



ABLYNX REPORTS DETAILED POSITIVE PHASE Ib RESULTS FOR ITS ANTI-THROMBOTIC NANOBODY[®] ALX-0081

GHENT, Belgium, 30 March 2009 - Ablynx [*Euronext Brussels: ABLX*], a pioneer in the discovery and development of Nanobodies[®], a novel class of antibody-derived therapeutic proteins, announced today the detailed results from the Phase Ib study of its anti-thrombotic ALX-0081. The primary endpoint, demonstrating the complete inhibition of the target protein as measured by a specific biomarker, was reached in December 2008. These positive detailed data support the progression of ALX-0081 into Phase II testing, expected to commence in Q3 2009.

During the period May to December 2008, the study recruited a total of 25 patients with stable angina undergoing an elective percutaneous coronary intervention (PCI) procedure. Total daily doses of ALX-0081 ranging from 2 to 18 mg were added to a standard anti-thrombotic regimen including aspirin, heparin and Plavix[®]. The double blind study randomized patients in a 3:1 ratio to either active study drug (ALX-0081) or placebo, resulting in a total of 19 patients receiving ALX-0081 intravenous infusions and six patients receiving placebo. The biological effect of ALX-0081 was determined via a biomarker, indicating the complete inhibition of von Willebrand Factor (vWF) and its mediated effect on platelet aggregation and clotting in coronary arteries.

The study included a single dose and a multiple dose escalation. Single doses were escalated until the required biological effect (complete biomarker inhibition for at least six hours in all ALX-0081 treated patients) was confirmed. The subsequent multiple dosing was aimed to ensure complete inhibition of the biomarker for at least 24 hours. All patients who received ALX-0081 showed complete inhibition of the biomarker with a duration of 4 to 18 hours in the single dose group and for at least 24 hours in the multiple dose group. In all patients, the pharmacological markers returned to normal 12-36 hours after dosing.

The study treatment was safe and well tolerated. There were no apparent clinical differences in the number of patients with adverse events and in the intensity of these adverse events between the placebo group and the ALX-0081 treatment groups. Importantly, the treatment with ALX-0081 was not associated with any clinical signs of bleeding. Neither the single nor the multiple dose treatment resulted in detectable immunogenicity and no human anti-vWF antibody responses were detected during the 30 day follow up after the last injection, suggesting inherently low immunogenicity of the drug.

The pharmacological profile of ALX-0081 in this Phase Ib study confirmed the findings of the Phase Ia study in healthy volunteers, with a vWF adopted plasma half-life of 27 hours in the single ascending dose. The pharmacodynamic profile of the multiple dosing resulted in effective drug concentrations that correlate with the favorable pharmacodynamic effect (inhibition of biomarker) and did not result in adverse findings in the pharmacodynamic profile, i.e. no signs of drug accumulation were detected. The resulting pharmacokinetic and pharmacodynamic profiles of the four sequential administrations of ALX-0081 support the progression into Phase II testing.

In order to gain additional information on optimal dosing and scheduling in preparation for a Phase II trial, Ablynx has extended its Phase Ib study to look in more detail at biological markers, optimization of concurrent treatment with the standard anti-thrombotic regimen, tolerance and administration.

Edwin Moses, CEO and Chairman commented:

“We are delighted with the rapid progress made to date and these positive Phase Ib results for ALX-0081 mean that we expect to proceed to a multi-centre Phase II study in PCI patients. The positive detailed analysis of our Phase Ib clinical trial is a significant milestone for Ablynx and represents a major step towards the potential development of an improved treatment option for PCI patients. We look forward to a positive outcome from our discussions with the regulatory authorities which should lead to initiation of the Phase II study in the third quarter of this year.”

Ablynx continues to advance its development portfolio. ALX-0681, which also targets vWF but is administered subcutaneously rather than intravenously, entered a healthy volunteer study in December 2008 and Ablynx expects to announce the final results of this Phase I study before the end of the third quarter of this year. By the end of 2009, Ablynx also aims to start a Phase I study for ALX-0141, which targets RANKL, an important target in osteoporosis.

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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 minimize bleeding complications.

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 TPP 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 200 employees. Ablynx completed a successful IPO on Euronext Brussels [ABLX] 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 100 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 25 *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 reached its primary endpoint in a multi-dose Phase Ib study in patients undergoing PCI and ALX-0681, also an anti-thrombotic but with a subcutaneous route of administration has started Phase I in healthy volunteers. Ablynx has progressed ALX-0141, an anti-RANKL Nanobody[®] for bone disorders into preclinical development. In addition, Ablynx's partner Wyeth Pharmaceuticals has initiated a Phase I study in December 2008 for an anti-TNF alpha Nanobody[®].

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

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