ABLYNX WILL HOST A WEBCAST TO DISCUSS ADDITIONAL DATA FROM ITS PHASE III HERCULES STUDY OF CAPLACIZUMAB IN ACQUIRED TTP FOLLOWING ASH LATE-BREAKING DATA PRESENTATION

GHENT, Belgium, 7 December 2017 – Ablynx NV [Euronext Brussels and Nasdaq: ABLX] announced today that the Ablynx management team will host a conference call and webcast to present additional data from the Phase III HERCULES study of caplacizumab in acquired thrombotic thrombocytopenic purpura (aTTP), following its presentation by Professor Marie Scully in the late-breaking abstracts session at the 59th Annual Meeting of the American Society of Hematology (ASH) in Atlanta, GA, USA.

The late-breaking data presentation will include positive topline results from the Phase III HERCULES study of caplacizumab announced on 2 October 2017 together with important data from additional analyses on the use of plasma exchange (PEX) and length of intensive care unit and hospital stay. The slides will be made available on the Ablynx website under Events & Presentations immediately after the presentation on 12 December 2017 at 7.30 am ET/1.30 pm CET.

Following the late-breaking data presentation, the Ablynx management team will host a conference call and webcast on 12 December 2017 at 4.00 pm CET/10.00 am ET. The live webcast and replay will be available via this link. If you wish to participate in the Q&A session, please dial +32(0)2 400 69 26 or +1 646 828 8193 and use confirmation code 9477994.

Late-breaking abstracts session at ASH, Atlanta, GA, USA

Date: Tuesday 12 December 2017
Abstract (LBA-1): Results of the Randomized, Double-Blind, Placebo-Controlled, Phase III HERCULES study of Caplacizumab in Patients with Acquired Thrombotic Thrombocytopenic Purpura
Presentation Time: 7.30 am ET (1.30 pm CET)
Presenter: Professor Marie Scully, M.D., Department of Haematology, University College London Hospitals NHS Trust, London, UK
Room: Building C, Level 1, Hall C2-C3 (Georgia World Congress Center)

About HERCULES

The HERCULES study recruited 145 patients and is the largest randomised, double-blind, placebo-controlled study conducted in patients with aTTP. Patients with an acute episode of aTTP were randomised 1:1 to receive either caplacizumab or placebo in addition to daily plasma exchange and immunosuppression. Patients received a single intravenous bolus of 10mg caplacizumab or placebo followed by a daily subcutaneous dose of 10mg caplacizumab or placebo for 30 days after the last daily PEX. If at the end of this treatment period there was evidence of persistent underlying disease activity (indicative of an imminent risk for recurrence), treatment could be extended for additional seven-day periods up to a maximum of 28 days and was to be accompanied by optimisation of immunosuppression. Patients were followed for a further 28 days after discontinuation of treatment.

A three-year follow-up study (NCT02878603) of patients who have completed the HERCULES study is in progress and will further evaluate the long-term safety and efficacy of caplacizumab and repeated use of caplacizumab, as well as characterising the long-term impact of aTTP.

About caplacizumab

Caplacizumab is a bivalent anti-vWF Nanobody® that received Orphan Drug Designation in Europe and the United States in 2009. Caplacizumab blocks the interaction of ultra-large vWF multimers (ULvWF) with platelets and, therefore, has an immediate effect on platelet aggregation and the ensuing formation and accumulation of the micro-clots that cause the severe thrombocytopenia, tissue ischemia and organ dysfunction in aTTP. This immediate effect of caplacizumab has the potential to protect the patient from the manifestations of the disease while the underlying disease process resolves.

In February 2017, based on the Phase II study results, a Marketing Authorisation Application (MAA) was submitted to the European Medicines Agency (EMA) for approval of caplacizumab in aTTP. In July 2017, Ablynx received Fast Track designation from the Food and Drug Administration (FDA) for caplacizumab for the treatment of aTTP. In October 2017, positive results from the Phase III HERCULES study, meeting primary and two key secondary endpoints, were announced. These data are expected to further support the MAA, as well as a planned Biologics License Application (BLA) filing in the United States in 2018. If approved by regulatory authorities, caplacizumab would be the first therapeutic specifically indicated for the treatment of aTTP.

About aTTP

aTTP is a rare, acute, life-threatening, autoimmune blood clotting disorder. It is caused by impaired activity of the ADAMTS13 enzyme, leaving ULvWF molecules uncleaved (vWF is an important protein involved in the blood clotting process). These ULvWF molecules spontaneously bind to blood platelets, resulting in severe thrombocytopenia (very low platelet count) and clot formation in small blood vessels throughout the body[1], leading to ischemia and widespread organ damage[2].

Despite the current standard-of-care treatment consisting of PEX and immunosuppression, episodes of aTTP are still associated with a mortality rate of up to 20%, with most deaths occurring within 30 days of diagnosis[3]. Furthermore, patients are at risk of acute thromboembolic complications (e.g. stroke, myocardial infarction) and of recurrence of disease. Some patients are refractory to therapy[1], which is associated with a poor prognosis for survival of an acute episode of aTTP. Long term, patients are at increased risk for hypertension, major depression, and premature death[4].

About Ablynx

Ablynx is a biopharmaceutical company engaged in the development of Nanobodies, proprietary therapeutic proteins based on single-domain antibody fragments, which combine the advantages of conventional antibody drugs with some of the features of small-molecule drugs. Ablynx is dedicated to creating new medicines which will make a real difference to society. Today, the Company has more than 45 proprietary and partnered programmes in development in various therapeutic areas including inflammation, haematology, immuno-oncology, oncology and respiratory disease. The Company has collaborations with multiple pharmaceutical companies including AbbVie; Boehringer Ingelheim; Eddingpharm; Merck & Co., Inc., Kenilworth, New Jersey, USA; Merck KGaA; Novartis; Novo Nordisk; Sanofi and Taisho Pharmaceuticals. The Company is headquartered in Ghent, Belgium. More information can be found on www.ablynx.com.

[1] Veyradier, NEJM 2016: "von Willebrand Factor – A new target for TTP treatment?"
[2] Scully *et al.*, Br J Hem 2012; Sarode *et al.*, J Clin Apher 2014; Chaturvedi *et al.*, Am J Hem 2013
[3] Benhamou, Y. *et al.*, Haematologica 2012
[4] Deford *et al.*, Blood 2013

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