Press Release
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XSpray Pharma achieves significant milestone – demonstrating bioequivalence with absorption advantages compared to Tasigna

Xspray Pharma has now completed the population pharmacokinetic (PopPK) modeling that constitutes key regulatory documentation ahead of submitting a New Drug Application (NDA) for the product candidate XS003. The analysis confirms bioequivalence with the reference drug Tasigna®, at less than half the dose – a strong indication marking a potential paradigm shift in the treatment of CML with nilotinib.

The analysis is based on modeling and simulation of data from a comparative study in healthy volunteers. The developed PopPK model, which simulates repeated dosing until steady state is reached, shows a strong correlation with observed concentrations – supporting its regulatory relevance.

The results confirm formal bioequivalence between XS003 and Tasigna in terms of systemic exposure (AUC and Cmax) – despite the XS003 dose being less than half that of the reference drug. In addition, a clinical study has shown that XS003 has significantly improved food interaction and a more predictable dose response, which can facilitate precise dose adjustments in clinical practice. Previously communicated data showed that bioavailability increased by only 28% with food intake – compared to up to 82% for Tasigna. This absorption stability with food intake may reduce the risk of concentration-dependent side effects, such as abnormal heart rhythm (QTc prolongation), particularly in real-world settings where strict fasting can be difficult to maintain

“The data announced today form the pivotal foundation for our regulatory submission with XS003, this confirms our HyNap™ platform which can create bioequivalent improved formulations with significantly lower dosing and stable absorption even with food intake. This represents a crucial step forward in our strategy to expand the commercialization of our products,” says Per Andersson, CEO of Xspray Pharma.

With these results, Xspray Pharma plans to submit a NDA application in the near future. XS003 will be the company’s second product candidate submitted for FDA approval following Dasynoc, both based on the HyNap™ technology: An innovative amorphous formulation technique that has shown potential to improve absorption for a range of products including protein kinase inhibitors.

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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.

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 2025-07-11 14:10 CEST.

Attachments

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