

## ***Positive results from PK study of VAL001***

**Respiratorius announces that analysis of data from the PK study has now been completed and that the results from an important biomarker are also available. The results show that VAL001 has a favorable PK profile as well as a greater histone acetylating effect compared to the reference.**

The tailored release profile of VAL001, which combines immediate-release properties and extended-release sodium valproate, was evaluated in a pharmacokinetic (PK) study in healthy subjects. The total plasma concentration of valproate from VAL001, with dosing twice daily, was similar to that achieved with the reference formulation, which was dosed three times daily. Advantageously, VAL001 gave lower peaks of the maximum valproate concentration than the reference formulation, which is of importance for the occurrence of side effects, especially at these relatively high concentrations of valproate that are necessary to provide the desired inhibition of histone deacetylase. VAL001 also showed more consistent plasma concentrations over time compared to the reference formulation.

In addition to the favorable PK profile, analysis of a biomarker for histone acetylation also showed positive results. Valproate potentiates the effect of chemotherapy by altering the chromatin structure of DNA via inhibition of histone deacetylase and the biomarker in question thus predicates the effect of valproate. The expression of the biomarker was higher at all measured time points and at most 40 percentage points higher at 48 hours after dosing with VAL001 compared to the reference formulation.

In addition to enabling dosing 2 times daily instead of 3 times daily, the results suggest that the effect of the new formulation may be better, even though the overall exposure, and thus the likely risk of side effects, does not increase. A modified PK profile is also an important part of a better differentiation towards generic valproate and better regulatory protection.

*"The results show that the formulation of VAL001 has been successful by showing both similarity and advantageous differentiation from an existing formulation of valproate, says CEO Johan Drott in a comment.*

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 20-01-2023 08:10 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](http://www.respiratorius.com).