



ABLYNX INITIATES PHASE II CLINICAL TRIAL FOR ALX-0081

GHENT, Belgium, 1 September 2009 - Ablynx [*Euronext Brussels: ABLX*] today announced the initiation of a Phase II study for its anti-thrombotic Nanobody[®] ALX-0081, a first-in-class Nanobody[®] targeting von Willebrand Factor (vWF).

The open-label, randomized Phase II study is designed to evaluate the safety and efficacy of multiple doses of ALX-0081 versus the GPIIb/IIIa inhibitor ReoPro[®] in patients undergoing percutaneous coronary intervention (PCI). Patients with unstable angina or patients with stable angina with at least two factors indicating high risk will be included in this study. ALX-0081 or ReoPro[®] will be added to a standard anti-thrombotic regimen including aspirin, heparin and Plavix[®]. This multi-institutional, pan-European Phase II study is planned to enroll close to 370 patients.

Ablynx recently concluded a successful ALX-0081 Phase Ib study in patients with stable angina undergoing a planned PCI procedure. The drug's biological effect was determined using a biomarker, indicating the complete inhibition of vWF and its mediated effect on platelet aggregation and clotting in coronary arteries. ALX-0081 showed an excellent efficacy and safety profile in this patient study. In order to gain additional information on optimal dosing and scheduling, Ablynx has extended this Phase Ib study to look in more detail at biological markers, optimization of concurrent treatment with the standard anti-thrombotic regimen, tolerance and administration. Data from this Phase Ib study extension will be reported in a few months.

"Initiation of Phase II clinical development of ALX-0081 is a major milestone for Ablynx," commented Edwin Moses, CEO and Chairman. "This study builds on our recent rapid progress and success, generating encouraging safety and efficacy data in patients. ALX-0081 has the potential to become a safe, first-in-class anti-platelet agent. We are delighted that the first patient in this important study was treated in Aalst, Belgium."

There are currently three Nanobodies[®] in clinical development of which ALX-0081 is the most advanced. Ablynx's ALX-0681, also an anti-thrombotic but with a subcutaneous route of administration, is currently in Phase I in healthy volunteers. The third Nanobody[®] is in development with Wyeth Pharmaceuticals targeting tumor necrosis factor alpha (TNF-alpha), which entered Phase I in December 2008. Ablynx believes Wyeth may initiate a Phase II proof-of-concept study in patients with rheumatoid arthritis with its licensed anti-TNF-alpha Nanobody[®], which will trigger a milestone for the Company.

-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 reached orphan drug designation in May 2009 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 the cardiologist's 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 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 that 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 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. This incidence estimate suggests that orphan drug designation should be achievable for this indication, which would enable an accelerated development and approval timetable. 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 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 220 employees. Ablynx completed a successful IPO on Euronext Brussels [ABLYX] on 7 November 2007.

Ablynx is developing a portfolio of Nanobody[®]-based therapeutic programmes 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 has entered Phase II in patients undergoing percutaneous coronary intervention (PCI). ALX-0681, also an anti-thrombotic but with a subcutaneous route of administration has concluded a Phase I study in healthy volunteers. 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, Ablynx's partner Wyeth Pharmaceuticals is currently in 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.