Press Release
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Xspray Pharma provides regulatory update on its US product candidates Nilopki® and Dasynoc® and notes continued progress with its third-party manufacturer NerPharMa

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) provides an update on the FDA review of its two US new drug applications. For Nilopki®, Xspray has defined an approach to address the items raised in the Complete Response Letter (CRL) of 4 June 2026 and has requested a Type A meeting with the FDA, expected within the next 30 days. For Dasynoc®, the FDA is conducting labeling review at a stage typically reached in the later part of the review cycle, ahead of the PDUFA date of 25 August 2026.

Separately, the FDA has accepted Xspray's request for a Type C meeting to discuss a potential labeling enhancement for Dasynoc®. The proposed enhancement, suggested by Xspray following an advisory board with leading international CML specialists, could, if supported by the FDA, further strengthen Dasynoc®'s clinical value.

Nilopki®
When the FDA issued the Complete Response Letter, the FDA had not yet conducted an inspection of the manufacturing site and a satisfactory CGMP status of the contract manufacturer remains to be established. The CRL also identifies two additional regulatory items: dose correspondence with Tasigna® at a dose level relevant only to a patient sub-population and a request for additional information from commercial-scale manufacturing batches that were already planned. Importantly, the FDA has not raised questions regarding the stability package or the overall clinical data supporting the Nilopki® application. Xspray has requested a Type A meeting with the FDA, expected within 30 days, to confirm this approach before implementing the proposed response strategy.

Dasynoc®
The FDA is conducting labeling review for Dasynoc®, including the prescribing information and product labeling. The comments received in June relate to language, format and design, and have already been addressed in accordance with FDA's suggestions. Since the re-submission of the NDA, the FDA has not raised any questions relating to the product quality section of the application. Review of prescribing information and product labeling is typically conducted during the later stages of an NDA review cycle. The PDUFA date for Dasynoc® is 25 August 2026. As previously communicated, approval remains subject to establishment of satisfactory CGMP status at the contract manufacturer.

Xspray CEO Blake Leitch commented:
“The remaining regulatory activities across both programs are well defined, and we continue to have productive dialogues with the FDA. A common item to both programs is the inspection status at our contract manufacturer, NerPharMa. Following a recent meeting with NerPharMa's new owners, Benta Group, we were informed that NerPharMa’s manufacturing operation was recently inspected by the Italian Medicines Agency (AIFA). According to Benta Group, the

inspection had a positive outcome, and a follow-on FDA inspection is anticipated. I am confident that we are making enhanced progress and await further communication from the FDA for potential inspection at NerPharMa.

On Dasynoc, the FDA's detailed work on the prescribing information and labeling is consistent with the later stages of an NDA review cycle. On Nilopki, our dialogue with the FDA was already advanced before the CRL, and we have defined a clear path to address the items raised and requested a Type A meeting to confirm it."

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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.

Attachments

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