Press Release
Stockholm November 20, 2026

Xspray Pharma informs that FDA has completed its inspection of NerPharMa's manufacturing facility

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) has been informed by its contract manufacturing NerPharMa that the U.S. Food and Drug Administration (FDA) has completed its follow-up inspection of NerPharMa's manufacturing facility in Italy. The FDA is expected to determine the facility's inspection classification within 90 days.

Consistent with the FDA inspection procedure, at the conclusion of the inspection, the FDA issued a Form FDA 483 containing observations to which NerPharMa will provide its written response by December 9, 2026. Observations are not graded by the FDA individually and it is not currently possible to determine what the outcome will be of the FDA's holistic assessment of the inspection and the manufacturer's actions. Nerpharma has confirmed that none of the observations specifically refer to Xspray's manufacturing lines or the manufacturing of Dasynoc® or Nilopki®.

The FDA is expected to determine the facility's inspection classification within 90 days, i.e. around mid-February 2027.

NerPharMa has confirmed that the work to address the observations is already under way. NerPharMa is fully committed to address the observations and will submit its response to the FDA by December 9, 2026.

"*While we emphasize that the FDA has not yet reached a decision regarding the manufacturer's cGMP status, we are encouraged by NerPharMa's commitment and pleased that the FDA process is progressing with a clear timeframe ahead. We will continue to work closely with NerPharMa and support them where appropriate. We remain focused on completing the work required to resubmit the NDAs for Dasynoc and Nilopki and anticipate the FDA's decision regarding NerPharMa*," says Blake Leitch, CEO of Xspray Pharma.

The plan to resubmit both NDAs during the fourth quarter of 2026 remains unchanged.

Xspray Pharma will inform the market when material new information is 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 2026-11-20 16:13 CET.

Attachments

Xspray Pharma informs that FDA has completed its inspection of NerPharMa's manufacturing facility