

Xspray Pharma reports strong interim data for product candidate XS003 - confirms plan to apply for market approval in H1 2025

Xspray Pharma AB (publ) today presents interim data from a food interaction study with the nilotinib product candidate (XS003). The results confirm the benefits of the company's patented HyNap™ technology platform and its ability to deliver significant benefits for patients compared to existing PKI drugs.

Key findings from interim data:

- Food interaction and safety: Xspray's amorphous formulation of nilotinib has shown a marked improvement over all currently approved nilotinib products. It eliminates problems with food interaction, a common limitation of the crystalline version. The study shows that bioavailability remains stable and consistent, regardless of food intake. These results confirm that Xspray's product may offer an improved safety profile outperforming the existing approved products, improving patients' quality of life and reducing the risk of serious side effects.
- Innovative technology platform and patent protection: Xspray Pharma is a pioneer in the development of amorphous PKI products and has built a strong patent portfolio around its HyNap™ technology. This offers unique properties that mean clear patient benefits compared to existing nilotinib products. The current study results together with the product candidate's strong patent protection provide unique competitive advantages that enable Xspray Pharma to take considerable market shares regardless of when the original product's patent protection expires.

In previous studies, Xspray's nilotinib product candidate has shown matching bioavailability with Tasigna at more than 50% lower dose. Xspray Pharma is now completing the remaining studies for the nilotinib product candidate and still plans to submit the New Drug Application (NDA) to the FDA in the first half of 2025.

"Xspray Pharma develops PKI products that are 100% amorphous and that improve safety and efficiency for patients. It is gratifying to see that our patented HyNap technology platform continues to show strong results and that we continue to make important progress with several product candidates," says Per Andersson, CEO of Xspray Pharma.

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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.

Attachments

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