



ABLYNX TO PRESENT ADDITIONAL DATA FOR ITS ANTI-IL-6R NANobody, VOBARILIZUMAB, A POTENTIAL BEST-IN-CLASS TREATMENT FOR RHEUMATOID ARTHRITIS

Data from the Phase IIb study in patients with moderate-to-severe disease already being treated with methotrexate to be presented at the Canadian Rheumatology Association (CRA) Annual Scientific Meeting

GHENT, Belgium, 9 February 2017 – Ablynx [Euronext Brussels: ABIX; OTC: ABYLY] announced that today it will present additional data from the Phase IIb RA combination study of its anti-IL-6R Nanobody®, vobarilizumab, at the Annual Scientific Meeting of the Canadian Rheumatology Association, being held from 8-11 February 2017 in Ottawa, Ontario (Canada). These data will be presented in two posters which will be available on the Ablynx website shortly after the conference.

In this 24-week, double-blind, international study, patients were randomised to receive subcutaneously administered placebo or one of four dose regimens of vobarilizumab, in addition to methotrexate. The primary endpoint was the proportion of patients achieving an ACR20 response at week 12. The secondary endpoints included assessments of higher levels of ACR response and disease activity ($DAS28_{CRP}$). Adverse events and routine safety parameters including laboratory assessments were also recorded.

The data show that in patients with active RA despite use of methotrexate, treatment with vobarilizumab (150mg q4w, 150mg q2w and 225mg q2w) had a positive impact on disease activity with a compelling safety profile. Overall, the results support the advancement of vobarilizumab into Phase III development.

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 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 systemic lupus erythematosus (SLE).

In [July 2016](#), Ablynx announced strong topline results from a 12-week Phase IIb study of vobarilizumab as a monotherapy in patients with moderate-to-severe RA which demonstrated that vobarilizumab was very effective and resulted in ACR20, ACR50 and ACR70 scores of up to 81%, 49% and 24% respectively at week 12. Moreover, vobarilizumab induced clinical remission (based on $DAS28_{CRP} < 2.6$) in up to 41% of patients, as compared to 27% for tocilizumab-treated patients, and it had a favourable safety profile at all administered doses.

In [August 2016](#), Ablynx reported compelling results from a 24-week Phase IIb study of vobarilizumab administered as a combination therapy with methotrexate (MTX) in patients with moderate-to-severe RA. ACR20, ACR50 and ACR70 scores at week 24 were high and vobarilizumab had a rapid and strong impact on disease activity with up to 49% of vobarilizumab-treated patients achieving clinical remission (based on $DAS28_{CRP}$) at week 24.

Collectively the impressive effects on clinically relevant efficacy endpoints, such as ACR70 and DAS28 remission, confirm its potential to be a best-in-class drug candidate in RA. Importantly, the collective results also confirmed the favourable safety profile of vobarilizumab in a larger patient population and the potential for convenient monthly administration.

An open-label extension study in RA patients is currently ongoing (94% roll-over rate) as well as a Phase II study in patients with systemic lupus erythematosus (SLE). The results from both of these studies are expected in 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., Merck KGaA, Novartis, Novo Nordisk and Taisho Pharmaceuticals. The Company is headquartered in Ghent, Belgium. More information can be found on www.ablynx.com.

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