

Flerie's portfolio company Xspray Pharma receives CRL from FDA for Nilopki™

Flerie AB's (publ) portfolio company Xspray Pharma has announced that the FDA is currently unable to approve the New Drug Application for Nilopki™. Xspray Pharma is now analysing the FDA's response in detail and intends, together with its partners, to address the agency's comments as soon as possible. Nilopki™ is an improved formulation of nilotinib for the treatment of chronic myeloid leukaemia (CML).

In a Complete Response Letter (CRL) to Xspray Pharma, the FDA has raised three issues: a requirement for dose correspondence with Tassigna®, a request for additional manufacturing data at commercial scale, and GMP observations at the contract manufacturer that need to be addressed.

"It is, of course, disappointing that the approval of Nilopki has been delayed, but we remain confident in the strength of the underlying product profile and the value that the HyNap platform can deliver. We take a long-term view of our ownership in Xspray and are confident in the company's ability to address the FDA's observations in a structured manner," says Ted Fjällman, CEO of Flerie.

Xspray Pharma's overall strategy and pipeline remain unchanged. The company has a further product candidate under FDA review, Dasynoc®, an improved formulation of dasatinib for the treatment of CML and ALL, with a PDUFA date of 25 August 2026.

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

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

For more information:

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About chronic myeloid leukemia

Chronic myeloid leukemia (CML) is a blood cancer that today is a chronic, manageable disease thanks to tyrosine kinase inhibitors (TKIs). An estimated 300,000 people are living with CML in Europe and the United States, and globally the prevalence is estimated to potentially reach up to 10 million. Despite the efficacy of existing TKI therapies, challenges around tolerability and adherence remain, creating a significant market opportunity for improved formulations with lower development risk and shorter time to market.

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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