



ABLYNX COMPLETES PATIENT RECRUITMENT IN THE PHASE IIb RESPIRE STUDY OF ITS INHALED ANTI-RSV NANOBODY ALX-0171

GHENT, Belgium, 30 April 2018 - Ablynx [Euronext Brussels and Nasdaq: ABLX] today announced that it has successfully completed patient recruitment in the Phase IIb RESPIRE dose-ranging efficacy study of ALX-0171, the Company's novel inhaled drug candidate to treat respiratory syncytial virus (RSV) infections.

A total of 180 infants (aged 1-24 months) diagnosed with RSV and hospitalised for a lower respiratory tract infection have been enrolled. The study consists of a sequential dose escalation part which enrolled 36 infants, followed by a parallel part in which 144 infants were randomly assigned to one of three dose groups of inhaled ALX-0171 or placebo. The study drug is administered once daily for three consecutive days.

Data from this Phase IIb study are expected to be reported in the second half of 2018.

Dr Robert K. Zeldin, Chief Medical Officer at Ablynx, commented:

"Completing study recruitment is an important step in the development of our inhaled anti-RSV Nanobody and we look forward to reporting the data later this year. Recruiting 180 infants with RSV younger than two years of age in just over 16 months confirms the urgent need for effective therapies in RSV. We thank everyone involved in this trial for their contribution and enabling us to evaluate ALX-0171 as a potential therapeutic for RSV infections, which today impact millions of infants and young children and place a significant burden on their families."

About RSV

RSV is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide. It is the primary cause of infant hospitalisation and virus-associated deaths in infants, with estimated global annual infection of 33 million infants and young children and the resulting hospitalisation of 3-4 million¹. RSV is associated with an estimated 3,000-8,500 deaths in infants <2 years globally per year², and it has been linked to an increased risk of asthma development later in life³.

Current treatment of RSV infections is primarily focused on symptomatic relief, hence the need for an effective and specific anti-RSV therapeutic.

About ALX-0171

ALX-0171 is a wholly-owned trivalent Nanobody that binds to the F-protein of RSV, thereby inhibiting viral replication and neutralising RSV activity by blocking virus uptake into cells. The physical robustness of the Nanobody allows administration via inhalation directly to the site of infection, i.e. the respiratory tract. ALX-

¹ Shi *et al*, Lancet 2017

² Byington *et al*, Pediatric 2014

³ Sigurs *et al*, Thorax 2010; Backman *et al*, Acta Paediatr 2014

0171 has shown a potent anti-viral effect against a broad range of RSV strains *in vitro* and it has demonstrated a marked therapeutic effect following administration via nebulisation in a neonatal animal model for infant RSV infection⁴.

Repeated daily inhalation of ALX-0171 was proven to be well-tolerated in multiple Phase I clinical studies in adults and a Phase I/IIa study in 53 hospitalised infants (aged 1-24 months) with a RSV infection. In addition, repeated daily inhalation of ALX-0171 had an immediate and significant impact on viral replication and an encouraging initial therapeutic effect in the Phase I/IIa study.

The randomised, double-blind, placebo-controlled, international, multi-centre dose-ranging Phase IIb RESPIRE study is evaluating three different doses of inhaled ALX-0171 in 180 hospitalised infants (aged 1-24 months) with a RSV infection. The sequential dose escalation part, which enrolled 36 infants, was completed in July 2017, after which the Data Monitoring Committee recommended to continue the study without changes to the protocol. The parallel dose part of the study in 144 infants was initiated in August 2017. The primary endpoint of the trial is to evaluate the anti-viral effect of treatment measured in samples taken by nasal swabs. Secondary endpoints include safety, pharmacokinetics and clinical activity determined by assessment of the composite Global Severity Score. Topline results from the RESPIRE trial are expected in H2 2018.

A randomised, double-blind, placebo-controlled, multi-centre Phase II study of ALX-0171 in 60 Japanese infants (aged 1-24 months) diagnosed with RSV and hospitalised for a lower respiratory tract infection is also ongoing since [March 2018](#), with topline results expected in H2 2019.

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., Kenilworth, New Jersey, USA; Merck KGaA; Novo Nordisk; Sanofi and Taisho Pharmaceuticals. The Company is headquartered in Ghent, Belgium. More information can be found on www.ablynx.com.

