



ABLYNX ANNOUNCES POSITIVE PHASE I RESULTS FOR SUBCUTANEOUS ADMINISTRATION OF ITS ANTI-THROMBOTIC NANOBODY[®] (ALX-0681)

GHENT, Belgium, 18 August 2009 - Ablynx [*Euronext Brussels: ABLX*] today announced the positive results from its double-blind, randomized, placebo-controlled, single and multiple dose Phase I study with ALX-0681, a subcutaneous formulation of its novel anti-thrombotic Nanobody[®] that selectively targets von Willebrand factor (vWF). The positive Phase I data support the progression of ALX-0681 towards Phase II testing in patients with thrombotic thrombocytopenic purpura (TTP), expected to commence in Q2 2010. The anti-vWF Nanobody[®] received orphan drug designation by the EMEA and the FDA for the treatment of TTP in May this year.

The Phase I study was designed to investigate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of single and repeated subcutaneous administrations of ALX-0681. A total of 36 healthy volunteers were treated with either single subcutaneous doses of ALX-0681 ranging from 2mg to 16mg or daily 10 mg subcutaneous injections for 7 or 14 days.

All administrations of ALX-0681 were well tolerated and did not result in clinically significant adverse events. No signs of local intolerance or clinically significant bleeding events occurred and no evidence of immunogenicity was observed for 45 days after completion of treatment.

The desired biological effect, determined by complete inhibition of a biomarker, was achieved for more than 14 days with daily injections of 10mg of the anti-vWF Nanobody[®] confirming the biological efficacy of ALX-0681. The PD parameters for coagulation Factor VIII and vWF showed a fast and reversible decrease compared to pre-dose values, with normalisation between 24 and 72 hours after the last administration, depending on dose. The PK profile remained unchanged after multiple administrations, confirming the favourable pharmacological behaviour of ALX-0681.

ALX-0681 is being developed for the treatment of patients with TTP. It is also anticipated that the subcutaneous administration of ALX-0681 will provide access to additional patient populations suffering from unwanted blood-clot formation, such as those with acute coronary syndrome (ACS), which are not currently addressed by the intravenous administration of ALX-0081.

CEO and Chairman Edwin Moses commented:

“We are very pleased with the positive ALX-0681 Phase I results. We believe selective inhibition of von Willebrand factor will provide new safe treatment options for patients with TTP where there is a large unmet medical need. This drug has the potential to provide a major advance in the treatment regime for TTP” He added: “We are delighted with the positive progress made to date in our anti-thrombotic programmes, ALX-0081 and ALX-0681. This Phase I study demonstrates that Nanobodies[®] can be administered safely via a subcutaneous route and we also will consider this route for other therapeutic programmes where subcutaneous administration is appropriate. With this novel biologics platform > 100 patients and healthy volunteers have now been treated in both short term and prolonged treatment settings and we have seen no immunogenicity to date.”

There currently are three Nanobodies[®] in clinical trials, including a TNF-alpha Nanobody[®] programme partnered with Wyeth Pharmaceuticals. Wyeth has exclusive rights to develop and commercialise anti-TNF-alpha Nanobodies[®] developed under collaborative agreement and Ablynx is eligible to receive milestones and royalties on product sales.

- ends -

About ALX-0081 and ALX-0681

ALX-0081 and ALX-0681 are novel "first-in-class" therapeutic Nanobodies® targeting von Willebrand factor ("vWF"), a protein found in the blood that acts at a very early stage in the coagulation cascade, namely platelet adhesion, in contrast to currently available anti-platelet drugs which act only in the late stage of platelet aggregation. ALX-0081 is administered intravenously while ALX-0681 is administered subcutaneously. ALX-0081 is a bivalent Nanobody® with a molecular weight of 28,000 daltons, designed to selectively prevent unwanted thrombus formation in vessels under high shear conditions without interfering with desirable haemostasis and, as such, to minimize bleeding complications. ALX-0681 was assigned orphan drug designation in May 2009 by EMEA and FDA and is currently being developed for TTP.

About the Thrombosis Market

Ablynx believes that ALX-0681 and ALX-0081 target a key opportunity in the anti-thrombotic market, as they may provide a solution to cardiologists' current dilemma in acute coronary syndrome (ACS) which typically involves achieving a balance between the prevention of unwanted blood clots and potentially life-threatening bleeding complications. ALX-0081 and ALX-0681 could potentially prevent arterial thrombosis following angioplasty, which is a serious clinical problem. Other potential indications for ALX-0081 and ALX-0681 include thrombotic thrombocytopenic purpura (TTP), myocardial infarction (MI) and stroke.

