ABLYNX'S FIRST INHALED NANOBODY SUCCESSFULLY COMPLETES PHASE I STUDY

ALX-0171 has the potential to become a first-in-class therapy

GHENT, Belgium, 18 September 2012 - Ablynx [Euronext Brussels: ABLX] today announced that it has achieved positive results from a Phase I study with the first ever inhaled Nanobody, ALX-0171, a trivalent molecule which has been specifically designed by Ablynx for direct lung delivery, via a nebuliser, to treat respiratory syncytial virus (RSV) infections.

The Phase I data showed that ALX-0171 could be successfully administered via nebulisation directly into the lung in a clinical trial setting, confirming its potential as a first-in-class therapy to treat RSV infections. The stability of the Nanobody, together with its specific structure, small size and robustness, make this convenient route of administration possible and provides a potential solution to the pulmonary delivery of biologics where antibodies have been unsuccessful so far.

The double-blind, randomised trial was conducted in healthy adult males to investigate the safety, tolerability and PK profile of ALX-0171. The Phase I study included a single-ascending dose part in 44 subjects, in which six dose levels ranging from 2.1 mg to 210 mg were tested. Subsequent, a multiple dose part was initiated in 16 healthy males, in which the subjects received ALX-0171, twice daily at a total daily dose of 140 mg and 210 mg respectively, for five days.

The Phase I study results indicated that the Nanobody administration was well tolerated and did not induce any significant clinically relevant adverse events or clinically significant changes in lung function, at any of the dose levels tested. In addition, no dose-limiting toxicity or treatment-emergent local or systemic immunogenicity was observed.

Dr Edwin Moses, Chairman and CEO of Ablynx, said:

“We are very excited about the outcome of this study as we believe it is the first time that an antibody-derived drug, which is delivered through inhalation, has completed a Phase I trial, with no treatment-emergent immunogenicity being observed. This is a major safety breakthrough in the search for potential new treatment options for patients with RSV infections, and furthermore supports the potential pulmonary delivery of Nanobodies in a range of lung-based diseases as well as offering another route for systemic administration. We are looking forward to continuing the development of this novel programme and are excited by the recent findings of a causal link between RSV infections and asthma which may considerably increase the potential clinical need for the treatment of RSV infections with ALX-0171.”
Prof Kris De Boeck, Paediatric Pulmonology, University Hospital in Leuven, Belgium, commented:
“RSV infection is the most common cause of lower respiratory tract disease and hospital admission in infants. No effective therapy is available at present. Current prophylaxis with a monoclonal antibody is expensive and only partially protective. Any new treatment strategy for RSV bronchiolitis is very welcome.”

About Respiratory Syncytial Virus (RSV)
RSV is a respiratory virus that infects the lungs and respiratory tract. It is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia in children under one year of age. It is the leading cause of infant hospitalisation and also a leading cause of virus-associated deaths in infants. There are more than 300,000 infant hospitalisations in the seven major pharmaceutical markets (USA, Japan, Germany, France, UK, Italy, Spain) and the reported infection rate is 70-80% in children under two years old. The mortality rate for hospitalised patients is less than 1% in healthy children but 3.5% in those with high risk conditions. Today, treatment is mostly symptomatic and there is a high need for an effective specific anti-RSV drug.

About Ablynx

Ablynx is a biopharmaceutical company engaged in the discovery and development of Nanobodies®, a novel class of therapeutic proteins based on single-domain antibody fragments, for a range of serious human diseases, including inflammation, haematology, oncology and pulmonary disease. Today, the Company has approximately 25 programmes in the pipeline and seven Nanobodies at clinical development stage. Ablynx has ongoing research collaborations and significant partnerships with major pharmaceutical companies, including Boehringer Ingelheim, Merck Serono and Novartis. The Company is headquartered in Ghent, Belgium. More information can be found on www.ablynx.com.

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