Press Release
Stockholm June 27, 2025

Xspray Pharma Passes FDA Pre-Approval Inspection – Key Regulatory Milestone Achieved for Dasynoc

Xspray Pharma AB (publ) today announces that the U.S. Food and Drug Administration (FDA) has conducted a successful Pre-Approval Inspection (PAI) of the company's manufacturing lines, located at a contract manufacturing partner. The inspection confirms that production of the product candidate Dasynoc is fully compliant with current Good Manufacturing Practice (cGMP) standards, marking a key regulatory milestone.

"The result of the FDA's inspection represents a major milestone on our path toward marketing approval for Dasynoc," said Per Andersson, CEO of Xspray Pharma. "In parallel, and in consultation with the FDA, we have revised the tablet strengths to address previously identified risks of medication error with the reference product. Together, these steps significantly reduce regulatory uncertainty ahead of our October 7 PDUFA date."

Xspray continues to prepare for the commercial launch of Dasynoc—an improved formulation of dasatinib designed to deliver more predictable and consistent exposure, developed for patients with chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL). The proprietary HyNap™ platform is central to these improvements and enables future expansion into additional oncology indications.

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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 2025-06-27 15:55 CEST.

Attachments

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