Press Release
Stockholm March 11, 2026

Xspray Pharma: FDA accepts resubmitted application for market approval of Dasynoc® – PDUFA date August 25, 2026

The U.S. Food and Drug Administration (FDA) has accepted Xspray Pharma's resubmitted New Drug Application (NDA) for Dasynoc® for review under the 505(b)(2) procedure. The FDA has set a PDUFA date of August 25, 2026, which is the date when the agency is expected to announce a decision on the application. Xspray thus plans to be able to launch both Dasynoc and the drug candidate XS003 (nilotinib) in the second half of 2026.

Dasynoc is an improved formulation of dasatinib (Sprycel®) for the treatment of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL), developed on Xspray's proprietary HyNap™ platform. Studies confirm that Dasynoc is unaffected by the stomach's pH value, provides a more even and consistent absorption in the body compared to the reference product, and can be administered at a 30 percent lower dose.

The resubmission of the NDA for Dasynoc follows the FDA's previous request for additional information. In the latest process, the FDA has clearly specified survey studies and documentation required to address the previously identified risk of medication error, providing a clearer and more predictable regulatory process going forward. Xspray has conducted the requested studies according to the agency's instructions and has submitted the results within the scope of the application that has now been accepted.

During the application process, Xspray has also conducted scientific studies, published clinical data and established advisory expert groups with leading CML specialists in the US. This work has improved clinical understanding for the product and strengthened the company's commercial readiness for a potential launch.

"We have not been standing still, on the contrary, time has given us the opportunity to build close relationships with leading KML specialists in the United States. This has resulted in broad clinical support ahead of launch, which we believe can be decisive for a quick uptake in the market. With Dasynoc and XS003, we now have two drug candidates with PDUFA dates in 2026, approximately two months apart, enabling a coordinated launch within the same indication in the US market. Together, they address a market of approximately USD 2.7 billion," comments Xspray Pharma's CEO Per Andersson.

The previously communicated GMP-related observations against the company's third-party manufacturer remain. The responsibility for resolving these issues rests with the facility's new owner Benta Group, who themselves emphasize the importance of quality and regulatory compliance. Measures are being implemented with the goal of getting the facility approved for new drugs in time for Xspray's launch plans. Xspray is in close dialogue with the facility's new owners.

"The resubmitted application is based on the amendments previously requested by the FDA, and we are now fully focused on preparations for a potential launch of both products in the second half of 2026. Dasynoc and XS003 have shown an improved pharmacokinetic profile in

clinical studies compared to their respective reference drugs. We are now looking forward to establishing HyNap™ as a leading platform and developing more products that significantly improve the lives of chronically medicated cancer patients," says CEO Per Andersson.

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 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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