Press Release
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Xspray Pharma Receives CRL from U.S. FDA for Nilopki™

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY), a pharmaceutical company leveraging its proprietary HyNap™ technology platform to develop improved versions of marketed protein kinase inhibitors (PKIs) for cancer treatment, has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for Nilopki™, an optimized formulation of nilotinib. The company will address remaining questions with FDA; long#term strategy and HyNap™ platform remain unchanged.

The FDA has determined that they are currently not able to approve the NDA based on three reasons. Firstly, they require that each Tasigna dose level must have a single corresponding Nilopki dose level starting from a dose with an exposure similar to the Tasigna 200 mg. Secondly, the FDA has requested more data to adequately demonstrate commercial manufacturing capability of nilotinib ASD batches. Thirdly, as previously communicated, Xspray's third-party manufacturer needs to provide satisfactory responses to FDA's inspection findings and a pre-approval inspection of the facility related to Xspray's manufacturing may need to be conducted.

Xspray will now carefully analyze the CRL in detail and seek clarification where needed in dialogue with the FDA and industry experts.

Xspray Pharma's CEO Blake Leitch commented:
"Receiving a CRL is of course not the outcome we were hoping for, especially considering the advanced state of labeling discussions we have had with FDA since March this year, but we will address these product specific issues with the goal of resubmitting as soon as possible," says Blake Leitch, Chief Executive Officer of Xspray Pharma. "Our immediate priority is to fully understand the FDA's comments, address the remaining questions together with our partners and determine the most efficient path towards launching Nilopki. Although we now believe a launch of Nilopki within this year is unlikely, we remain confident in Nilopki's profile and in the long#term value of our HyNap#based pipeline for patients and shareholders."

Xspray's broader strategy and pipeline remain unchanged. The Company continues to progress its portfolio of HyNap#based product candidates targeting established PKI therapies, including Dasynoc®, for which the NDA is currently under review with PDUFA-date set to August 25, 2026. The Company will update the market on timing and next regulatory steps for Nilopki™ once it has completed its review of the CRL and aligned with the FDA on the way forward.

About Nilopki™
Nilopki™ is Xspray's HyNap#based, improved formulation of nilotinib, developed as an improved version of Tasigna® for the treatment of chronic myeloid leukemia. It is designed to address well#recognized limitations of current nilotinib therapy. 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. Nilopki™ has demonstrated matching bioavailability at 52 percent lower dose, thanks to the improved properties of the HyNap™ platform.

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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 2026-06-05 00:56 CEST.

Attachments

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