
Press Release

Lund, Nov 4, 2016

European Patent Office grants patents for VAL001

European Patent Office (EPO) has announced the intent to grant Respiratorius patent for VAL001, "A Pharmaceutical Composition Comprising a HDAC inhibitor and a steroid and the use thereof."

The patent applies to a combination of a HDAC inhibitor and a steroid for pretreatment 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.

After the formal fees are paid, the application will be validated in the individual countries within the EU, for which Respiratorius want to maintain patent protection.

A fully enrolled Phase I/IIa study of VAL001 progress at Skåne Oncology Clinic, SUS Lund / Malmo, oncology clinic at the University Hospital in Uppsala and at the Cancer Centre, University Hospital in Umeå. In the study, of VAL001 as a pretreatment prior to standard chemotherapy with the addition of Rituximab (R-CHOP), in the treatment of diffuse large B-cell lymphoma. Results of the interim analysis of the Phase I/IIa study showing that VAL001 combined with R-CHOP is significantly better than 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).

As previously announced, the company expects information from the European Commission regarding the orphan drug designation application, after COMP's positive opinion and recommendation. COMP (Committee of Orphan Medicine Products) within the European Medicines Agency (EMA) prepares matters of orphan drug designation for the formal decision by the EU Commission.

"The approval of the patent in Europe for VAL001 is for the company a further important information. Europe and Japan is potentially important markets for VAL001. Patent approval complements an expected orphan drug status in Europe and further strengthens our market position," says CEO Johan Drott in a statement.

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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.

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