On 29 January 2018, Sanofi made an offer to acquire all of Ablynx's outstanding ordinary shares (including shares represented by American Depositary Shares (ADSs), warrants and convertible bonds) at a price of €45 per share, which represents an aggregate equity value of approximately €3.9 billion. The proposed transaction was unanimously approved by both the Sanofi and Ablynx Board of Directors. The offer is comprised of two separate but concurrent tender offers: (i) a tender offer under the laws of Belgium for all of the outstanding shares, warrants and convertible bonds of Ablynx (the **"Belgian Offer"**) and (ii) a tender offer under the laws of the U.S. for all of the outstanding shares held by U.S. holders and ADSs held by holders, wherever located (the **"U.S. Offer"**). The initial acceptance period of the tender offers commenced on 4 April 2018 and will expire at 5:00 p.m. ET / 11:00 p.m. CET on 4 May 2018, subject to extension.

⁴ Oral presentation at the 9th International RSV Symposium, [November 2014](#)

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


Lies Vanneste

Director IR

t: +32 (0)9 262 0137

m: +32 (0)498 05 35 79

e: lies.vanneste@ablynx.com

 @AblynxABLX

Ablynx media relations:

Consilium Strategic Communications

Mary-Jane Elliott, Philippa Gardner, Sukaina Virji

t: +44 (0)20 3709 5700

e: ablynx@consilium-comms.com

Joele Frank, Wilkinson Brimmer Katcher

Dan Katcher or Joseph Sala

t: +1 212-355-4449

Disclaimer

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company or, as appropriate, the Company directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its parent or subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.

Additional information on the Belgian Offer

An electronic version of the prospectus (including the forms) can be found on the websites of the Receiving & Paying Agents (for BNP Paribas Fortis NV/SA, <https://www.bnpparibasfortis.be/epargneretplacer> (French and English) and <https://www.bnpparibasfortis.be/sparenenbeleggen> (Dutch and English); for KBC Securities NV/SA in cooperation with KBC Bank NV/SA, <https://www.kbcsecurities.com/prospectus-documents-overviews/prospectus-overview>, <https://www.kbc.be>, <https://www.cbc.be> and <https://www.bolero.be>), Sanofi (<https://www.sanofi.com/en/investors/tender-offers-ablynx> and <https://www.sanofi.com/fr/investisseurs/offres-ablynx>) and Ablynx (<http://www.ablynx.com/investors/sanofi-takeover-bid/>). The Prospectus can also be obtained in hard copy free of charge (i) at the counters of the Receiving & Paying Agents or (ii) by contacting the Receiving & Paying Agents at +32 (0)2 433 41 13 (BNP Paribas Fortis NV/SA), +32 (0)78 15 21 53 (KBC Bank NV/SA, Dutch & English), +32 (0) 800 92 020 (CBC Banque NV/SA, French & English) or +32 32 83 29 81 (Bolero by KBC Securities NV/SA, Dutch, French & English). The Prospectus is available in English and Dutch. The summary of the prospectus is also available in French.

The Response Memorandum is annexed to the prospectus. The Response Memorandum can also be obtained in hard copy free of charge at the registered office of Ablynx (Technologiepark 21, 9052 Zwijnaarde (Belgium)). The Response Memorandum is available in English and Dutch.

Additional Information on the U.S. Offer

The tender offer for the outstanding ordinary shares (“Shares”), American Depositary Shares issued by J.P. Morgan Chase Bank, N.A., acting as depositary (“ADSs”), warrants (“Warrants”) and convertible bonds of Ablynx (“Bonds” and, together with the Shares, ADSs and Warrants, the “Securities”) has commenced. This communication is for informational purposes only and is neither a recommendation, an offer to purchase nor a solicitation of an offer to sell any Securities of Ablynx.

Sanofi has filed a tender offer statement on Schedule TO with the SEC and Ablynx has filed a solicitation/recommendation statement on Schedule 14D-9 with respect to the U.S. Offer. Ablynx stockholders and other investors should read the tender offer statement (including the offer to purchase, related letter of transmittal and other offer documents) and the solicitation/recommendation statement carefully because they contain important information, including the terms and conditions of the U.S. Offer.

The offer to purchase, the related letter of transmittal and certain other tender offer documents, as well as the solicitation/recommendation statement, are available to all holders of Securities of Ablynx at no expense to them. These documents are available for free at the SEC’s website at www.sec.gov. Additional copies may be obtained for free by contacting Sanofi at ir@Sanofi.com or on Sanofi’s website at <https://en.Sanofi.com/investors>. Stockholders and other investors should read the filings made by Sanofi and Ablynx with the SEC carefully before making a decision concerning the U.S. Offer.