Press Release
Stockholm April 14, 2026

FDA accepts trade name Nilopki® for Xspray's drug candidate XS003 (nilotinib)

The US Food and Drug Administration (FDA) has accepted Nilopki® as the proprietary name for Xspray Pharma's drug candidate XS003 (nilotinib). Nilopki is an improved, amorphous formulation of nilotinib (Tasigna®) for the treatment of chronic myeloid leukemia (CML), developed on Xspray's proprietary HyNap™ platform. Upon market approval, Xspray plans to launch Nilopki® in the US during the secont half of 2026, coordinated with the planned launch of Dasynoc®.

Xspray Pharma's application for market approval (NDA) for Nilopki® is under review by the FDA with a PDUFA date of June 18, 2026. The application is made under the 505(b)(2) procedure with Tasigna® as the reference product. Nilopki® is developed on Xspray's proprietary HyNap™ platform and is an improved version of the reference product Tasigna®.

“The name Nilopki® gives our nilotinib candidate a clear identity ahead of a possible approval and an upcoming launch,” says Per Andersson, CEO of Xspray Pharma. “With Dasynoc® and Nilopki®, we have the opportunity to launch two enhanced CML drugs in the US in the second half of 2026, subject to market approval. Because both reach the same prescribers and the same patients, we get full leverage on our commercial organization from day one.”

Two crucial advantages of Nilopki®
Nilopki® effectively eliminates the requirement for fasting at dosing that currently forces Tasigna® patients to abstain from food for up to six hours per day, one of the biggest challenges for adherence to CML treatment. The requirement is found in Tasigna's boxed warning because concomitant food intake results in an 82 percent increase in exposure and thus an increased risk of heart rhythm disturbances (QT prolongation).

In clinical studies in healthy volunteers, Nilopki® has shown reduced food interaction to 29 percent, which would be the lowest on the market if approved. Nilopki® is expected to be taken with or without food. The food interaction warning is thus expected to be removed from Nilopki’s® boxed warning.

The benefit profile is made possible by a simultaneous dose reduction. Nilopki® has demonstrated matching bioavailability at 52 percent lower dose, thanks to the improved properties of the HyNap™ platform. A patient who currently takes 800 mg of Tasigna® per day can get the same uptake in the blood with Nilopki® with 384 mg. The rest today passes straight through the body.

Two CML products, one coordinated launch
Xspray’s lead drug candidate Dasynoc® (dasatinib) is also being reviewed by the FDA, with a PDUFA date of August 25, 2026, for the treatment of CML and acute lymphoblastic leukemia (ALL). Upon market approval, Xspray plans to launch both products in the US in the second half of 2026. The launch plan assumes that the previously communicated GMP-issues at the contract manufacturer NerPharMa have been addressed prior to the FDA’s decision, in line with what the company previously reported.

Since both target the same CML prescribers and the same patient population, a coordinated rollout creates clear synergies in areas such as market access, sales and patient support programs, where Xspray has a well-established collaboration with EVERSANA. Xspray thus addresses the entire US CML market, which in 2025 had sales of approximately USD 6.6 billion and grew by about 12 percent.

About Xspray Pharma
Xspray is building a portfolio of enhanced, amorphous versions of established protein kinase inhibitors (PKIs) in oncology. In addition to Dasynoc® and Nilopki® – both for CML – the portfolio includes XS008 (axitinib) and XS025 (cabozantinib) for kidney cancer. Nilopki® has been granted orphan drug designation by the FDA for CML.
The shares in Xspray Pharma AB are traded on Nasdaq Stockholm (Nasdaq Stockholm: XSPRAY). www.xspraypharma.com

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Attachments

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