
Press Release

Lund, October 7, 2016

EMA Recommends a European Orphan Drug Designation for Respiratorius Drug Candidate VAL001 for the Treatment of Diffuse Large B-cell Lymphoma

The European Medicines Agency's Committee for Orphan Drugs in Europe (the Committee for Orphan Medicinal Products - COMP) has informed Respiratorius of a positive decision regarding Respiratorius application for VAL001 to obtain Orphan Drug Designation in Europe. This means that the COMP has determined that the application meets all the criteria and therefore recommends that the European Commission grants a formal Orphan Drug Designation. Shortly thereafter, the European Commission is to issue a formal decision on Orphan Drug Designation.

Respiratorius application for orphan drug designation is based on preclinical data and results from the interim analysis of the Phase I / IIa study. The results from the interim analysis shows that VAL001 combined with R-CHOP is significantly better than for the reference group, which consisted of a matched population of the Swedish Lymphoma Registry, which was only treated with R-CHOP for both the 1-year survival (95% significance) and 2-year survival (90% significance).

"The assessment of the COMP is based on objective analysis of pre-clinical and clinical data, which gives additional strength to the project. The corresponding process is also started for the United States where market exclusivity is valid for 7 years from the approval. Orphan Drug Designation is of significant importance for the discussions with potential partners" says CEO Johan Drott in a statement.

Short on Orphan Drug

When obtaining orphan drug status, the product receives market exclusivity for ten years in the EU, from the date of marketing approval. In addition, Respiratorius is to receive free consultation at scientific advice on contact with the Agency, which among other things includes support for designing clinical trial protocols and reduced costs for regulatory applications for the commercialization.

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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.