cabozantinib (an optimized version of Cabometyx®).

The Xspray Pharma AB-share is trading at Nasdaq Stockholm (Nasdaq Stockholm: XSPRAY). www.xspraypharma.com.

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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 2025-05-14 21:10 CEST.

Attachments

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