**Press Release**
Stockholm July 11, 2023

# Xspray Pharma receives request for additional information concerning Dasynoc from FDA

**Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) announces an update on recent developments regarding the company's first product, Dasynoc, currently under review by the United States Food & Drug Administration ("FDA"). The company has received a Complete Response Letter ("CRL") whereby the FDA request additional information particularly regarding additional information to doctors and users related to Dasynoc dosinga and a third-party manufacturing facility. At the same time, the CRL accepted critical aspects of the application as it did not identify any deficiencies with the stability or clinical data submitted to the FDA to date.**

"It's reassuring that the CRL confirms the stability and clinical data of Dasynoc. As the review of our New Drug Application continues, we will work together with FDA and our third-party production facility in order to ensure a swift handling of the outstanding questions. As we further review and evaluate, we will announce up-dates if and when we see any deviations from our previously communicated plans," comments Xspray Pharma CEO Per Andersson.

On July 10, Xspray Pharma received a Complete Response Letter ("CRL") relating to its Dasynoc New Drug Application ("NDA") for all six strengths (15 mg, 36 mg, 50 mg, 57 mg, 70 mg, and 100 mg) under review by FDA. In the CRL, the agency noted that the agency received Xspray's amendment filed on January 10, 2023, which was a complete response to FDA's prior action letter issued September 1, 2022.

In the CRL, the FDA accepted Xspray's proposed product name, Dasynoc, and did not identify any deficiencies with the stability or clinical data submitted in support of the NDA to date. The FDA, however, did request that Xspray provide additional information to doctors and users to avoid confusion about the proper dosing of Dasynoc.

Patient safety is always a primary concern for Xspray, which developed Dasynoc to have no interference when used with PPIs. Whereas, the label for Bristol-Myers Squibbs's Sprycel® instructs that Sprycel® should not be administered with H2 antagonists or proton pump inhibitors. Xspray will compile the requested information to mitigate any risk of dosing confusion. In light of this, the FDA's review of the Dasynoc label remains ongoing. The CRL also informed Xspray that the inspection and review of a third-party manufacturing facility is ongoing, and the CRL also requested that Xspray provide additional information in support of its NDA. Xspray will promptly compile all the information requested by FDA.

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## About Xspray Pharma

Xspray Pharma AB (publ) is a pharmaceutical company with numerous product candidates in clinical development, utilizing its innovative, patented HyNap-technology to create improved versions of marketed protein kinase inhibitors (PKI), the largest oncology segment often with high drug prices. The company's goal is to become a market leader of enhanced PKIs for cancer treatment. Xspray Pharma's primary drug candidate, Dasynoc (XS004-dasatinib), is currently undergoing FDA review. It is an amorphous form of dasatinib, demonstrating bioequivalence at a 30% lower dose because of better solubility profile. Its compatibility with proton pump inhibitors (PPIs), commonly co-prescribed to chronic myeloid leukemia patients, provides 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®).

Xspray Pharma's shares are traded 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 2023-07-11 08:50 CEST.*

## Attachments

Xspray Pharma receives request for additional information concerning Dasynoc from FDA