Press Release
Stockholm July 9, 2024

Xspray Pharma's XS003 Study shows Matching Bioavailability to Tasigna at more than a 50% Lower Dose

Xspray Pharma provides an update on its second product candidate, XS003: New data shows matching bioavailability to Tasigna® at more than a 50% reduced dose.

Stockholm, Sweden, July 9, 2024 – Xspray Pharma AB (Stockholm/Nasdaq: XSPRAY), a biotechnology company focused on developing improved protein kinase inhibitors (PKIs) for cancer treatment using its proprietary HyNap™ technology, announced today new clinical data from its XS003 registration study program. XS003 is an amorphous, non-crystalline formulation of nilotinib designed to overcome significant limitations of currently marketed crystalline formulations. In the announced study, XS003 demonstrates matching bioavailability to Tasigna, with a 50% reduced dose.

XS003 is designed to reduce food interactions for nilotinib, that currently complicate prescribing and adherence to existing therapies which may increase the risk of sudden death caused by prolongation of the QTc interval, for which Tasigna carries a boxed warning.

"We are very pleased with the progress of our second product candidate, XS003. Our goal is to complete the pivotal clinical program within this year and submit the approval application to the FDA in the first half of 2025. This represents a slight delay caused by an unexpectedly long processing time by the authority in the study country, which has now been resolved.", said Per Andersson, PhD, CEO of Xspray Pharma.

Crystalline PKI formulations often lead to a substantial portion of the drug being unabsorbed and excreted, ending up in the sewage system. The results show that the XS003 amorphous formulation of nilotinib uses less than 50% of the active ingredient compared to crystalline forms. Thus, there is significantly less excess material available for overdosing, potentially making it a safer drug.

About XS003
XS003 demonstrated these results in a comparative bioavailability study involving healthy volunteers. It is Xspray's second product candidate developed using the HyNap™ technology. XS003 is being developed under the 505(b)(2) NDA process, which streamlines the approval process, and is expected to be submitted to the FDA in the first half of 2025. In 2020, XS003 received orphan drug status from the FDA for the treatment of chronic myeloid leukemia (CML). US sales for Tasigna approached $1.2 billion in 2023.

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About Xspray Pharma

Xspray Pharma AB (publ) is a pharmaceutical company focused on the development of improved PKIs for cancer treatment, leveraging its proprietary HyNap™ technology platform. The company aims to enhance clinical outcomes for cancer patients by improving the efficacy, safety, and patient experience of existing cancer therapies. Xspray Pharma's shares are traded at Nasdaq Stockholm (Nasdaq Stockholm: XSPRAY). For more information about Xspray Pharma AB and its innovative approach to cancer treatment, please visit 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 2024-07-09 17:15 CEST.

Attachments

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