ABLYNX REPORTS COMPPELLING TOPLINE PHASE IIb STUDY RESULTS WITH ITS ANTI-IL-6R NANOBODY, VOBARILIZUMAB, IN RA PATIENTS, CONFIRMING ITS BEST-IN-CLASS POTENTIAL

- ACR20, ACR50 and ACR70 scores of up to 79%, 59% and 43% respectively at week 24
- Strong impact on disease activity with up to 49% of patients in clinical remission at week 24
- Excellent safety profile at all administered doses
- Opportunity for convenient monthly dosing confirmed
- Results demonstrate clear potential advantages of vobarilizumab compared to other anti-IL-6/IL-6R drugs

**Conference call and webcast today at 4pm CET/10am ET**

GHENT, Belgium, 9 August 2016 - Ablynx [Euronext Brussels: ABLX; OTC: ABLY] today announced compelling topline results from a second Phase IIb RA study with its anti-IL-6R Nanobody®, vobarilizumab, which showed that treatment with vobarilizumab strongly decreased signs and symptoms of rheumatoid arthritis (RA) in patients with moderate to severe disease already being treated with methotrexate (MTX).

The double-blind study enrolled 345 subjects in Europe, Latin America and the United States, who were randomly assigned to one of the four dose groups of subcutaneously (sc) administered vobarilizumab plus methotrexate [75 mg every 4 weeks (Q4W), 150 mg Q4W, 150 mg Q2W, 225 mg Q2W] or placebo plus methotrexate. Subjects were evaluated for efficacy up to and including week 24 and for safety up to and including week 34. Following completion of the 24-week treatment period, eligible subjects were invited to enroll in an open-label extension study of vobarilizumab, with 94% accepting. Subjects who were not eligible to roll over or who did not elect to do so were followed for safety for an additional 12 weeks after the last dosing. Evaluation is ongoing for a minority of these subjects.

At week 12, a 20% improvement in American College of Rheumatology scores (ACR20), the primary endpoint of the study, was seen in up to 81% of vobarilizumab-treated patients. From week 12 to week 24, vobarilizumab induced continued improvement in higher level responses with ACR50 and ACR70 scores of up to 59% and 43% respectively at week 24. Moreover, the results demonstrate that vobarilizumab has a rapid and strong impact on disease activity with up to 49% of vobarilizumab-treated patients achieving clinical remission at week 24 compared to 17% of patients receiving placebo.

A summary of the efficacy results in the intent-to-treat (ITT) population is presented below:

% responders based on ITT analysis with non-responder imputation

<table>
<thead>
<tr>
<th>Efficacy parameter</th>
<th>placebo (N=69)</th>
<th>vobarilizumab 75mg, Q4W (N=69)</th>
<th>vobarilizumab 150mg, Q4W (N=70)</th>
<th>vobarilizumab 150mg, Q2W (N=68)</th>
<th>vobarilizumab 225mg, Q2W (N=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR20†</td>
<td>W12</td>
<td>62%</td>
<td>74%</td>
<td>75%</td>
<td>74%</td>
</tr>
<tr>
<td></td>
<td>W24</td>
<td>62%</td>
<td>74%</td>
<td>74%</td>
<td>74%</td>
</tr>
<tr>
<td>ACR50†</td>
<td>W12</td>
<td>28%</td>
<td>39%</td>
<td>29%</td>
<td>48%</td>
</tr>
<tr>
<td></td>
<td>W24</td>
<td>28%</td>
<td>39%</td>
<td>48%</td>
<td>48%</td>
</tr>
<tr>
<td>ACR70†</td>
<td>W12</td>
<td>9%</td>
<td>17%</td>
<td>14%</td>
<td>23%</td>
</tr>
<tr>
<td></td>
<td>W24</td>
<td>9%</td>
<td>17%</td>
<td>23%</td>
<td>23%</td>
</tr>
<tr>
<td>Clinically meaningful improvement in HAQ-DI score (≥ 0.25)‡</td>
<td>W12</td>
<td>71%</td>
<td>71%</td>
<td>68%</td>
<td>68%</td>
</tr>
<tr>
<td></td>
<td>W24</td>
<td>71%</td>
<td>68%</td>
<td>68%</td>
<td>68%</td>
</tr>
<tr>
<td>DAS28CRP remission§</td>
<td>W12</td>
<td>9%</td>
<td>17%</td>
<td>10%</td>
<td>23%</td>
</tr>
<tr>
<td></td>
<td>W24</td>
<td>9%</td>
<td>17%</td>
<td>23%</td>
<td>23%</td>
</tr>
<tr>
<td>DAS28CRP low disease activity or remission§</td>
<td>W12</td>
<td>23%</td>
<td>29%</td>
<td>25%</td>
<td>38%</td>
</tr>
<tr>
<td></td>
<td>W24</td>
<td>23%</td>
<td>29%</td>
<td>25%</td>
<td>38%</td>
</tr>
</tbody>
</table>

*nominal p<0.05 vs. placebo; **nominal p<0.01 vs. placebo; ***nominal p<0.001 vs. placebo

† ACR criteria measure improvement in tender and swollen joint counts and improvement in three of five other disease-activity measures; ACR20 measures % of patients with 20% improvement; ACR50 measures % of patients with 50% improvement and ACR70 measures % of patients with 70% improvement


