

Xspray presents novel scientific data for XS004 in the Chronic Myeloid Leukemia (CML) session at the 2022 Meeting of the American Society of Hematology

Xspray Pharma AB (NASDAQ Stockholm: XSPRAY), a biopharmaceutical company focused on developing high performing, amorphous forms of tyrosine kinase inhibitors (TKIs), has presented two posters examining the pharmacokinetics of XS004-dasatinib in healthy volunteers at the 64th Annual Meeting of the American Society of Hematology (ASH), December 10-13 in New Orleans, USA.

“The treatment of CML has been revolutionized by tyrosine kinase inhibitors (TKI), but many patients are still not receiving their full clinical benefit. Our data suggest that the amorphous solid dispersion formulation of dasatinib - XS004, produced with HyNap technology, have the potential to reduce variability in drug exposure and unleash the full therapeutic power of TKI for more patients. We are pleased with the opportunity to present our findings for XS004 to the international CML community at ASH, the world’s largest and leading conference venue in hematology”, says Thomas Walz, CMO of Xspray Pharma.

Xspray in collaboration with researchers from Uppsala University & Karolinska University Hospital, presented two posters examining the pharmacokinetics of XS004. Dr Larfors et al demonstrated that the absorption of XS004 is less pH-sensitive than of crystalline dasatinib, showing that XS004 may be more compatible for comedication with acid-reducing agents. In a separate presentation, Dr Lennernäs et al shared data from a phase 1 bioavailability study demonstrating that the inter- and intrasubject variability in drug plasma concentration was reduced for XS004, relative to crystalline dasatinib. The improved biopharmaceutical properties of XS004 may lead to reduced exposure outside the therapeutic window with the potential to decrease the risk of adverse events and optimize the therapeutic efficacy of dasatinib.

“The concomitant use of TKIs and acid-reducing agents is widespread in CML. By reducing the pH sensitivity of TKIs we believe this can assist more patients to benefit from the treatment,” says Per Andersson, CEO of Xspray Pharma.

The 2 posters are available for download:

- Comedication of Proton Pump Inhibitors and Dasatinib Is Common in CML but XS004, a Novel Amorphous Solid Dispersion Formulation of Dasatinib, Provides Improved Uptake and Low pH-Dependency, Minimizing Unwanted Drug-Drug Interactions
- XS004 Dasatinib (XS004) Improves Variability and Bioavailability in Humans Using Amorphous Solid Dispersion Formulation of Dasatinib with Potential Implications for Its Clinical Use

“I believe these results are an important step forward in addressing real-world challenges associated with crystalline TKIs,” said Dr Leif Stenke of the Karolinska University Hospital.

The US Food and Drug Administration (FDA) has granted XS004 orphan drug designation in the use of the treatment of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL). XS004 is currently under FDA review for market approval under the 505(b)(2) NDA regulatory pathway.

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About Xspray Pharma

Xspray Pharma AB (publ) is a pharmaceutical company with several product candidates in clinical development. Xspray Pharma uses its innovative, patented RightSize™ technology to develop improved versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. The segment is the second largest in oncology, and drug prices are very high.

The company's innovative technology allows Xspray Pharma to gain entry as the first competitor to today's original drugs before the secondary patents expire. Xspray's goal is to become the leader in the development of improved drugs of PKIs already marketed for the treatment of cancer, which numbered to 72 in the end of 2021.

The company has patented manufacturing technology, equipment, and the resulting products. The shares in Xspray Pharma are traded on Nasdaq Stockholm (Nasdaq Stockholm: XSPRAY). www.xspraypharma.com

Attachments

[Xspray presents novel scientific data for XS004 in the Chronic Myeloid Leukemia \(CML\) session at the 2022 Meeting of the American Society of Hematology](#)
[Gunnar Larfors Et Al 3013 ASH 2022](#)
[Hans Lennernäs Et Al 4341 ASH 2022](#)