ABLYNX’S ANTI-IL-6R NANOBODY, ALX-0061, SHOWS EXCELLENT 24 WEEK SAFETY AND EFFICACY RESULTS IN A PHASE II CLINICAL TRIAL IN RHEUMATOID ARTHRITIS

- ACR20, ACR50 and ACR70 scores of up to 100%, 75% and 63% respectively
- Up to 75% of patients in DAS28 remission
- Attractive safety profile at all administered doses
- No anti-drug antibodies detected
- No disease progression as determined by MRI radiography

Results will be discussed during a webcast presentation today at 16h CET, 10 am EST
Click here to register, call number +32 (0)2 620 01 38

GHENT, Belgium, 13 February 2013 - Ablynx [Euronext Brussels: ABLX] today announced efficacy and safety data for its anti-IL-6R Nanobody, ALX-0061, at the 24 week final analysis of the Phase II part of a combined Phase I/II study in patients with moderately to severely active rheumatoid arthritis (RA) on a stable background of methotrexate.

In this Phase II part, 37 RA patients were recruited and were randomised to three dose groups of intravenously administered ALX-0061 (1mg/kg Q4W, 3mg/kg Q4W and 6mg/kg Q8W) or to placebo. A total of 34 patients were eligible for determination of efficacy parameters at the 12 week interim period, and all these patients continued the study until week 24.

Depending on the patient’s disease status at week 10, the monthly dose was increased (from 1mg/kg to 3mg/kg; or from 3mg/kg to 6mg/kg) or the dosing regimen intensified (from 6mg/kg Q8W to 6 mg/kg Q4W), and patients on placebo could start monthly ALX-0061 treatment at 3mg/kg. The vast majority of patients (86%, N=24) completed the study at their ALX-0061 starting regimen (the ‘unmodified’ group), for 4 patients the dosing regimen was modified (the ‘modified’ group) and 3 patients were switched from placebo to ALX-0061 treatment (the ‘switchers’).

At all doses tested, ALX-0061 was well-tolerated and the safety profile compared favourably to data reported for other biological DMARDs. No clinically relevant neutropenia (moderate or severe decrease in neutrophils, a type of white blood cell), no clinically significant increases in lipid levels (cholesterol and triglycerides) were observed, and there were no serious infections. Infrequent elevation of liver enzymes were reported; the events were transient, generally mild to moderate, and did not result in a discontinuation of the treatment. Additionally, the side effect profile of ALX-0061 did not change with increased dose or treatment duration and no anti-drug antibodies were detected.

The efficacy results for the ‘unmodified’ patient population at week 24 are presented below:

<table>
<thead>
<tr>
<th>Efficacy parameter</th>
<th>1mg/kg Q4W (N=8)</th>
<th>3mg/kg Q4W (N=8)</th>
<th>6mg/kg Q8W (N=8)</th>
<th>Pooled ‘unmodified’ (N=24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR20(^1)</td>
<td>75%</td>
<td>100%</td>
<td>75%</td>
<td>83%</td>
</tr>
<tr>
<td>ACR50(^2)</td>
<td>63%</td>
<td>75%</td>
<td>75%</td>
<td>71%</td>
</tr>
<tr>
<td>ACR70(^2)</td>
<td>50%</td>
<td>63%</td>
<td>63%</td>
<td>58%</td>
</tr>
<tr>
<td>DAS28 remission(^3)</td>
<td>50%</td>
<td>75%</td>
<td>63%</td>
<td>63%</td>
</tr>
<tr>
<td>Boolean remission(^4)</td>
<td>25%</td>
<td>38%</td>
<td>25%</td>
<td>29%</td>
</tr>
</tbody>
</table>

\(^1\) Q4W: every 4 weeks \(\approx\) Q8W: every 8 weeks
\(^2\) DMARDs: disease modifying anti-rheumatoid arthritis drugs
\(^3\) ACR [American College of Rheumatology] criteria measure improvement in tender or 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
\(^4\) DAS28 is an RA disease activity score based on C-reactive protein (CRP), tender and swollen joint counts of 28 defined joints and physician’s global health assessment; a total score of >5.1 is associated with high disease activity, moderate from 3.2 to 5.1, low disease activity from 3.2 to 2.6, and remission of disease if <2.6
The efficacy results at week 24 for the ‘modified’ patient population and patients switching from placebo to ALX-0061 treatment are presented below:

