

# Xspray Publication Demonstrates High Concomitant PPI and TKI Use in CML Resulting in Risk of Increased Mortality Which May be Mitigated by DASYNOC™

## **Xspray Publication Demonstrates High Concomitant Proton Pump Inhibitor and Tyrosine Kinase inhibitor Use in Chronic Myeloid Leukemia Resulting in Risk of Increased Mortality Which May be Mitigated by DASYNOC™.**

- Nearly half of all chronic myeloid leukemia (CML) patients receiving tyrosine kinase inhibitor (TKI) treatment also receive contraindicated proton pump inhibitors (PPI)
- Risk of death was significantly increased in CML patients taking both TKI and PPI
- DASYNOC (XS004, amorphous, (non-crystalline) dasatinib), a TKI developed by Xspray, features greater solubility than Sprycel® (crystalline dasatinib) resulting in identical blood bioavailability with or without concomitant administration of PPI, in normal healthy volunteers

**Stockholm, Sweden, October 26, 2023** – Xspray Pharma AB (Stockholm/Nasdaq: XSPRAY) a biotechnology company developing improved TKIs for cancer treatment, through its proprietary HyNap™ technology, today announced that CML patients have a high incidence of concomitant PPI and TKI co-administration that increases the risk of mortality. This may be mitigated by an improved amorphous dasatinib formulation that avoids drug-drug interaction and improves pharmacokinetics with concomitant PPI administration. These findings were published in the October issue of the peer-reviewed European Journal of Haematology ([Larfors, et al. Eur. J. Haematol. 2023; 1-11. DOI: 10.1111/ejh.14059](#)).

In collaboration with researchers at Uppsala University and Karolinska Institute, Xspray evaluated the Swedish CML and Prescribed Drug Registers and demonstrated that 47% of 676 TKI-treated CML patients were concomitantly administered PPI, despite labeled contraindications. Of these patients, 5-year survival was 79% as compared with 94% among non-PPI users, resulting in a 3.5-fold increased risk of death (Hazard Ratio, 3.5; 95% Confidence Interval, 2.1-5.3;  $p < 0.0001$ ).

“The finding that concurrent medication with TKIs, such as Sprycel® (crystalline dasatinib), and PPIs are common was highly surprising, especially since there are clear warnings against this practice,” said Gunnar Larfors, MD, PhD, Researcher, Department of Medical Sciences, Hematology, Uppsala University, Sweden, and primary author of the publication. “Co-administration of TKIs and PPIs can lead to reduced availability of the active pharmaceutical substance and therefore its effectiveness. It’s noteworthy that we found lesser 5-year survival and a 3.5-fold increase in the risk of death in those taking both TKIs and PPIs.”

### **Dasynoc has potential to improve outcomes in CML patients**

The bioavailability of DASYNOC (XS004, amorphous (non-crystalline) dasatinib), developed through Xspray’s HyNap technology, was also presented in the publication. In healthy

volunteers, neither the peak blood concentration nor the overall exposure of DASYNOC was affected by co-administration of the PPI, omeprazole; compared with DASYNOC administration alone.

“These results demonstrate that DASYNOC avoids drug-drug interactions with PPIs and has the potential to improve outcomes in CML patients who receive TKIs such as dasatinib, and who also require PPI therapy,” said Per Andersson, PhD, chief executive officer of Xspray. “We look forward to making DASYNOC available to doctors and patients soon. These findings validate Xspray’s HyNap technology which serves as a platform to create and produce drugs with improved bioavailability and fewer interactions with other drugs, leading to clinically important improvements.”

### **About CML and Its Treatment**

CML is a myeloproliferative neoplasm with an incidence of 1–2 cases per 100 000 adults.<sup>1</sup> TKIs are first line treatment for CML. Sprycel (dasatinib) is a leading, oral, second generation TKI, with a 350-fold greater potency than imatinib.<sup>2</sup> Numerous doses of dasatinib have been tested in phase III and IV clinical trials, demonstrating the efficacy and safety of dasatinib when used broadly, including 2-year overall survival of 100%<sup>3</sup> and 5-year survival of 91%.<sup>4</sup>

### **About Xspray and HyNap Technology**

Xspray Pharma AB is a biotechnology company developing improved TKIs for cancer treatment, through its proprietary HyNap technology. HyNap is a patented pharmaceutical technology platform designed to create amorphous, non-crystalline forms of protein kinase inhibitors to improve their pharmaceutical shortcomings and allow for the absorption and bioavailability necessary to unleash their full clinical potential in the treatment of cancer and other diseases, following oral therapy. Xspray’s product portfolio consists of a number of similar improved product candidates for various cancers.

DASYNOC, is Xspray’s most advanced product candidate. The US Food and Drug Administration (FDA) has granted DASYNOC orphan drug status for the treatment of CML. The FDA is currently reviewing DASYNOC for market approval under the so-called regulatory 505(b)(2) NDA process, and the expected launch date for DASYNOC in the US is September 1, 2024. Sales of the original drug, Sprycel, in the US are expected to reach 1.8 billion USD in 2023.

### **Forward Looking Statement**

This press release contains forward-looking statements. Forward-looking statements reflect management’s current knowledge, assumptions, judgment and expectations regarding future performance or events. Although Xspray’s management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual events or results may differ materially from those contained in the forward-looking statements. Words such as “will,” “expect,” “intend,” “plan,” “potential,” “possible,” “goals,” “accelerate,” “continue,” and similar expressions identify forward-looking statements, including, without limitation, statements regarding Xspray’s beliefs relating to the technologies in Xspray’s current pipeline. These forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the risks inherent in Xspray’s lack of profitability and need for additional capital to grow Xspray’s business; Xspray’s dependence on partners to further the development of

Xspray's product candidates; the uncertainties inherent in the development, attainment of the requisite regulatory approvals or authorization for patient use for the product candidate and launch of any new pharmaceutical product; the outcome of pending or future litigation.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You should not place undue reliance on any forward-looking statements, which speak only as of the date of this release. Xspray undertakes no obligation to revise or update any forward-looking statements made in this press release to reflect events or circumstances after the date hereof or to reflect new information or the occurrence of unanticipated events, except as required by law.

**Xspray Media**

Charlotte Wray  
RXMD  
cwray@rxmedyn.com  
646-599-8601

**Xspray Investors**

Kerstin Hasselgren  
CFO Xspray  
kerstin.hasselgren@xspray.com

**References**

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**Attachments**

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