Press Release

Lund, March 5, 2019

EMA recommends Phase III study for VAL001

The European Medicines Agency (EMA) recommends, following scientific advice, that Respiratorius conduct a Phase III study as the next step in the clinical development of VAL001.

EMA's Scientific Advice Working Party (SAWP) assesses in the feedback from a scientific advice meeting regarding clinical strategy that VAL001 is qualified for a direct start of a phase III study and that inclusion of approximately 700 patients should be satisfactory for such a study to be able to constitute the basis for market approval. Prior to the start of a Phase III study, with the new dedicated formulation, the EMA considers that a pharmacokinetic study is appropriate for the purpose of ensuring that the dosage with the new formulation is in line with the previously defined maximum tolerated dose. An estimate of a realistic start of study for a Phase III study is Q2-Q3 2020, to enable the completion of development and production of VAL001, the completion of the pharmacokinetic study, and the acquisition of all permits for study start.

"EMA's advice, that the next step is to directly initiate a Phase III study instead of first carrying out a Phase II study, means a repositioning for VAL001 and likely a reduction in development costs." comments CEO Johan Drott.

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 March 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.