Press Release
Stockholm May 24, 2024

Xspray to present data at ASCO highlighting frequent comedication of PPIs with TKIs in CML-patients and greater than expected negative effects on the bioavailability of crystalline dasatinib

i) 54% of TKI-treated CML-patients received a PPI. ii) 66% of concomitant prescribing was by a different healthcare provider. iii) Crystalline dasatinib Cmax and AUC24 reduced by 96% and 88% respectively.

Stockholm, Sweden – Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY), a Swedish pharmaceutical company which uses its innovative Hynap technology to develop 505(b)(2) improved versions of marketed drugs for the treatment of cancer announced today the online publication of its abstract titled *"Frequency of Comedication of Proton Pump Inhibitors with Crystalline Dasatinib in Chronic Myeloid Leukemia and Effects on TKI-Bioavailability"* for presentation at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on June 3rd, 2024 at 9-12 AM, Poster nr. 120 (1).

While Tyrosine Kinase Inhibitors (TKI), including dasatinib, have profoundly improved clinical outcomes in patients with chronic myeloid leukemia (CML), the bioavailability and systematic exposure of the crystalline formulation of dasatinib is reduced by comedication with acid reducing agents which may affect the clinical response and comedication with proton pump inhibitors, such as omeprazole, should be avoided (2).

The collaborative analysis with Uppsala University and the Karolinska Institute and University Hospital demonstrates that 54% of CML patients identified in the Swedish CML-register were prescribed at least one PPI and 34% of TKI-treated patients were comedicated with a PPI. Of those prescribed a PPI, 66% of the prescriptions were by a different healthcare provider. Further, the presentation provides new information on the bioavailability of crystalline dasatinib when comedicated with a PPI, demonstrating a substantially higher than previously reported impact of PPIs on the bioavailability of crystalline dasatinib, with Cmax and AUC24 being reduced by 96% and 88% respectively.

"Consistent absorption and bioavailability of dasatinib are critical for adequate disease control and patient outcomes, this is however often overlooked in clinical practice as our data demonstrates" said Per Andersson, CEO of Xspray. "To address this important issue, we are on track to launch Dasynoc®, our optimized version of dasatinib, with a Prescription Act Use Fee Amendment date (PDUFA-date) of 31st of July 2024 and the US commercial launch of Dasynoc on 1st September 2024".
The abstract is now available online at https://meetings.asco.org/2024%20ASCO%20Annual%20Meeting/15766?presentation=239588#239588

References:
1. Dahlén T, Larfors G, Lennernäs H et al. Frequency of Comedication of Proton Pump

Inhibitors with Crystalline Dasatinib in Chronic Myeloid Leukemia and Effects on TKI-Bioavailability. American Society of Clinical Oncology, Annual Meeting 2024. Chicago. Abstract 6561. Poster 120. https://meetings.asco.org/2024%20ASCO%20Annual%20Meeting/15766?presentation=239588#239588

2. Sprycel® (dasatinib) Tablets for oral use. Labeling, Supplement 27. 02 Aug 2023. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021986. Accessed 22 May 2024.

For further information, please contact:

Kerstin Hasselgren
Senior Advisor & Investor Relations
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.

Attachments

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