



ABLYNX ANNOUNCES TOPLINE RESULTS FROM THE PHASE II STUDY OF VOBARILIZUMAB IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

GHENT, Belgium, 26 March 2018 – Ablynx [Euronext Brussels and Nasdaq: ABLX] today announced that the Phase II dose-ranging study of vobarilizumab, the Company's anti-IL-6R Nanobody®, did not meet the primary endpoint of dose response based on the modified BILAG-based combined lupus assessment (mBICLA) at Week 24.

The study enrolled 312 patients with moderate to severe, active seropositive systemic lupus erythematosus (SLE) across five treatment arms (four dose regimens of vobarilizumab and placebo). Demographics and baseline characteristics were similar across treatment arms, and reflective of a typical SLE population.

Safety findings through Week 58 were favourable for vobarilizumab. Treatment-related serious adverse events were reported in 2.0% of all vobarilizumab treated patients compared to 6.5% in the placebo group. The percentage of patients experiencing a serious infection was also lower in the vobarilizumab arms compared to the placebo arm (2.8% versus 6.5%). Treatment-emergent adverse events that led to study drug discontinuation were reported in 12.4% of all vobarilizumab treated patients compared to 6.5% in the placebo group. Two deaths were reported in the vobarilizumab group.

Dr Robert K. Zeldin, Chief Medical Officer at Ablynx, said:

"We are disappointed that vobarilizumab didn't show a dose response in the analysis of the study's primary endpoint, however, vobarilizumab was well tolerated in all tested dose groups, confirming its favourable safety profile. We will continue to analyse the full data set and thank the study participants and their families as well as the investigators and staff who contributed to this study."

About the Phase II STEADY study

This multi-centre, randomised, double-blind, placebo-controlled, dose-range finding Phase II study was initiated in August 2015 and enrolled 312 patients with moderate to severe, active seropositive SLE across the USA, Europe, South America and Asia. Patients were randomly assigned to one of four dose groups of subcutaneously (sc) administered vobarilizumab (75mg every 4 weeks, 150mg every 4 weeks, 150mg every 2 weeks, 225mg every 2 weeks) or placebo. Subjects were evaluated for efficacy up to and including Week 48 and for safety up to and including Week 58.

The primary endpoint of the study was the percentage of subjects who achieved a response at Week 24 according to the modified BICLA (BILAG-based combined lupus assessment) score. This is a composite measure of SLE disease activity across all body systems, driven by an improvement in the BILAG (British Isles Lupus Assessment Group) index, no worsening of the modified SLEDAI-2K (SLE disease activity index excluding the low complement scoring) and no significant worsening of the physician global assessment (PGA), compared to baseline. The primary endpoint was analysed using the Multiple Comparison Procedure Model (MCP-Mod) methodology to evaluate the dose-response relationship. Secondary endpoints included the modified SRI (SLE responder index), a composite measure of SLE disease activity based on an improvement in the modified SLEDAI-2K without worsening of the BILAG index or of the PGA, the individual components of the composite endpoints, as well as the effects of vobarilizumab on flare rate, use of corticosteroids and health-related quality of life.

About SLE

SLE is a complex, multi-organ, autoimmune disorder characterised by the production of pathogenic autoantibodies and tissue deposition of immune complexes, which result in widespread tissue damage. Although the aetiology of SLE is not fully understood, multiple genetic, environmental, and hormonal factors have been implicated in its development. The disease displays a broad variety of symptoms and highly variable clinical features, including systemic, cutaneous, renal, musculoskeletal, neurological and haematological manifestations. Approximately five million people worldwide suffer from a form of SLE and 90% of people diagnosed are women.

The management of SLE typically requires a comprehensive assessment of disease activity, the damage from the disease, and the careful tailoring of the treatment according to the involved organs and the disease severity. In general, treatment aims to manage and control symptoms during the acute periods of active disease, and to minimise the risk of flares during periods of remission. Conventional therapies include anti-malarials, corticosteroids and immunosuppressants and are often associated with significant risks and adverse effects. Belimumab, a B-lymphocyte stimulator-specific inhibitor, is the only approved targeted therapy for the treatment of adult patients with active autoantibody-positive SLE who are receiving standard therapy. Overall, there is a substantial unmet medical need for more effective and better tolerated therapies for the treatment of SLE.

