Press Release
Stockholm February 26, 2026

Xspray Pharma re-submits its FDA application for Dasynoc

Xspray Pharma AB (publ) has re-submitted its application for market approval for Dasynoc® to the U.S. Food and Drug Administration (FDA). Dasynoc® is the company's lead product candidate – an amorphous dasatinib for the treatment of leukemia. The resubmission includes the additional information requested by the FDA. A new PDUFA-date is expected to be set for August 2026 at the latest.

Xspray Pharma has submitted its response to the CRL (Complete Response Letter) received from the FDA in October 2025. The CRL related to the company's NDA application (New Drug Application) for market approval in the United States for Dasynoc, an amorphous dasatinib for the treatment of CML (chronic myeloid leukemia) and ALL (acute lymphoblastic leukemia).

The current resubmission includes additional data specifically designed to address FDA's concerns regarding risk for medication error. A qualitative human factors study has been completed to address this, confirming high prescriber comprehension using the new tablet strengths. The requested documentation confirming the effectiveness of previously implemented manufacturing measures was also submitted.

The GMP-observations in the company's third-party manufacturing facility are being handled by the facility itself, and corrective measures are being implemented. Xspray welcomes the recent acquisition of the facility by Benta Group, a well-established company with core operations in pharmaceutical contract manufacturing and a strong reputation for quality, regulatory compliance and operational standards.

"Although the progress and approval process of the facility is not under our direct control, current information that is available to us reassures us that the issues in the facility will be resolved. We maintain our plan to launch two products, Dasynoc and XS003 nilotinib during the second half of 2026," comments Per Andersson, CEO of Xspray Pharma.

The Dasynoc application will now undergo FDA review. Once the FDA formally confirms acceptance of the application, a new PDUFA date will be announced, expected no later than August 2026.

For further information, please contact:

Jacob Nyberg, IR
Xspray Pharma AB (publ)
Tel: + 46 (0) 70 767 08 83
E-mail: ir@xspray.com

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® and XS003-nilotinib (an optimized version of Tasigna®) are currently undergoing FDA review. Dasynoc 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 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.

Attachments

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