Press Release
Stockholm November 21, 2023

Xspray Pharma's XS003 Achieves Superior Bioavailability Milestone, Matching TASIGNA® at Reduced Dosage

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- **XS003, an amorphous non-crystalline nilotinib, designed to overcome therapeutic limitations of the currently available crystalline formulation of nilotinib (TASIGNA®), is the second protein kinase inhibitor (PKI) product candidate developed with Xspray's HyNap™ technology**
- **TASIGNA is an import treatment for chronic myeloid leukemia (CML), with worldwide sales in 2022 approaching $2.0 billion, despite a labeled warning for food interactions and a boxed warning in the US**
- **New Drug Application (NDA) is expected to be submitted to the US Food and Drug Administration (FDA) in the second half of 2024.**

Stockholm, Sweden, November 21, 2023 – Xspray Pharma AB (Stockholm/Nasdaq: XSPRAY) a biotechnology company developing improved PKIs for cancer treatment, through its proprietary HyNap™ technology, today announced that XS003, its amorphous, non-crystalline formulation of nilotinib, has demonstrated bioavailability within the 80-125% range to TASIGNA® following oral administration with significantly lower dose. This is the second of three announced amorphous PKIs under development by Xspray using the HyNap platform to address critical limitations with currently marketed crystalline formulations.

"Our goal is to submit the NDA to the FDA in the second half of 2024 once all required studies are finalized; such as e.g. food effect and proton pump inhibitor interaction," says Xspray Pharma Chief Executive Officer, Per Andersson, PhD.

"XS003 is designed to reduce food interactions, inherent with TASIGNA, that may increase the risk of sudden death caused by prolongation of the QTc interval, and for which TASIGNA carries a boxed warning. We have now demonstrated that XS003 exhibits improved absorption, matching TASIGNA at lower dose."

About XS003
XS003 demonstrated the results in a comparative bioavailability study involving healthy volunteers. It is Xspray's second product candidate developed using the HyNap technology. XS003 is being developed under the regulatory 505(b)(2) NDA process, which streamlines the approval process, and XS003 is expected to be submitted to the FDA for approval in the second half of 2024. In 2020, XS003 received orphan drug status by the FDA for the treatment of CML. Worldwide sales for TASIGNA approached $2.0 billion in 2022.

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

For additional information
Per Andersson, PhD, CEO
Xspray Pharma AB
Mob: +46 (0) 706 88 23 48
E-mail: per.andersson@xspray.com

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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

Attachments

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