



## **ABLYNX'S PARTNER, MERCK KGaA, HAS PRESENTED NEW DATA FROM A PHASE Ib PSORIASIS STUDY OF THE BI-SPECIFIC ANTI-IL-17A/F NANOBODY AT THE ANNUAL AAD CONFERENCE**

- All patients in the highest dose group achieved 90% skin clearance (PASI 90) compared to 0% for placebo
- Skin biopsy showed complete reversal of disease pathology in the majority of patients in the high dose group
- The onset of clinical effect was rapid and sustained throughout the study
- Favourable safety and tolerability profile across all doses tested

**GHENT, Belgium, 6 March 2017** - Ablynx [*Euronext Brussels: ABLX; OTC: ABYLY*] today announced that its partner, Merck KGaA (Darmstadt, Germany), has presented new data from a Phase Ib study demonstrating strong efficacy with the bi-specific anti-IL-17A/F Nanobody® (M1095; ALX-0761) in patients with moderate-to-severe chronic plaque psoriasis. The results were presented at the 75<sup>th</sup> Annual Meeting of the American Academy of Dermatology Conference, taking place from 3-7 March 2017, in Orlando, Florida.

The Phase Ib study was a multi-centre, double-blind, randomised, placebo-controlled trial in 41 patients with moderate-to-severe chronic plaque psoriasis to evaluate the safety, tolerability and immunogenicity of multiple ascending doses of M1095, ranging from 30mg to 240mg administered subcutaneously on days 1, 15 and 29. The study also evaluated pharmacokinetic profiles and efficacy of multiple subcutaneous doses of M1095.

A reduction in disease activity, as measured by the Psoriasis Area Severity Index (PASI) and improvement in static Physician Global Assessment (sPGA) was seen for all doses of M1095 versus 0% for placebo. At day 85, all patients treated with 240mg M1095 experienced a 75% reduction in disease activity (PASI 75) and had clear or almost clear skin (PASI 90); moreover, 56% of patients in this highest dose group had clear skin (PASI 100). In addition, rapid onset of clinical effect was observed after the first administered dose and sustained through to completion of the study at day 85.

M1095 had a favourable safety and tolerability profile, with no treatment-related serious adverse events reported and no dose-dependent increase in frequency or severity of adverse events. There was no apparent effect of anti-drug antibodies on pharmacokinetics.

The presentation '**Safety and efficacy of multiple ascending doses of subcutaneous M1095, an anti-interleukin-17A/F bi-specific Nanobody®, in patients with moderate-to-severe psoriasis**' is available on the Ablynx website under [R&D portfolio](#).

**Dr Edwin Moses, CEO of Ablynx, commented:** "This Nanobody was developed as part of a deal we signed with Merck KGaA in 2008 and was the first functional bi-specific Nanobody to reach the clinic. We were responsible for the discovery and some of the pre-clinical work and Merck KGaA is now responsible for the clinical development and commercialisation of this drug candidate. These initial clinical data are very encouraging compared to other psoriasis therapeutics commercially available, and in development. We believe that the results are a further validation of the enormous potential of the Nanobody platform to generate differentiating multi-specific drug candidates for the treatment of a wide range of diseases."

### **About M1095 (anti-IL-17A/F)**

The interleukin (IL)-17A/F bispecific Nanobody neutralizes the pro-inflammatory cytokines IL-17A and IL-17F, which are each expressed at inflammatory sites, and have both been implicated in the pathogenesis of psoriasis and several auto-immune disorders. The interleukin-17 (IL-17) family of cytokines includes six IL-17-family ligands, and five receptors. IL-17A is the most studied family member and most often mentioned as IL-17. IL-17F is the closest relative to IL-17A based on sequence and receptor binding. Indeed, while both IL-17A and IL-17F exist as homodimers, an IL-17A/F heterodimer has also been described. In addition, both IL-17F and IL-17A bind the IL-17RA and IL-17RC receptors. A difference between IL-17A and IL-17F is that their expression may be differentially regulated at both the cell-type and transcriptional levels accounting for non-redundant roles *in vivo*. IL-17A and IL-17F are important mediators of local and systemic inflammation. Their activities are often additive or synergistic to that of other inflammatory mediators such as tumour necrosis factor (TNF). This described biology of IL-17A and IL-17F supports a role for both cytokines in the initiation and perpetuation of Th17-associated chronic auto-immune and inflammatory diseases and in subsequent organ damage.

The bi-specific anti-IL-17A/F Nanobody (M1095) was discovered by Ablynx. Merck KGaA is now responsible for the clinical development and commercialisation of M1095 with Ablynx set to potentially receive milestones and royalties as the programme progresses.

### **About the Psoriasis Area Severity Index (PASI)**

Psoriasis Area and Severity Index (PASI) is the most widely used tool for the measurement of severity of psoriasis. It assesses treatment efficacy by measuring the reduction in redness, scaling and thickness of psoriatic plaques and the extent of involvement in each region of the body. PASI combines the assessment of the severity of lesions and the area affected into a single score. PASI is widely used in clinical trials of therapies to treat psoriasis. Although absolute PASI score is often used to define entry into a trial, it is response to treatment that is important to measure efficacy and outcomes. This is usually presented as a percentage response rate; e.g. PASI 50, PASI 75, PASI 90, PASI 100. PASI 75, for example, represents the percentage (or number) of patients who have achieved a 75% or more reduction in their PASI score from baseline. PASI 100 indicates patients who have achieved a complete resolution of all disease.

### **About static Physician Global Assessment (sPGA)**

A key measure used in clinical trials of psoriasis is the physician global assessment (PGA). Global assessments can be done for extensive disease as well as localized plaques. The static PGA measures the physician's impression of the disease at a single point. The static Physician's Global Assessment (sPGA) scale rates the investigator's overall clinical assessment of a subjects plaque thickness, erythema, and scaling on a 6-point scale ranging from 0 (clear, except for residual discoloration) to 5 (majority of plaques have severe thickness, erythema, and scale). To assign a sPGA score, the investigator examines all psoriatic lesions and assigns a severity score ranging from 0 to 5 for thickness, erythema, and scaling. Scores for thickness, erythema, and scaling are summed and the mean of these 3 scores equals the overall sPGA score. Overall sPGA scores range from 0 to 5, where lower scores indicate clinical improvement. In this study, the percentage of subjects who achieved a sPGA rating of 0 (clear) or 1 (minimal) and had at least a 2 level reduction from baseline score were reported.

### **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., Merck KGaA, Novartis, Novo Nordisk and Taisho Pharmaceuticals. The Company is headquartered in Ghent, Belgium. More information can be found on [www.ablynx.com](http://www.ablynx.com).

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