Press Release
Stockholm October 21, 2025

Xspray Pharma: FDA accepts New Drug Application for XS003 (nilotinib) for the treatment of CML – PDUFA date set for June 18, 2026

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) announces that the U.S. Food and Drug Administration (FDA) has accepted the company's New Drug Application (NDA) for XS003 (nilotinib) for review under the 505(b)(2) regulatory pathway. The FDA has set a PDUFA date to June 18, 2026, which is the date by when the agency is expected to announce a decision on the application.

XS003 is an improved formulation of nilotinib (Tasigna®) for the treatment of chronic myeloid leukemia (CML), developed using Xspray's proprietary HyNap™ technology. Data demonstrate bioequivalence to the reference product at less than half the dose, as well as a significantly reduced food effect (29% compared to 82% for Tasigna). The food effect associated with the reference product complicates patient adherence and is related to the requirement that the patient must be in a fasting state, which is included in its so-called "boxed warning" regarding QTc prolongation and the risk of sudden death. The significantly reduced food effect with XS003 means it is expected that it may be taken with or without food and thereby avoid warning text regarding food interaction. Any final labeling and related warnings will be determined by the FDA during the review process.

"The FDA's decision to accept our NDA for review marks an important milestone," says Per Andersson, CEO of Xspray Pharma. "With two product candidates under FDA review, we are demonstrating that the HyNap™ platform has broad applicability and the potential to deliver more improved TKIs to the market."

Together with the company's first product candidate Dasynoc, XS003 addresses a U.S. market of approximately USD 2.7 billion. The FDA's notification confirms that the application is complete and that a full review is now underway. XS003 is manufactured at the same external facility as Dasynoc.

"Since the FDA now has a solid understanding of our manufacturing process, I am confident that the upcoming Pre-Approval Inspection will be completed without observations. It is essentially the same process that has previously been inspected. Furthermore, we are working closely with the manufacturer to ensure that all planned improvements to the other parts of the facility that previously received observations are completed well ahead of the PDUFA date," comments CEO Per Andersson.

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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, patented 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®, is currently undergoing FDA review. It 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 (an optimized version of Tasigna®) 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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