About Thrombotic Thrombocytopenic Purpura (TTP)

TTP is a disease related to the formation of white clots. The underlying abnormality in TTP is the formation of small platelet clots, which leads to occlusions of small vessels throughout the body particularly within blood vessels supplying the brain and the kidneys. It has been shown that these small platelet clots are caused by the presence of large clusters or strings of activated vWF. Approximately four cases of TTP per million inhabitants are diagnosed per year in Europe and the United States. There is currently no approved drug therapy for TTP and plasma exchange is the only available treatment for these patients today. Plasma exchange involves the removal of the patient's plasma (the non-cellular component of blood) and its replacement by donor plasma. TTP remains a condition with extremely high morbidity and mortality, even with timely plasma exchange, and so there is still a significant unmet medical need for this disease.

About Acute Coronary Syndrome (ACS)

ACS is expected to afflict approximately 2.9 million people in the United States, Japan and certain European countries in 2009 according to *Datamonitor's Pipeline Insight: Antithrombotics, Reaching the untreated prophylaxis market report, DMHC2284 March 2007*, and is the leading cause of mortality in the area of cardiovascular disease. Experts believe the prevalence and incidence of acute infarcts due to arteriosclerosis will increase further, due to the ageing population. Peripheral artery occlusive disease (PAOD) will affect an estimated 22.1 million individuals in the US, Japan and certain European countries in 2009 and is associated with significant morbidity and mortality.

About Percutaneous Coronary Intervention (PCI)

The term percutaneous coronary intervention (sometimes called PTCA, angioplasty or stenting) describes a range of procedures that treat narrowing or blockages in coronary arteries supplying blood to the heart. Many patients undergoing this procedure will have previously had cardiac catheterisation (sometimes called coronary angiography) to examine the condition of the coronary vessels. Alternatively, percutaneous coronary intervention may be undertaken immediately after the diagnostic angiogram. Most patients with angina can be helped substantially by coronary stenting. For some patients with very mild disease stents are not required and medication is sufficient. For a small number of people bypass surgery is necessary. Almost all stent procedures are successful and completed in < 2 hours. Inevitably however there are risks and it is important that patients understand these risks before accepting treatment.

Source: <http://www.thecardiologist.co.uk/coronary.htm>

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 210 employees. Ablynx completed a successful IPO on Euronext Brussels [*ABLX*] on 7 November 2007.

Ablynx is developing a portfolio of Nanobody[®]-based therapeutic s in a number of major disease areas, including inflammation, thrombosis, oncology and Alzheimer's disease. Nanobodies[®] have been generated against more than 150 different disease targets. Importantly the Nanobodies[®] which naturally exist in llamas have a very high homology with humans. Efficacy data has been obtained in over 26 *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 50 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 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 reached its primary endpoint in a multi-dose Phase Ib study in patients undergoing PCI on 30 March 2009 and is on track to enter Phase II during Q3 2009. ALX-0681, a subcutaneous formulation of the novel anti-thrombotic Nanobodies[®] that also selectively targets von Willebrand factor (vWF) has concluded Phase I. Ablynx has progressed ALX-0141, an anti-RANKL Nanobody[®] for bone disorders into preclinical development and aims to initiate a Phase I study before the end of 2009. ALX-0061, an anti IL6R Nanobody[®] is in preclinical development for the treatment of autoimmune and inflammatory diseases. In addition, in December 2008, Ablynx's partner Wyeth Pharmaceuticals entered a Phase I study with an anti-TNF-alpha Nanobody[®].

Nanobody[®] is a registered trademark of Ablynx NV.

For more information, please contact:

**For international media enquiries:
College Hill Life Sciences**

Sue Charles, Justine Lamond,
Dr. John McIntyre
t: +44 (0)20 7866 7857
e: ablynx@collegehill.com

Ablynx:

Dr. Edwin Moses
Chairman and CEO
t: +32 (0)9 262 00 07
m: +44 (0)7771 954 193 /
+32 (0)473 39 50 68
e: edwin.moses@ablynx.com

Eva-Lotta Allan
Chief Business Officer
t: +32 (0)9 262 00 75
m: +32 (0)475 78 36 21 /
+44 (0)7990 570 900
e: eva-lotta.allan@ablynx.com

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company's directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its or their parent or subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.