Press Release
Stockholm August 19, 2026

Xspray Pharma receives Complete Response Letter (CRL) from FDA for Dasynoc

The FDA's Complete Response Letter relates to the previously communicated observations at NerPharMa, concerning outstanding GMP (Good Manufacturing Practice) observations, as well as a request for additional commercial scale consecutive batch data following already implemented corrective actions. Importantly, the FDA has not raised questions regarding Dasynoc's clinical data, bioequivalence or stability. Furthermore, the risk of medication error raised in previous CRLs has been resolved.

NerPharMa, the Company's third-party manufacturer, has completed and announced to the FDA that its remediation work at the facility is complete. The FDA has yet to determine if a reinspection is required for the agency to finalize their assessment of the facility's status.

Since Xspray's launch planning necessitated additional commercial scale batches to be produced, the manufacture of these batches will now be prioritized to satisfy the FDA's request for additional data.

Xspray intends to resubmit the application as soon as possible within 2026 to secure a new PDUFA date and subsequently accelerate the launch.

Blake Leitch, CEO of Xspray Pharma, comments:
"The CRL confirms that the remaining uncertainty is now linked to NerPharMa sufficiently addressing the FDAs observations at their manufacturing site and batch data from consecutive manufacturing runs being provided. As expected, this will require a NDA resubmission.

We had already targeted to proceed with commercial manufacturing as part of our operational plan. We will accelerate this step to ensure a resubmission will occur this as soon as possible in 2026 while simultaneously remain focused on working with our partner to ensure that the remaining FDA requirements of NerPharMa can be met as efficiently as possible.

The CRL does not change the company's financial position as communicated in the recent Q2-report and we will continue to ensure the right balance between financial discipline and execution readiness as a key priority."

Xspray will continue preparing for commercial launch in the United States, so that the Dasynoc can rapidly reach oncologists and patients with CML and ALL once all regulatory conditions have been fulfilled.

About Dasynoc
Dasynoc is Xspray's product candidate based on dasatinib, an established treatment for, among other indications, chronic myeloid leukemia and acute lymphoblastic leukemia. Dasynoc is developed using Xspray's patented HyNap technology and is an amorphous formulation of dasatinib.

The product candidate has demonstrated bioequivalence at a 30 percent lower dose and is designed to enable concomitant use with acid-reducing medicines, a common co-medication that may affect the absorption of conventional dasatinib.

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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 2026-08-19 03:17 CEST.

Attachments

Xspray Pharma receives Complete Response Letter (CRL) from FDA for Dasynoc