

Xspray Pharma provides regulatory status update for Dasynoc and Nilopki

Xspray Pharma AB (publ) today provides an update on the regulatory status for its two lead product candidates, Dasynoc and Nilopki. The Company reiterates its plan to resubmit the New Drug Applications, NDAs, for both product candidates to the U.S. Food and Drug Administration, FDA, in the fourth quarter of 2026.

Preparations for the resubmission of both NDAs are progressing as expected. Following dialogue with the FDA, Xspray has confirmation that both Nilopki and Dasynoc resubmissions may occur independent of the cGMP status of NerPharMa.

For both Dasynoc and Nilopki, the required additional consecutive commercial-scale batches and related analytics have commenced. For Nilopki, Xspray continues to prepare the necessary documentation to establish dose correspondence with Tasigna® at a dose level relevant only to a patient sub-population with the 96mg.

Xspray's assessment is that the remaining Xspray-controlled activities required for resubmission of both NDAs can be completed in time to support resubmission in the fourth quarter of 2026.

With respect to both NDAs, the cGMP status of Xspray's third-party manufacturing facility, NerPharMa, remains an important part of FDA's approvability assessment. Final facility clearance remains necessary before approval can be granted. NerPharMa has informed FDA that it considers the facility inspection-ready since June 2026. They have completed the CAPA plan agreed with the FDA and communicated this accordingly. What remains is the FDA's assessment. The timing and nature of FDA's next step remain outside of Xspray's control.

"Xspray remains focused on completing the remaining regulatory steps for both Dasynoc and Nilopki as efficiently and comprehensively as possible," says Blake Leitch, CEO of Xspray Pharma. "The corrective work at the manufacturing site has been carried out and reported to FDA, and what remains there is FDA's assessment of it. We continue to target resubmission of both NDAs in the fourth quarter of 2026, while maintaining launch readiness and financial discipline."

Xspray will hold a live-streamed Investor Update in Gothenburg on 2 October 2026, starting 12.30-14.00 CET. Link to follow the Investor Update live: [Click here](#)

For further information, please contact:

Jacob Nyberg, IRO
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, patent protected 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 Nilopki® (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 Nilopki 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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