Flerie's portfolio company Xspray Pharma receives CRL from FDA for Dasynoc®

Flerie AB's (publ) portfolio company Xspray Pharma has announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the NDA application for Dasynoc®, an improved formulation of dasatinib for the treatment of CML and ALL.

In a CRL to Xspray Pharma, the FDA has raised the outstanding GMP observations at the third-party manufacturer NerPharMa, which have previously been communicated, along with a request for additional batch data from commercial manufacturing following previously implemented corrective actions. Flerie notes that, consistent with prior communications, the FDA has not raised any objections regarding Dasynoc's clinical data, bioequivalence, or stability, and that the previously identified risk of medication errors has now been addressed.

The contract manufacturer NerPharMa has informed the FDA that the remediation measures required at the facility have been completed. Xspray had already planned to manufacture additional commercial batches as part of its launch preparations – this work is now being prioritised to provide the data requested by the FDA. The company intends to resubmit the application as soon as possible during 2026.

"We have seen this type of GMP-related issue before in Xspray's regulatory process, and the content of this CRL confirms that the uncertainty is confined to the manufacturing documentation and does not concern the product's clinical profile. It is positive that NerPharMa has been able to inform the FDA that the requested measures have been completed, and that Xspray can benefit from already-planned commercial manufacturing to meet the agency's requirements. We continue to have great confidence in Xspray's technology platform and in the company's ability to advance Dasynoc and the rest of the pipeline projects towards launch in the U.S.," says Ted Fjällman, CEO of Flerie.

Read Xspray Pharma's full press release here: https://xspraypharma.com/modular_finance_pressmeddelande/xspray-pharma-receives-complete-response-letter-crl-from-fda-for-dasynoc/

Flerie's holding in Xspray Pharma amounts to 17%.

For more information:
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About chronic myeloid leukaemia and acute lymphoblastic leukaemia
Chronic myeloid leukaemia (CML) and acute lymphoblastic leukaemia (ALL) are two forms of blood cancer with different disease courses. CML is today a chronic, manageable disease thanks to tyrosine kinase inhibitors (TKIs), with an estimated 300,000 people living with CML in Europe and the US, and a global prevalence that could reach up to 10 million. ALL is an aggressive, rapidly

progressing form of leukaemia that requires intensive treatment and is most common in children, though it also occurs in adults, where the prognosis is generally poorer. Despite effective treatments, challenges remain around tolerability, adherence and outcomes following relapse – creating a significant market opportunity for improved treatment options.

Flerie in brief

Flerie is an active long-term life science investor, with a broad and diversified portfolio of innovative companies based on pioneering science. We invest in product development and commercial growth opportunities globally alongside other leading investors, focusing predominantly on private companies that are otherwise difficult to access. Flerie's active ownership model, broad network and resources support and accelerate the development of the portfolio projects, creating value for shareholders. Flerie AB's ordinary share is listed on Nasdaq Stockholm with the ticker FLERIE. For further information please visit www.flerie.com

Attachments

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