Press Release
Stockholm November 5, 2026

Xspray Pharma notified that the FDA has commenced an inspection at NerPharMa's manufacturing facility

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) has today been informed by its contract manufacturer NerPharMa that the U.S. Food and Drug Administration (FDA) has commenced an unannounced follow-up inspection at NerPharMa's manufacturing facility in Italy. The inspection relates to the previously identified cGMP observations at the site.

As communicated earlier, approval of the New Drug Applications (NDAs) for Dasynoc® and Nilopki® is subject to the establishment of satisfactory cGMP status at NerPharMa. The Company cannot at this stage assess the duration or outcome of the inspection but welcomes it as an important step in the on-going regulatory process.

Xspray's plan to resubmit both NDAs in the fourth quarter of 2026 remains unchanged. As communicated on 2 October 2026, the FDA has confirmed that the resubmissions of the NDAs for Dasynoc® and Nilopki® may occur independent of NerPharMa's cGMP status.

The FDA generally aims to notify a facility of its final inspection classification within 90 days after an inspection has been conducted. Xspray will inform the market when new material information becomes available.

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, 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.

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 2026-11-05 17:56 CET.

Attachments

Xspray Pharma notified that the FDA has commenced an inspection at NerPharMa's manufacturing facility