



REGULATED INFORMATION

**PFIZER'S ANTI-TNF-ALPHA NANOBODY (ATN-103) SUCCESSFULLY COMPLETES
A PHASE II STUDY AND DEMONSTRATES CLINICAL PROOF-OF-CONCEPT (POC)
IN PATIENTS WITH RA**

GHENT, Belgium, 17 May 2011 – *Ablynx [Euronext Brussels: ABLX]* today announced top-line results from the recently completed POC Phase II clinical trial of ozoralizumab (ATN-103), an anti-TNF-alpha Nanobody licensed to Pfizer, in patients with active rheumatoid arthritis (RA). The study evaluated five different dosing groups plus placebo, and preliminary analysis of the data indicates that the study met its pre-defined primary efficacy endpoint with the highest dose of ozoralizumab (80 mg every 4 weeks) resulting in a statistically significant improvement of ACR20 responses compared with placebo at week 16. In addition, an improvement over placebo was also observed for secondary endpoints such as improvements of clinical scores, DAS28, ACR50, ACR70 and EULAR response at this dose level at week 16. No dose limiting toxicities were observed, and the adverse events and serious adverse events that did occur, did not show a clinically significant increase on increased dosing.

Pfizer have now confirmed that clinical proof-of-concept has been achieved and they are now engaged in a full technical, clinical and commercial evaluation to determine whether and how to take ATN-103 forward.

Dr Edwin Moses, Chairman and CEO commented: "We are delighted to announce the first clinical proof-of-concept for a Nanobody. This has extremely important implications for Ablynx, the whole Nanobody technology platform and our R&D pipeline containing more than 25 programmes. Our progress has been rapid and we are excited to have passed this critical milestone in our development into a potentially leading biopharmaceutical company. We look forward to the completion of Pfizer's internal decision making process."

About the clinical development programme

Pfizer successfully completed Phase I studies with ATN-103 in the summer of 2009, and then initiated two randomized, double-blind Phase II trials in Japan, US and Rest of the World in September 2009, which finished recruitment of a total of 312 patients in September 2010. In the US and Rest of the World Phase II POC trial (not including Japan), 253 patients with active RA, on a stable background therapy of methotrexate, were randomly assigned to four subcutaneous injections of ATN-103 in five dose groups (10mg, 30mg, 80mg every 4 weeks; 10mg, 80mg every 8 weeks) or four subcutaneous injections of placebo every 4 weeks. In February 2010, Pfizer started a long-term safety study for ATN-103, which is an open-label extension study of the Phase II trials. The study is expected to be completed by the beginning of 2012.

About ozoralizumab ([ATN-103](#))

ATN-103 is a bivalent (i.e. two Nanobodies with identical binding sites for the same epitope) anti-TNF-alpha Nanobody construct with a half-life extension moiety.

About rheumatoid arthritis

RA is a chronic, progressive inflammatory disease of the joints and surrounding tissues that is associated with pain, irreversible joint destruction and systemic complications such as fatigue and anaemia. The disease affected ~4.1 million people in 2010 in the seven major markets¹.

About the Pfizer and Ablynx collaboration

Ablynx announced the exclusive research collaboration and license agreement with Pfizer (originally signed with Wyeth Pharmaceuticals) in November 2006, a deal potentially worth \$212.5 million in past and future milestone payments, research funding and upfront payments. In addition, Ablynx is eligible to receive royalties on product sales. Under this agreement, Pfizer has exclusive rights to develop and commercialise anti-TNF-alpha Nanobodies developed under the collaboration for all therapeutic indications. The lead Nanobody-based candidate, ATN-103, recently completed Phase II studies in patients with RA. Following completion of this Phase II study, Pfizer has confirmed that clinical proof-of-concept has been achieved and is currently assessing whether and how to take the asset forward. The second development candidate, PF-05230905, is in a Phase I study.

About Ablynx

[Ablynx](#) (Euronext: ABLX) 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 and life-threatening human diseases, including inflammation, thrombosis, oncology and respiratory diseases. Today, the Company has over [25 projects in the pipeline](#) and there are six Nanobodies in clinical development. Ablynx has ongoing research collaborations and significant partnerships with major pharmaceutical companies, including Boehringer Ingelheim, Merck Serono, Novartis and Pfizer. The Company is headquartered in Ghent, Belgium and currently employs over 270 people. More information can be found on www.ablynx.com.

Webcast and presentation

The Ablynx management team will host a conference call webcast during which the clinical trial results for ozoralizumab (ATN-103) will be presented, followed by a Q&A session. This event will be held today, 17 May 2011 at 7.00 p.m. CET. The conference call will be webcast live and may be accessed on the home page of the Ablynx website at www.ablynx.com. Shortly thereafter, a replay of the webcast and the presentation used in connection with the conference call webcast will be available on the Company's website.

¹ Datamonitor 2010

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