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## Press Release

Lund, Nov. 5, 2019

### **Canada grants patent for VAL001**

**The Canadian Intellectual Property Office (CIPO) has announced the intent to grant Respiratorius patent for VAL001, "A Pharmaceutical Composition Comprising a HDAC inhibitor and a steroid and the use thereof."**

After the formal fees have been paid, the patent will be granted, which will give Respiratorius market exclusivity in Canada until 2031. Previously the patent has been granted in Europe, US, Japan and Korea under equivalent conditions.

The patent applies to a combination of a HDAC inhibitor and a steroid for pre-treatment before chemotherapy (R-CHOP) in the treatment of diffuse large B-cell lymphoma (DLBCL), a lymphoma which annually affects about 60,000 people in the United States and Europe. DLBCL is the most common type of Non-Hodgkin's lymphoma, which comprises 30% of diagnosed patients in the EU.

In Q2 2018, a phase I/IIa study of VAL001, in combination with R-CHOP, was completed with the following results:

- Potential synergistic effect with Rituximab as VAL001 increases the levels of the surface protein CD20.
- Overall Survival Analysis for 32 patients treated with VAL001 and R-CHOP shows that 1-year survival is 100% and 2-year survival is 96.8%. Comparative data from a matched reference population of 330 patients from The Swedish lymphoma registry treated with R-CHOP alone provides 1-year survival of 89.6% and 2-year survival of 81.7%. This shows a statistically assured survival benefit ( $p = 0.034$ ) for patients treated with VAL001 and R-CHOP compared to those treated between 2000–2015 with R-CHOP alone.

VAL001 thus differs significantly from other treatments by the results of the phase I / IIa study, in which VAL001 + R-CHOP gives a very large reduction in mortality, > 50%, compared to the 20-30 percent reduction in mortality considered to be clinically relevant to oncology drugs in general.

As previously communicated, VAL001 has received Orphan Drug Designation in Europe and the United States, giving market exclusivity for 10 and 7 years from market approval.

"A patent approval in Canada for VAL001 fits well with the ongoing exit process, as North America is an important market for VAL001," says CEO Johan Drott in a comment.

*This information is information that Respiratorius AB (Publ) is required to disclose under the EU Market Abuse Regulation. The information was provided by the above contact person for publication on Nov 5, 2019.*

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Respiratorius AB (publ) is developing drug candidates with the goal to launch drugs for common diseases like cancer, chronic obstructive pulmonary disease (COPD) and severe asthma. In addition, the company portfolio also holds a project for improved diagnosis of certain cardiovascular diseases.