



## **ABLYNX SELECTS A NOVEL PRE-CLINICAL DEVELOPMENT CANDIDATE FOR ADMINISTRATION VIA PULMONARY DELIVERY**

**GHENT, Belgium, 26 March 2010** - Ablynx [*Euronext Brussels: ABLX*] announced today that it has advanced ALX-0171, a new Nanobody<sup>®</sup>-based therapeutic programme, into pre-clinical development for the treatment of respiratory syncytial virus (RSV) infections. ALX-0171 is a Nanobody product which binds to RSV and neutralizes the virus. The Nanobody will be administered via the lungs and based on the *in vivo* data it has the potential to be effective both in the prevention of infection as well as in treatment once infection has occurred.

This is Ablynx's first Nanobody pre-clinical development candidate to be delivered through a route other than injection. Like many Nanobodies, ALX-0171 is very stable with a low propensity to aggregate making it suitable for inhalation. It can also be manufactured at relatively low cost in microbial systems.

"Ablynx's anti-RSV Nanobody potentially has a clearly differentiated product profile compared with other options currently available for RSV. We expect to conveniently deliver ALX-0171 via the lungs directly to the site of potential disease to provide prophylactic protection, as well as therapeutic treatment which we don't believe can be offered for this infectious agent by any other marketed drugs today. We also believe ALX-0171 will have a significantly lower cost of goods compared to other biologics currently used in this indication. We are very pleased to illustrate the power of our Nanobody product engine with this announcement of our second pre-clinical candidate nomination in 2010. Earlier this year we nominated ALX-0651, an anti-CXCR4 Nanobody for stem cell mobilization, for preclinical development", commented Dr. Edwin Moses, Chief Executive Officer and Chairman of Ablynx.

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**About Ablynx [*Euronext Brussels: ABLX*] - <http://www.ablynx.com>**

Founded in 2001 in Ghent, Belgium, Ablynx is a biopharmaceutical company focused on the discovery and development of Nanobodies, a novel class of therapeutic proteins based on single-domain antibody fragments, for a range of serious and life-threatening human diseases. The Company currently has over 230 employees. Ablynx completed a successful IPO on Euronext Brussels [*ABLX*] on 7 November 2007 and raised €50 million through an SPO in March 2010.

Ablynx is developing a portfolio of Nanobody-based therapeutics in a number of major disease areas, including inflammation, thrombosis, oncology and Alzheimer's disease. Ablynx now has over 25 programmes in its therapeutic pipeline including four Nanobodies in clinical development. So far, Nanobodies have been successfully generated against more than 190 different protein targets including several complex targets such as chemokines, GPCRs, ion channels and viruses, which are typically very difficult to address with conventional monoclonal antibodies. Efficacy data have been obtained in 28 *in vivo* models for Nanobodies against a range of different targets.

Ablynx has an extensive patent position in the field of Nanobodies for healthcare applications. It has exclusive and worldwide rights to more than 130 families of granted patents and pending patent applications, including the Hamers patents covering the basic structure, composition, preparation and uses of Nanobodies.

Ablynx has ongoing research collaborations and significant partnerships with several major pharmaceutical companies, including Boehringer Ingelheim, Merck Serono, Novartis and Pfizer (previously Wyeth

Pharmaceuticals). Ablynx is building a diverse and broad portfolio of therapeutic Nanobodies through these collaborations as well as through its own internal discovery programmes.

The Company's lead programme ALX-0081, an intravenously administered novel anti-thrombotic, entered a Phase II study in patients undergoing percutaneous coronary intervention (PCI) in September 2009. Ablynx demonstrated proof-of-concept by biomarker for ALX-0081 in December 2009. ALX-0681, a subcutaneous administration of the anti-von Willebrand factor (vWF) Nanobody recently concluded a Phase I study.

In September 2009, Ablynx's partner Pfizer entered a Phase II study in RA patients, with an anti-TNF-alpha Nanobody.

In December 2009, Ablynx initiated a double-blind, randomised, placebo-controlled Phase I study with ALX-0141, a Nanobody targeting Receptor Activator of Nuclear Factor kappa B Ligand (RANKL), in healthy postmenopausal women. ALX-0061, an anti-IL6R Nanobody is in preclinical development for the treatment of autoimmune and inflammatory diseases. In February 2010, Ablynx announced that it had reached its criteria for initiating the preclinical development of ALX-0651, a Nanobody against CXCR4, and will progress this programme towards the clinic. CXCR4 plays an important role in cell mobility, tumor growth and metastasis.

### **About RSV**

Respiratory syncytial virus, or RSV, is a respiratory virus that infects the lungs and respiratory tract. Most otherwise healthy people recover from RSV infection within 1 to 2 weeks. However, the clinical picture of the infection can be severe in immunocompromised patients, the elderly, infants, and young children. RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia in children under 1 year of age, and is increasingly recognized as an important cause of respiratory illness in the elderly.

RSV is the leading cause of infant hospitalization, and a leading cause of virus-associated deaths in infants. There are more than 250,000 infant hospitalizations in the seven major pharmaceutical markets (USA, Japan, Germany, France, UK, Italy, Spain) and the reported infection rate is 70-80% in children under 2 years old. Of those children hospitalised, it is believed 30% will have a so-called prolonged wheezing. The mortality rate for hospitalized patients is less than 1% in healthy children but 3.5% in those with high risk conditions.

RSV infections also occur in adults with cardiopulmonary disease, in the elderly and in transplant patients. Every year >3% of otherwise healthy elderly people are at risk of RSV infection and in the seven major pharmaceutical markets over 500,000 elderly people are hospitalized. Of these between 5-10% will die as a result of the infection.

The main intervention in RSV infection today is prophylaxis during the RSV outbreak season. Synagis<sup>®</sup>, a humanized mouse antibody, is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease, such as those with chronic lung disease, congenital heart disease, or who are born prematurely. Synagis<sup>®</sup> is administered intramuscularly once per month for 5 months. Sales of Synagis<sup>®</sup> in 2009 were \$1,1 billion.

There is currently no specific therapeutic that has been shown to reduce the severity of the infection and improve the clinical outcome, once infection has occurred.

### **For more information, please contact Ablynx:**

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