Press Release
Stockholm August 19, 2025

Xspray Pharma Submits XS003 to the FDA – The Company's Second Product Candidate from the HyNap Platform

Xspray Pharma (Nasdaq Stockholm: XSPRAY) has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its product candidate XS003 (nilotinib) for the treatment of chronic myeloid leukemia (CML). The application is based on successful studies demonstrating bioequivalence with the reference product Tasigna®. XS003 demonstrates the lowest documented food interaction within the nilotinib class and improved dose linearity, which gives physicians greater predictability when adjusting the dose, enabling more consistent exposure and potentially reducing the risk of side effects. Due to XS003's improved food interaction profile, the warning about three hours of fasting, currently included in the reference product's so-called boxed warning, is not expected to apply to XS003. This may simplify treatment and improve adherence.

XS003 is an improved formulation of nilotinib (Tasigna®) and developed using the company's proprietary HyNap™ technology.

"Patients with chronic leukemia live not only with their disease—but also with side effects from medications, often related to food interaction and concomitant treatments. Our proprietary HyNap technology addresses these challenges and may help improve treatment outcomes and quality of life for this patient group. Our goal is to develop and commercialize a portfolio of next-generation Protein Kinase Inhibitor products with stable absorption, low variability, and minimal food interaction. With XS003, we now have two product candidates under FDA review with strong clinical potential, addressing a total U.S. market worth USD 2.7 billion," says Per Andersson, CEO of Xspray Pharma.

Data from registration studies demonstrate bioequivalence with the reference product, despite XS003 being administered at less than half the dose of the reference product. In addition, the studies confirm clearly improved dose linearity, which may provide physicians with better predictability when adjusting doses, and thereby a greater ability to achieve improved treatment outcomes. The uptake of XS003 is only slightly affected when taken with food, while the reference product is significantly affected as reflected in their label (28% vs. 82%). This may indicate improved control and a lower risk of side effects when taken with food.

Xspray expects the FDA to initiate its review within 60 days, with a regulatory decision anticipated approximately eight months thereafter.

Global 2024 nilotinib sales reached USD 1.67 billion in 2024, of which USD 850 million came from the U.S.

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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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