

Respiratorius Receives Meeting Minutes from FDA Pre-IND Meeting

Respiratorius AB (publ) today announced that the company has received the official meeting minutes from the pre-IND (Investigational New Drug) meeting recently held with the US Food and Drug Administration (FDA).

The purpose of the meeting was to discuss strategic considerations ahead of the forthcoming clinical development of the company's drug candidate VAL001. The candidate is intended for the treatment of previously untreated diffuse large B-cell lymphoma (DLBCL).

The minutes provide a clear summary of the key topics discussed, including study design and the conduct of the planned Phase III trial. Overall, the content is consistent with the company's own interpretation of the FDA's recommendations. Respiratorius therefore considers that the outcome of the pre-IND meeting further strengthens the attractiveness of VAL001 and improves the company's opportunities to secure a development partner. The documentation will thus form an important part of the company's data room.

"It is an important step for Respiratorius to now be able to include the FDA meeting minutes in our data room," said Johan Drott, CEO of Respiratorius. "We are grateful for the FDA's valuable input and the support provided for the conduct of the Phase III trial. The United States is our most important and most valuable market for VAL001, and we look forward to the next stage of development."

About VAL001

VAL001 is an innovative oral formulation of sodium valproate designed to enhance tolerability and efficacy when administered prior to standard cancer therapy. Preclinical data suggest that VAL001 may sensitize tumour cells to chemotherapy, potentially improving patient outcomes across multiple indications.

This disclosure contains information that Respiratorius is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 01-09-2025 08:32 CET.

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Respiratorius AB (publ) is developing candidates for new effective drugs for the treatment of aggressive lymphoma. The company's business concept is to develop candidates for new drugs based on patent-pending substances, which in preclinical studies have shown superior results compared to what is currently considered standard treatment. For more information about Respiratorius, visit www.respiratorius.com.