Press Release
Stockholm September 19, 2024

Xspray Pharma Announces Positive FDA Meeting and Plans for Dasynoc NDA Resubmission

Stockholm, Sweden – September 19, 2024, Xspray Pharma AB (publ) (Nasdaq Stockholm: XSPRAY), a pharmaceutical company leveraging its proprietary HyNap™ technology to develop enhanced cancer therapies, today announced significant progress following a productive meeting with the U.S. Food and Drug Administration (FDA). The company plans to resubmit its New Drug Application (NDA) for Dasynoc in Q4 2024, incorporating feedback from the Complete Response Letter (CRL) issued by FDA in July 2024. If the FDA sets a two-month review period upon resubmission, the launch of Dasynoc could be expected as early as Q1 2025.

The FDA recommends adjustments to Dasynoc's tablet strengths to reduce the risk of medication errors. Although these changes are minor (within normal variability), the FDA has requested new batches to be produced before submission. Xspray Pharma has already initiated production of these batches. The company will also provide further clarification on the manufacturing process to ensure full alignment with the FDA's requirements.

Per Andersson, CEO of Xspray Pharma, commented: "We are very encouraged by the positive and collaborative discussions with the FDA. The new tablet strengths will enhance patient safety by reducing the potential for dosing errors, and we are working diligently to meet all the necessary requirements. Our production process is well underway, and we are on track to resubmit the NDA in Q4 2024."

He continued: "Xspray Pharma is particularly eager to bring Dasynoc to market because of the critical need we have identified in our research. Many patients, especially those relying on pH-altering medications like antacids, face challenges with existing cancer treatments due to inconsistent absorption. Dasynoc's innovative pH-independent formulation directly addresses this issue, which minimizes the risks associated with fluctuating drug absorption ensuring that patients can receive consistent treatments. We believe this solution will be welcomed by healthcare providers and patients alike, who are in need of more reliable treatment options."

Upon resubmission, Xspray Pharma expects the FDA to assign a new Prescription Drug User Fee Act (PDUFA) date, with a final decision anticipated within two or six months of the resubmission, depending on the review timeline set by the FDA.

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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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