ABLYNX PRESENTS UNIQUE NANOBODY DRUG INHALATION TECHNOLOGY AT THE RESPIRATORY DRUG DELIVERY EUROPE 2015 CONFERENCE


The presentation focused on Ablynx’s wholly-owned, innovative, anti-RSV inhaled Nanobody therapeutic, ALX-0171, which is being developed for the treatment of established RSV infections in the general paediatric population.

*In vitro* studies\(^1\) have demonstrated that ALX-0171 is potent and shows superior virus neutralisation. The robustness of the Nanobody also allows administration via inhalation, enabling delivery of ALX-0171 directly to the site of viral infection (i.e. the respiratory tract, including the lower airways) where it inhibits viral replication and neutralises viral activity by blocking virus uptake in the cells.

*In vivo* proof-of-concept with ALX-0171 has been achieved using a neonatal animal model, demonstrating that daily inhalation of the Nanobody for three consecutive days in animals with established infection, resulted in a marked reduction of symptoms of illness, viral titres and RSV-associated lung pathology. Clinically, ALX-0171 has been shown to be well tolerated in more than 100 adults, including subjects with sensitive (hyper-reactive) airways.

In December 2014, Ablynx initiated a first-in-infant Phase IIa study in the Northern Hemisphere to evaluate the safety, tolerability and clinical activity (including effect on feeding, respiratory rate, wheezing, coughing, general appearance and clinical scores) of inhaled ALX-0171 in otherwise healthy infants (aged 3-24 months) diagnosed with RSV and hospitalised for a lower respiratory tract infection. The lead-in part of the study with five infants has been successfully completed and recruitment is now on-going for the placebo-controlled part of the trial for which it is intended to recruit a total of 30 infants. Recruitment for this latter phase already started in the Northern Hemisphere but the RSV season has now finished there and preparations are currently on-going to open clinical study centres in the Asia-Pacific region where the RSV season occurs later in the calendar year. The goal is to complete recruitment by the end of 2015 with results expected during the first half of 2016.

The presentation at the RDD Conference has been made available on the Ablynx website under the section [R&D portfolio](#).

**Edwin Moses, Chief Executive Officer of Ablynx, said:** “Ablynx is pioneering the development of a potentially first-in-class treatment for RSV, which we believe is an area of major unmet need, especially in infants. We are utilising the robustness of Nanobodies to deliver them via nebulisation, a technique which may be beneficial in other pulmonary diseases. ALX-0171 is one of our wholly-owned, lead proprietary programmes in clinical development which we are currently advancing internally.”

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\(^1\) Study results presented at the Human Antibodies and Hybridomas conference in 2014; presentation on [Ablynx website](#)
**About Respiratory Syncytial Virus**

RSV remains the primary cause of infant hospitalisation and virus associated deaths in infants. In addition, RSV infections have been linked to an increased risk for asthma development later in life\(^2\). Current treatment of patients infected with RSV is primarily focussed on symptomatic relief, hence the need for an effective and specific anti-RSV therapeutic. It is estimated that there are more than 300,000 children (aged <5 years) hospitalised each year in the seven major pharmaceutical markets and the reported infection rate is 70-80% in children under two years of age\(^3\). In addition, RSV infection is a significant cause of pulmonary disease in transplant patients, immune-compromised subjects and the elderly.

**About Ablynx**

**Ablynx** is a biopharmaceutical company engaged in the development of Nanobodies\(^\circ\), proprietary therapeutic proteins based on single-domain antibody fragments, which combine the advantages of conventional antibody drugs with some of the features of small-molecule drugs. Ablynx is dedicated to creating new medicines which will make a real difference to society. Today, the Company has more than 30 proprietary and partnered programmes in development in various therapeutic areas including inflammation, haematology, oncology and respiratory disease. The Company has collaborations with multiple pharmaceutical companies including AbbVie, Boehringer Ingelheim, Eddingpharm, Merck & Co, Inc., Merck Serono and Novartis. The Company is headquartered in Ghent, Belgium. More information can be found on [www.ablynx.com](http://www.ablynx.com).

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\(^3\) Hall *et al*, NEJM, 2009; extrapolation based on estimated US prevalence
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