Press Release
Stockholm October 8, 2025

Xspray Pharma provides update on the FDA process for Dasynoc – observations at contract manufacturer delay approval

• FDA has issued a Complete Response Letter (CRL) regarding Xspray Pharma's New Drug Application (NDA) for Dasynoc™, referring to GMP (Good Manufacturing Practice) observations at a contract manufacturer. These observations do not concern the Xspray´s production line.

• Xspray discussed the product information for Dasynoc with the FDA up to the PDUFA date. The FDA has now requested information demonstrating that the proposed product information is appropriate.

Xspray Pharma has received a CRL from the U.S. Food and Drug Administration (FDA) concerning the Company's New Drug Application (NDA) for Dasynoc™ (dasatinib) for the treatment of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL).

The FDA's decision is based on GMP (Good Manufacturing Practice) observations at the Company's contract manufacturer. No observations were directed at the production line used for Dasynoc, but the FDA is pausing approvals of new products at the facility while corrective actions are being implemented. The manufacturer has confirmed that a remediation plan is already in place and that a meeting with the FDA is scheduled for December.

"It is unfortunate that manufacturing-related issues beyond our control are delaying our launch. We have made significant progress in the regulatory review and maintained discussions with the FDA regarding the product information for Dasynoc up to the PDUFA date," said Per Andersson, CEO of Xspray Pharma. "We will now work closely with both the manufacturer and the FDA to expedite the process and enable a resubmission as soon as the corrective actions have been completed."

The FDA has also requested information demonstrating that the discussed product information is appropriate and data confirming the outcome of previously implemented corrective actions at the production line.

Other programs
Xspray's other development programs are progressing according to plan. The review of the NDA for XS003 (nilotinib) is expected to be initiated by the FDA shortly, with an anticipated PDUFA date in June 2026.

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.

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 2025-10-08 02:40 CEST.

Attachments

Xspray Pharma provides update on the FDA process for Dasynoc – observations at contract manufacturer delay approval