ABLYNX COMMENCES DOSING IN ITS PHASE II STUDY OF ALX-0171 IN HOSPITALISED JAPANESE INFANTS WITH A RSV INFECTION

GHENT, Belgium, 2 March 2018 - Ablynx [Euronext Brussels and Nasdaq: ABLX] today announced that the first patient has been dosed in the Japanese Phase II study of ALX-0171, the Company's wholly-owned inhaled Nanobody® to treat respiratory syncytial virus (RSV) infections.

This Phase II study is a randomised, double-blind, placebo-controlled, multi-centre study of ALX-0171 in 60 Japanese infants (aged 1-24 months) diagnosed with RSV and hospitalised for a lower respiratory tract infection. The study will evaluate four different doses and a safety review by an independent Data Monitoring Committee will occur prior to proceeding to each higher dose. ALX-0171 will be administered via nebulisation once daily for three consecutive days and will be given along with standard-of-care treatment.

The primary objectives of this Phase II study are to evaluate the safety, tolerability and systemic pharmacokinetics (PK) of different doses of inhaled ALX-0171 in Japanese infants infected with RSV. Secondary objectives include the evaluation of the antiviral effect, clinical activity, immunogenicity and pharmacodynamics (PD) of different doses of inhaled ALX-0171. The study is expected to read out in the second half of 2019.

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

"We are very pleased to start this Phase II study of ALX-0171 in RSV-infected Japanese infants and look forward to reporting the results in the second half of 2019. There remains an urgent need for effective therapies in RSV and this is an important step in making our inhaled anti-RSV Nanobody available to patients worldwide. This year, we also plan to report the topline results from our global Phase IIb RESPIRE study in 180 RSV-infected hospitalised infants."

About RSV

Respiratory syncytial virus (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 and hospitalisation rates of 3-4 million[1]. It is associated with an estimated 3,000-8,500 deaths in infants <2 years globally per year[2], and it has been linked to an increased risk of asthma development later in life[3].

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

[1] Shi *et al*, Lancet 2017
[2] Byington *et al*, Pediatric 2014
[3] Sigurs *et al*, Thorax 2010; Backman *et al*, Acta Pediatr 2014

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-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 infection[4].

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.

A randomised, double-blind, placebo-controlled, international, multi-centre dose-ranging Phase IIb study (RESPIRE) of three different doses of inhaled ALX-0171 in 180 hospitalised infants (aged 1-24 months) with a RSV infection is currently ongoing. The sequential dose escalation part, which enrolled 36 infants, has been 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.

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.

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

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