Press Release
Stockholm February 12, 2024

FDA Accepts Xpray Pharma's NDA-resubmission for Dasynoc® – PDUFA Date set to 31 July

Stockholm, Sweden – Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY): The U.S. Food and Drug Administration (FDA) has accepted the resubmission of Xspray Pharma's New Drug Application (NDA) for Dasynoc®, following a Complete Response Letter (CRL) where additional information was requested. The FDA has now assigned a Prescription Drug User Fee Act (PDUFA) date to 31st of July, 2024. This is the FDA's deadline for completing the approval process, marking a significant milestone for Dasynoc®, Xspray's innovative protein kinase inhibitor (PKI) product candidate for CML treatment.

With the PDUFA date set to 31st of July, Xspray Pharma continues to strategically plan for the commercial launch of Dasynoc® on September 1, 2024. These dates align with the company's comprehensive preparation following the patent litigation settlement with Bristol Myers Squibb (BMS), paving the way for Dasynoc® to become a new option for chronic myeloid leukemia (CML) treatment pending FDA approval.

"With the new time line communicated by the FDA, I am pleased to confirm that Xspray Pharma is on track to launch our lead product candidate Dasynoc® on September 1, as previously communicated. We appreciate the FDA's diligent review of our resubmission and look forward to collaborating closely with the agency in the lead-up to the PDUFA date," said Per Andersson, CEO of Xspray Pharma AB. "Our team is fully committed to addressing the FDA' s requirements and ensuring that healthcare providers and patients have clear, comprehensive information on Dasynoc®'s dosing and administration."

Dasynoc®, an optimized version of dasatinib, highlights Xspray Pharma's dedication to advancing cancer treatment through innovative drug formulations. The product candidate has the potential to become a best-in-class product with a strong patent position for amorphous dasatinib products with improved properties for patients with CML. As the PDUFA date approaches, the company remains focused on its goal to improve the lives of those affected by CML with this novel therapy.

Forward-Looking Statements
This press release contains forward-looking statements regarding the regulatory approval process and potential commercial launch of Dasynoc®. Actual results may vary based on the FDA's final decision and other factors.

Press Release
Stockholm February 12, 2024

For further information, please contact:

Kerstin Hasselgren
Senior Advisor and IRO
Xspray Pharma AB
Mob: +46 (0) 70 311 16 83
E-mail: kerstin.hasselgren@xspray.com

About Xspray Pharma

About Xspray Pharma AB

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 2024-02-12 07:59 CET.

Attachments

FDA Accepts Xpray Pharma's NDA-resubmission for Dasynoc® – PDUFA Date set to 31 July