

## Xspray Pharma re-submits its FDA application

**Xspray Pharma AB (publ) has re-submitted its application for market approval for Dasynoc®, the company's lead product candidate, an amorphous dasatinib for the treatment of leukemia. The application procedure thus runs according to the most recently communicated plan. Within 2-4 weeks, the FDA is expected to announce a new PDUFA date, i.e. the date they intend to decide on the application.**

Xspray Pharma has submitted its response to the CRL (Complete Response Letter) that the company received from the FDA in July 2024. The CRL addressed the company's NDA application for market approval in the US of the product candidate Dasynoc, an amorphous dasatinib drug for the treatment of CML (chronic myeloid leukemia) and ALL (acute lymphoblastic leukemia). The response will now be reviewed by the FDA, which can apply two different processing times – two or six months from the re-submission date.

“Manufacturing and quality review of new tablet batches, which were required to address the FDA’s questions, have gone according to plan at Xspray’s US contract manufacturer, and live up to all the set quality requirements,” says Per Andersson, CEO of Xspray Pharma. “We are well prepared to launch Dasynoc on the US market upon approval later this year,” says Per Andersson.

The submission of the updated FDA application follows the plan communicated in January of this year. Xspray Pharma reiterates the assessment that the company has sufficient funding to take Dasynoc to approval, regardless of whether the FDA’s review takes two or six months from the re-submission.

### **For further information, please contact:**

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### **About Xspray Pharma**

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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](http://www.xspraypharma.com).

## Attachments

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