



ABLYNX DEMONSTRATES PROOF-OF-CONCEPT BY BIOMARKER FOR ITS ANTI-THROMBOTIC ALX-0081

GHENT, Belgium, 22 December 2009 - Ablynx [*Euronext Brussels: ABLX*] announced today detailed results from the open label extension of the Phase Ib study of its anti-thrombotic, ALX-0081, in patients with stable angina undergoing percutaneous coronary intervention (PCI). The results support those of the original Phase I study with ALX-0081 and collectively provide proof-of-concept that ALX-0081 is safe and well tolerated and a potent inhibitor of platelet aggregation.

The study was designed to investigate the effect of ALX-0081, which inhibits von Willebrand Factor (vWF), on vWF-mediated clotting, measured using platelet aggregation biomarkers. Additional objectives were to gather additional data regarding safety and administration. The study recruited a total of 22 patients with stable angina undergoing elective PCI. All patients received standard anti-thrombotic therapy, including aspirin, heparin and Plavix[®] in addition to ALX-0081 (20 patients; total dose 18mg) or placebo (2 patients).

All 22 patients received four bolus injections (i.v.) of ALX-0081 or placebo every six hours over 24 hours. vWF-mediated platelet aggregation was measured via the biomarker RICO (ristocetin cofactor). All 20 patients who received ALX-0081 experienced complete RICO inhibition, that was statistically significant compared with placebo, ($p < 0.0001$). ALX-0081 was safe and well tolerated and did not result in clinically relevant bleeding events. No evidence of anti-drug antibodies was detected up to 30 days after the last injection.

Professor Jozef Bartunek, (Aalst, Belgium) primary investigator of the Phase Ib study commented: "With the highly statistically significant inhibition of vWF, we have achieved proof-of-concept with the biomarker indicating ALX-0081 is a potent inhibitor of vWF-mediated clotting in patients with stable angina undergoing PCI."

Edwin Moses, CEO and Chairman at Ablynx, commented:

"We are delighted to see further evidence of efficacy and safety for ALX-0081 in patients with cardiovascular disease. This is a novel target and ALX-0081 could become an important next generation thrombosis treatment. Ablynx recently initiated a Phase II study with ALX-0081 and we look forward to obtaining data from this study by the end of 2010."

Ablynx continues to advance its development portfolio. ALX-0681, which also targets vWF and is administered subcutaneously rather than intravenously, concluded a successful Phase I study in August 2009. Earlier this month, Ablynx initiated a Phase I study for ALX-0141, which targets RANKL, an important target in osteoporosis. Including the Phase II trial being conducted by Pfizer with an anti-TNF-alpha Nanobody, there are now four Nanobody products in clinical development.

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About ALX-0681 and ALX-0081

ALX-0681 and ALX-0081 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 minimise bleeding complications. With the conclusion of the Phase Ib study in patients with stable angina, a total of 122 subjects and patients have been treated in the anti-vWF Nanobody programmes; ALX-0681 and ALX-0081. In September 2009, Ablynx initiated a Phase II study with ALX-0081 which is designed to evaluate the safety and efficacy of multiple doses of ALX-0081 versus the GPIIb/IIIa inhibitor ReoPro[®] (clopidogrel) in patients undergoing PCI. Ablynx was granted orphan drug designation for the vWF programme in May 2009 by both the U.S. Food and Drug Administration and the European Commission for the treatment of TTP, which will enable an accelerated development and approval timetable. Positive Phase I results were announced for ALX-0681 in August 2009.

About the open label extension Phase Ib study

The population was representative of patients with stable angina regarding age, gender, extent of disease and comorbidities, and 90% had a stent implanted during PCI procedure. Bare metal or drug eluting stents were implanted in 10 and 7 patients respectively, and 1 patient received both types. A total of 16 patients (80%) experienced 47 transient and fully reversible adverse events. The most frequent events were study drug unrelated injection and puncture site reactions characterised by mild hematomas or bruises at the catheters site or site of venous puncture. Only one case of mild epistaxis occurred in one patient, judged by the investigator as possibly related to study drug. None of the injection site reactions or the case of nose bleed met criteria for clinically relevant bleeding events and no signs of overt clinical bleeding were reported. A total of three patients experienced a study drug unrelated serious adverse event which completely resolved. At follow-up day 30, no patient developed a major adverse cardiac event (MACE), only one patient developed a MACE at day 44. No anti-drug antibody response was observed in the study. The PK parameters of multiple dose injections compared favorably with multiple dose one hour infusions and steady-state conditions were reached after the first dose without signs of drug accumulation following multiple administrations. The pharmacological effect on vWF-mediated platelet aggregation was measured via the biomarker RICO (ristocetin cofactor activity) and all 20 patients who received ALX-0081 experienced a rapid and complete RICO inhibition at 6 hours which lasted until Day 2 (30 hours) which was maintained for a maximum of 48 hours. Compared with placebo a highly statistically significant difference in the inhibition of vWF-mediated clotting, favoring ALX-0081 with a p-value of <0.0001 was observed, indicating the high potency of the study drug.

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 USA, 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. 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 230 employees. Ablynx completed a successful IPO on Euronext Brussels [ABLX] on 7 November 2007.

Ablynx is developing a portfolio of Nanobody-based therapeutics 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. Efficacy data have 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 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 has entered Phase II in patients undergoing percutaneous coronary intervention (PCI). ALX-0681, a subcutaneous formulation of the novel anti-thrombotic Nanobodies that also selectively targets von Willebrand factor (vWF) has concluded Phase I. 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 addition, in December 2008, Ablynx's partner Pfizer entered a Phase I study with an anti-TNF-alpha Nanobody and a Phase II study was initiated in September 2009.

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

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