Press Release
Stockholm July 26, 2024

Xspray Pharma Shares New Information on Dasynoc, a Novel CML Treatment in Development

Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY) has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for Dasynoc, a novel treatment for chronic myeloid leukemia (CML) and acute lymphocytic leukemia (ALL). The updated NDA was sent to the FDA on January 31, 2024. In the CRL the FDA requests additional information pertaining to the labeling comprehension and the pre-approval inspection at the third party's manufacturing site, which was conducted 10 to 19 of June, 2024. Importantly, the FDA does not request additional clinical studies, nor does it question any submitted stability or clinical data.

To meet the FDA's requirements, Xspray Pharma will work together with its third-party manufacturer to address the requests relating to the pre-approval inspection. In addition, the FDA has suggested a dialogue in the near term with Xspray to adapt the labeling strategy.

"We are encouraged that the FDA's feedback confirms the stability and clinical data of Dasynoc. While the additional requests from the FDA were unexpected, we are confident in our ability to address these in a timely manner" said Per Andersson, CEO of Xspray Pharma. "This delay of the anticipated September launch is unfortunate as it impacts patients who do not have a viable treatment option when they are prescribed dasatinib and co-medicate with acid reducing agents. Our team remains dedicated to ensure that Dasynoc reaches patients as soon as possible, offering a valuable new treatment option for CML. Xspray welcomes the opportunity to work with the FDA to expedite the resubmission of the NDA. We will revert within the coming weeks with an updated time plan."

About Dasynoc
Dasynoc is an innovative treatment designed for chronic myeloid leukemia (CML) and acute lymphocytic leukemia (ALL). Dasynoc leverages the proven safety and efficacy of dasatinib along with distinct patient benefits driven by Xspray's patented HyNap Technology.

Dasynoc offers bioequivalence at doses 30% less, which means patients are dosed lower. Additionally, bioavailability within patients may be more precise and predictable, ensuring patients get the benefit of their intended dose. Finally, it will be possible to prescribe Dasynoc freely with any acid reducing agent (ARA) including Proton Pump Inhibitors (PPIs), H2 antagonist or antacids.

Co-medication of both Tyrosine Kinase Inhibitors (TKIs) and ARAs is common as was recently highlighted at the American Society of Clinical Oncology, demonstrating that 54% of CML patients, despite a warning, were prescribed a PPI. This is not without potential consequence, as a separate published study demonstrated 5-year overall survival was reduced by 15% in patients who took both a TKI with PPI.

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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 2024-07-26 21:20 CEST.

Attachments

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