§ DAS28CRP is an objective RA disease activity score based on C-reactive protein (CRP), tender and swollen joint counts of 28 defined joints and patient’s global assessment of disease activity; a score of >5.1 is associated with high disease activity, 5.1 to 3.2 moderate disease activity, 3.2 to 2.6 low disease activity, and <2.6 is associated with remission
The interim safety results through week 24 confirm vobarilizumab’s excellent safety profile which offers the potential for a clear competitive advantage over other anti-IL-6/IL-6R drugs. Treatment-emergent adverse events that led to study drug discontinuation were reported in 6.5% of all vobarilizumab treated patients compared to 4.3% for placebo. Treatment-related serious adverse events were reported in only 1.8% of all vobarilizumab treated patients compared to 2.9% for placebo and there was no observed dose dependency. Clinically meaningful abnormalities in liver function and neutrophil counts were infrequent across the study. Moreover, no grade 3 decreases in absolute platelet counts were observed and vobarilizumab had no effect on the mean LDL/HDL cholesterol ratio across all doses tested.

Dr Robert K. Zeldin, CMO of Ablynx, commented: “We are pleased to have successfully completed the second Phase IIb study with vobarilizumab in RA patients which showed that it has a meaningful impact on stringent and clinically relevant efficacy criteria such as ACR70 and DAS28 remission, and which confirmed vobarilizumab’s very favourable safety profile in a larger patient population. In addition, we were delighted to demonstrate the potential for monthly administration of vobarilizumab which could be very beneficial to patients. Together with the positive results from the RA monotherapy trial reported last month, we believe we have a most compelling data set underlining the potential for vobarilizumab to become a best-in-class, differentiated treatment option for patients suffering from RA.”

Dr Edwin Moses, CEO of Ablynx, commented: “From 2012/2013 when we saw the first results from the Phase IIa study with vobarilizumab in RA patients, we have been convinced that we have a drug with the potential to make an important difference to the lives of patients suffering from RA. Having entered into a collaboration with AbbVie in 2013 to help ensure the proper resourcing of clinical and commercial development, we are excited to have now confirmed that vobarilizumab has potential efficacy, safety and administration advantages compared to the competition. We believe that these results and those from many other Nanobody therapeutic programmes emphasize the fact that Nanobodies are not just another type of antibody but rather a whole new class of powerful therapeutic agents with important promotable differentiating features compared with other platforms. We now look forward to initiating the Phase III programme with vobarilizumab and AbbVie’s decision on whether they will opt into this programme in RA, which we expect before the end of the year.”

Webcast and presentation
Ablynx will host a conference call/webcast today at 4 pm CET, 10 am EST. The webcast may be accessed by clicking here. To participate in the Q&A, please dial +32 (0)2 404 06 60, using confirmation code 3494034. Shortly thereafter, a replay of the webcast will be available on the Company’s website: http://www.ablynx.com/news/events-presentations/.

About the Phase IIb RA combination therapy study
This Phase IIb study is a randomised, double-blind, placebo-controlled, multi-centre, dose-ranging study of vobarilizumab, administered subcutaneously in combination with MTX in subjects with moderate to severe RA, despite MTX therapy.

The study enrolled 345 subjects in Europe, Latin America and the United States, who were randomly assigned to placebo plus MTX or one of the four dose groups of vobarilizumab administered subcutaneously plus MTX. Subjects were evaluated for efficacy up to and including week 24 and for safety up to and including week 34. Following completion of the 24-week study, eligible subjects were then invited to enroll in an open-label extension study, with 94% accepting.

The primary endpoint is the ACR20 response at week 12. In accordance with the study protocol, any subject who did not achieve a 20% improvement from baseline in both swollen and tender joint count at any of the visits at week 12, 16 or 20 had to discontinue from the trial – this was an unusual requirement brought about by the desire to carry out a 24-week study with sc vobarilizumab for which there was only limited supporting data available. The

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4 Grade 3: absolute platelet count of <50.0 to 25.0 x 10^9/L
secondary endpoints include higher levels of response assessments, documentation of efficacy over time, as well as the effects on the improvement in physical function and health-related quality of life. Other planned assessments include the determination of serum levels of vobarilizumab, biomarkers, safety, tolerability and immunogenicity.

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). 24-week data from a Phase I/IIa proof-of-concept combination study of ALX-0061 (vobarilizumab) together 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 positive Phase IIb topline results for vobarilizumab as a monotherapy in patients with moderate to severe RA who were intolerant to methotrexate or for whom continued methotrexate treatment was inappropriate, demonstrating ACR20, ACR50 and ACR70 scores of up to 81%, 49% and 24% respectively at week 12. In addition, vobarilizumab as a monotherapy induced clinical remission in up to 41% of patients and had a favourable safety profile at all doses tested.

An open-label extension study in RA patients is currently ongoing as well as a Phase II study in patients with systemic lupus erythematosus (SLE). The results from both 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 40 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, Genzyme, 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.

For more information, please contact:
Ablynx
Dr Edwin Moses
CEO
t: +32 (0)9 262 00 07
m: +32 (0)473 39 50 68
e: edwin.moses@ablynx.com

Marieke Vermeersch
Director IR & Corporate Communications
t: +32 (0)9 262 00 82
m: +32 (0)479 49 06 03
e: marieke.vermeersch@ablynx.com
@AblynxABLX

Ablynx media/analyst relations:
FTI Consulting
Julia Phillips, Brett Pollard, Mo Noonan, Matthew Moss
t: +44 20 3727 1000
e: ablynx@fticonsulting.com
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