About vobarilizumab

Vobarilizumab targets the interleukin 6 pathway via its IL-6 receptor (IL-6R). IL-6 is a pro-inflammatory cytokine that plays a role in T-cell activation, production of acute phase proteins in response to inflammation, induction of immunoglobulin production, and stimulation of osteoclast differentiation and activation. Vobarilizumab (26kD) is an anti-IL-6R Nanobody linked to an anti-human serum albumin (HSA) Nanobody (to increase the *in vivo* half-life of the molecule). Twenty-four-week data from a Phase I/IIa proof-of-concept study of ALX-0061 (vobarilizumab) in rheumatoid arthritis (RA) patients in combination with methotrexate were published in [February 2013](#), followed by the signing of a global exclusive option licensing deal with AbbVie in [September 2013](#) for the development and commercialisation of vobarilizumab in RA and SLE. AbbVie will review the complete data set when available from the Phase II STEADY SLE study to determine whether to exercise its option to license vobarilizumab. Should AbbVie exercise the option, it would trigger a payment to Ablynx. If the option is not exercised, Ablynx's agreement with AbbVie would terminate.

In [July 2016](#), Ablynx announced topline results from a 12-week Phase IIb study of vobarilizumab as a monotherapy in patients with moderate-to-severe RA. The study demonstrated that vobarilizumab reduced signs and symptoms of RA and resulted in ACR20, ACR50 and ACR70 scores of up to 81%, 49% and 24% respectively at week 12 as compared to 78%, 45% and 23%, respectively, at week 12 in the tocilizumab arm. Moreover, vobarilizumab induced clinical remission based on the disease activity score (DAS28_{CRP} <2.6) in up to 41% of patients, as compared to 27% of patients treated with tocilizumab. Vobarilizumab treatment resulted in improvement in physical function, and also had a favourable safety profile at all administered doses.

In [August 2016](#), Ablynx reported results from a 24-week, double-blind, placebo-controlled Phase IIb study of vobarilizumab administered as a combination therapy with methotrexate (MTX) to patients with moderate-to-severe RA. High ACR20 responses at week 12 were obtained in all treatment groups, ranging from 62% in the placebo group to between 73% and 81% in the vobarilizumab treatment groups. ACR20, ACR50 and ACR70 scores at week 24 were high with respectively 79%, 61% and 45% in the combined vobarilizumab dosing groups. In addition, vobarilizumab improved physical function and had a positive impact on disease activity with up to 70% of patients achieving low disease activity at week 24 (DAS28_{CRP} ≤ 3.2) and up to 51% of treated patients achieving clinical remission at week 24 (DAS28_{CRP} <2.6).

The results of the two Phase II studies in RA also confirmed the favourable safety profile of vobarilizumab and the potential for convenient monthly administration. An open-label extension study in RA patients is currently ongoing (94% roll-over rate) and results are expected in H2 2018.

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; Novo Nordisk; Sanofi and Taisho Pharmaceuticals. The Company is headquartered in Ghent, Belgium. More information can be found on www.ablynx.com.

On 29 January 2018, Sanofi made an offer to acquire all of Ablynx's outstanding ordinary shares (including shares represented by American Depositary Shares (ADSs), warrants and convertible bonds) at a price of €45 per share, which represents an aggregate equity value of approximately €3.9 billion. The proposed transaction was unanimously approved by both the Sanofi and Ablynx Board of Directors. The tender offer is expected to be launched in the beginning of the second quarter of 2018. Sanofi will publish an offer document in which it will set out the full details of its tender offer, and the Board of Directors of Ablynx will publish a response memorandum ('memorie van antwoord'), in which it will set out its position on the tender offer.

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Additional Information for US Investors

The tender offer for the outstanding ordinary shares ("Shares"), American Depositary Shares issued by J.P. Morgan Chase Bank, N.A., acting as depositary ("ADSs"), warrants ("Warrants") and convertible bonds of Ablynx ("Bonds" and, together with the Shares, ADSs and Warrants, the "Securities") has not yet commenced. This communication is for informational purposes only and is neither a recommendation, an offer to purchase nor a solicitation of an offer to sell any Securities of Ablynx.

At the time the tender offer is commenced, Sanofi will file, or cause to be filed, a tender offer statement on Schedule TO with the SEC and thereafter, Ablynx will file a solicitation/recommendation statement on Schedule 14D-9. Holders of Securities are urged to carefully review the documents that will be filed by Sanofi and Ablynx with the SEC because these documents will contain important information, including the terms and conditions of the tender offer.

The offer to purchase, the related letter of transmittal and certain other tender offer documents, as well as the solicitation/recommendation statement, are available to all holders of Securities of Ablynx at no expense to them. These documents are available for free at the SEC's website at www.sec.gov. Additional copies may be obtained for free by contacting Sanofi at ir@Sanofi.com or on Sanofi's website at <https://en.Sanofi.com/investors>. You should read the filings made by Sanofi and Ablynx with the SEC carefully before making a decision concerning the U.S. Offer.