<table>
<thead>
<tr>
<th>Efficacy parameter</th>
<th>Pooled ‘modified’ (N=4)</th>
<th>Pooled ‘switchers’ (N=3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR20</td>
<td>75%</td>
<td>100%</td>
</tr>
<tr>
<td>ACR50</td>
<td>50%</td>
<td>67%</td>
</tr>
<tr>
<td>ACR70</td>
<td>50%</td>
<td>0%</td>
</tr>
<tr>
<td>DAS28 remission</td>
<td>50%</td>
<td>33%</td>
</tr>
</tbody>
</table>

A magnetic resonance imaging (MRI) assessment was also included in this study. At week 24, there was a reduction of bone oedema, which is an early indicator of joint destruction. Additionally, the global radiographic score confirmed the absence of disease progression at this final time point.

Dr Josefin-Beate Holz, Chief Medical Officer of Ablynx, commented:
“We are very pleased with the 24 week results of this Phase II part of the study. We believe we have shown impressive clinical activity for ALX-0061 at the predicted dose levels as well as the potential for dosing every four or every eight weeks. The side effect profile of the Nanobody did not change over time or with dose escalation and the therapeutic effect improved even further with treatment duration. The majority of patients achieved a durable status of disease remission, some of them already after the first month of treatment. In addition, patients who had an inadequate response could be identified early on in the treatment schedule and could even be ‘rescued’. These findings confirm the potential for ALX-0061 and the drug could become an important addition to clinicians’ range of tools to treat this severely debilitating disease.”

Dr Edwin Moses, Chairman and CEO of Ablynx added:
“We believe that these new data provide additional confidence that ALX-0061 could become a very valuable treatment option for patients with RA. We are now investigating the various possibilities through which we can progress the development of ALX-0061, including discussions with potential partners and other paths which will allow us to maximise the value of this asset.”

Conference call and webcast presentation
The Ablynx management team will host a conference call and webcast during which the Phase II results at week 24 will be presented, followed by a Q&A session. This event will be held today, 13 February 2013 at 4.00 pm CET/ 10 am EST. The conference call will be webcast live and may be accessed on the home page of the Ablynx website at www.ablynx.com or by clicking here. If you would like to participate in the Q&A, please dial +32 (0)2 620 0138. Shortly after the call, a replay of the webcast and the presentation used in connection with the conference call webcast will be available on the Company’s website.

About ALX-0061 (anti-IL-6R)
ALX-0061 targets the interleukin 6 pathway via its IL-6 receptor (IL-6R), which plays a fundamental role in the inflammation process in RA.

ALX-0061 has been designed to become a best-in-class therapeutic. Its small size (26kD) should allow ALX-0061 to penetrate more effectively into tissues. The potent, monovalent interaction of the molecule with its target reduces the possibility of off-target effects. Its binding to human serum albumin prolongs the in vivo half-life of the product and can lead to improved trafficking to areas of inflammation. The Nanobody has a very strong affinity for soluble IL-6R which should ensure fast target engagement and could result in a fast onset of effect. ALX-0061 appears to benefit from the general Nanobody characteristic of having a very low immunogenic potential. ALX-0061 is a very robust and stable drug product that is already

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Boolean remission in RA is a more recent measure of disease activity and is achieved when at any time point, a patient satisfies all of the following: swollen and tender joint count, patient global assessment and CRP all ≤ 1
manufactured at a multi-thousand litre scale. It can be administered both intravenously and subcutaneously.

About Ablynx

Ablynx is a biopharmaceutical company engaged in the discovery and development of Nanobodies®, a novel class of therapeutic proteins based on single-domain antibody fragments, for a range of serious human diseases, including inflammation, haematology, oncology and pulmonary disease. Today, the Company has approximately 25 programmes in the pipeline and five Nanobodies at clinical development stage. Ablynx has ongoing research collaborations and significant partnerships with major pharmaceutical companies including Boehringer Ingelheim, Merck Serono, Novartis and Merck & Co. The Company is headquartered in Ghent, Belgium. More information can be found on www.ablynx.com.

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