Respiratorius has conducted a pre-IND meeting with the FDA

Respiratorius AB (publ) announces that the company has held an advisory pre-IND (Investigational New Drug) meeting with the US Food and Drug Administration (FDA).

The purpose of the meeting was to discuss strategic considerations ahead of the upcoming clinical development of the drug candidate VAL001, intended for the treatment of previously untreated diffuse large B-cell lymphoma (DLBCL). Prior to the meeting, Respiratorius submitted comprehensive background material to the FDA, including data from previous studies as well as specific questions regarding the planning and design of a future phase III trial.

The meeting with the FDA primarily focused on two key areas: the study design and the implementation of the phase III trial, with the aim of obtaining marketing authorisation in the United States. The FDA recommended that supplementary data for dose levels lower than the maximum tolerated dose – established in previous phase I/IIa studies – should be incorporated into the phase III study design.

Respiratorius views the constructive dialogue with the FDA and the guidance received as highly valuable in shaping the study design and subsequent execution of the phase III trial together with a partner. The company now plans to maintain continued engagement with the agency in order to follow the FDA's recommendations and optimise the study design.

Respiratorius believes that the completion of the pre-IND meeting increases the attractiveness of VAL001 and thereby strengthens the company's opportunities to secure a partner.

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 12-08-2025 08:30 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.