ABLYNX ANNOUNCES POSITIVE TOPLINE RESULTS FROM A PHASE IIb STUDY OF ITS ANTI-IL-6R NANOBODY, VOBARILIZUMAB (ALX-0061), AS A MONOTHERAPY IN RA

- ACR20, ACR50 and ACR70 scores of up to 81%, 49% and 24% respectively at week 12
- Very encouraging efficacy data compared to tocilizumab with up to 41% of patients in clinical remission at week 12
- Favourable safety profile, based on initial data, at all administered doses
- Results from the 24 week Phase IIb study of vobarilizumab, as a combination therapy with methotrexate in RA, are expected later in Q3 2016

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

GHENT, Belgium, 7 July 2016 - Ablynx [Euronext Brussels: ABLX; OTC: ABYLY] today announced that its anti-IL-6R Nanobody®, vobarilizumab (ALX-0061), successfully completed a 12 week treatment and assessment period in a Phase IIb monotherapy study in patients with moderately to severely active rheumatoid arthritis (RA) who are intolerant to methotrexate or for whom continued methotrexate treatment is inappropriate. The objective of the study was to explore the efficacy and safety of various dose regimens for vobarilizumab monotherapy to guide further clinical development, and to obtain parallel descriptive information for tocilizumab in the same clinical trial RA population.

The study enrolled 251 subjects in the United States, Europe and South America, who were randomly assigned to one of the three blinded dose groups of subcutaneously (sc) administered vobarilizumab [150 mg every 4 weeks (Q4W), 150 mg every 2 weeks (Q2W), 225 mg every 2 weeks (Q2W)] or open-label sc tocilizumab¹, with the vast majority (94%) receiving weekly tocilizumab dosing. Subjects were evaluated for efficacy and safety up to week 12 and eligible subjects on vobarilizumab were then invited to enroll in an open-label extension study, with 91% 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.

The topline ACR efficacy results demonstrate that vobarilizumab appears to be very effective with less frequent administration than tocilizumab. In addition, based on the change from baseline in the health assessment questionnaire disability score (HAQ-DI), vobarilizumab seems to have a rapid positive impact on patients’ physical function. Importantly, vobarilizumab induces either clinical remission or low disease activity (based on DAS28CRP) in up to 60% of patients at week 12.

A summary of the efficacy results at week 12 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>vobarilizumab 150mg, Q4W (N=62)</th>
<th>vobarilizumab 150mg, Q2W (N=62)</th>
<th>vobarilizumab 225mg, Q2W (N=63)</th>
<th>tocilizumab 162mg, Q1W (N=60) or Q2W (N=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR20¹</td>
<td>73%</td>
<td>77%</td>
<td>81%</td>
<td>78%</td>
</tr>
<tr>
<td>ACR50¹</td>
<td>44%</td>
<td>37%</td>
<td>49%</td>
<td>45%</td>
</tr>
<tr>
<td>ACR70¹</td>
<td>16%</td>
<td>24%</td>
<td>21%</td>
<td>23%</td>
</tr>
<tr>
<td>Clinically meaningful improvement in HAQ-DI score (≥ 0.25)²</td>
<td>65%</td>
<td>68%</td>
<td>71%</td>
<td>72%</td>
</tr>
<tr>
<td>DAS28CRP remission³</td>
<td>26%</td>
<td>27%</td>
<td>41%</td>
<td>27%</td>
</tr>
<tr>
<td>DAS28CRP low disease activity or remission⁴</td>
<td>42%</td>
<td>57%</td>
<td>60%</td>
<td>44%</td>
</tr>
</tbody>
</table>

¹Subjects received tocilizumab [RoActemra®, an anti-IL-6R monoclonal antibody marketed by Roche/Chugai] according to the following dosing regimen: 1) US: 162 mg every 2 weeks (subjects weighing < 100kg) or every week (for subjects weighing ≥ 100 kg). 2) EU/South-America: 162 mg every week for all subjects
²ACR 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
³DAS28CRP 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 12 confirmed the favourable safety profile of vobarilizumab at all doses tested and its side effect profile did not change with increased dose. Treatment-emergent adverse events were similar across the different groups and only 2.1% of vobarilizumab treated patients discontinued study drug due to adverse events compared with 6.3% for the tocilizumab group. Serious treatment-related adverse events occurred in 0.5% of vobarilizumab treated patients as compared to 3.1% for the tocilizumab group. Liver function abnormalities were not frequent across the study and no grade 3 decreases in absolute platelet counts were observed. While infrequent, study drug discontinuations due to a decrease in absolute neutrophil count were less commonly observed with vobarilizumab than with tocilizumab. At week 12, there were no meaningful changes from baseline in the mean LDL/HDL cholesterol ratio across all groups.

Dr Robert K. Zeldin, CMO of Ablynx, commented: “We are very pleased with the positive outcome from this first Phase IIb study of vobarilizumab in RA. The goal of RA treatment is to improve the signs and symptoms of the disease, reduce disease activity, induce remission, and improve physical function. We believe the data clearly demonstrate the potential of vobarilizumab as an important new treatment option for patients suffering from RA. We look forward to reporting the data from the methotrexate combination therapy study in RA later this quarter.”

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)2 402 30 92, using confirmation code 6440754. 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 monotherapy study
The objective of this Phase IIb monotherapy study was to explore efficacy and safety for various dose regimens for vobarilizumab monotherapy to guide further clinical development, and to obtain parallel descriptive information for tocilizumab in the same clinical trial RA population. The doses were selected in anticipation of providing active treatment as monotherapy; for this reason no low doses were included.

This randomised Phase IIb RA study consists of 2 parallel segments: a double-blind segment to assess the efficacy and safety of vobarilizumab sc and an open-label segment with tocilizumab sc (with a blinded joint assessor), which is intended to provide parallel efficacy and safety data for tocilizumab in the same RA population.

The study enrolled 251 subjects in the United States, Europe and South America, who were randomly assigned to one of three blinded dose groups of subcutaneously (sc) administered vobarilizumab (150 mg Q4W, 150 mg Q2W, 225 mg Q2W) or to the sc tocilizumab dose group.

Subjects were evaluated for efficacy and safety up to week 12 and subjects on vobarilizumab were then invited to enroll into an open-label extension study and 91% accepted. Subjects who were not eligible to roll over or chose not to do so were followed for safety for an additional 12 weeks after the last dosing, with evaluation currently ongoing for a minority of subjects.

The primary endpoint is the ACR20 response at week 12, a broadly accepted clinical response measure to demonstrate reduction in RA signs and symptoms. The 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.

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5 Grade 3: absolute platelet count of <50.0 to 25.0 x 10^9/L
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) comprises an anti-IL-6R Nanobody linked to an anti-human serum albumin (HSA) Nanobody (to increase the half-life of the molecule). Phase I/IIa proof-of-concept results with ALX-0061 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).

Recruitment of 345 RA patients in a Phase IIb combination therapy study of vobarilizumab with methotrexate has been completed and results from this study are expected later in Q3 2016. An open-label extension study in RA is currently ongoing as well as a Phase II study in patients with 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, immunology, 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.

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