Press release *Stockholm, Sweden 1st June, 2004*

Biolipox announces positive results from clinical Phase II trial in rhinitis

Biolipox, a Swedish research intensive pharmaceutical company targeting inflammation and respiratory diseases, today announced positive preliminary results from the first Phase II clinical trial with NLA (a Novel anti-allergy drug) in patients suffering from allergic rhinitis. Biolipox intends to start discussions with prospective partners, aiming to enter a collaboration agreement for further development and commercialisation of NLA. The targeted product profile for NLA is a drug with significant and rapid reduction of rhinitis symptoms which does not induce drowsiness.

NLA is administered as a nasal spray. The Phase II trial was a three-way crossover trial, in which 36 pollen- allergic patients were given three different treatments (NLA, cetirizine tablets and placebo) in a double- blind order (the different treatment orders were not known to either the patient or clinician). Patients were treated for 12 days, and a low dose of the pollen each patient was sensitive to was given over the last seven days of treatment. The primary variable was total nasal symptom score at 10 minutes after the allergen challenge, comparing NLA treatment with placebo treatment. The secondary variable was total nasal symptom score during NLA treatment, compared with cetirizine treatment.

NLA treatment led to a statistically significant reduction in symptoms measured as a lower total nasal symptom score compared with placebo treatment. No statistically significant difference was seen between treatments with NLA and cetirizine tablet. The most frequent adverse events reported were nasal irritation and headache. The lower systemic exposure resulting from a nasal spray compared to a tablet may indicate a potential for less systemic side effects with NLA-treatment.

“In my opinion the data from the phase II study support that the NLA spray could become a valuable treatment in allergic rhinitis” said Associate Professor Lennart Greiff at the ENT Clinic at Lunds University Hospital in Sweden, responsible investigator in the study. Associate Professor Lars Larsson, VP & Chief Medical Officer at Biolipox commented: “We are pleased to see that the NLA compound is effective in patients, and we are now looking forward to further development of a product that has the potential to increase quality of life for allergic patients”.

Dr Torbjörn Bjerke, President and Chief Executive Officer, commented: “Our goal is to develop a product which has rapid onset of action and does not cause drowsiness. The positive results underpin Biolipox’s confidence that this drug may have a promising future on the worldwide allergy market, a market with a value exceeding USD 6 billion. This is an important milestone in the process of Biolipox becoming a leading research-intensive pharmaceutical company within inflammatory diseases.”

Biolipox has an exclusive worldwide license to the NLA compound from NicOx S.A (Bloomberg: COX:FP, Reuters: NCOX.LN). NLA is the first compound selected from the ongoing research and co-development agreement between NicOx S.A and Biolipox for the discovery and development of novel compounds in the respiratory field

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Note to Editors

Biolipox AB is a pharmaceutical R&D company, focused on creating novel, efficacious and cost effective therapeutic opportunities for respiratory conditions and other inflammatory disorders. Biolipox' scientific platform is based on world-class arachidonic acid cascade research.

Phase I clinical trials are performed to establish the safety of a drug candidate, usually in healty volunteers.

Phase IIa clinical trials are performed to establish if a drug candidate has the desired initial efficacy in patients suffering from a specific disease or condition. If such efficacy can be demonstrated, Proof of Concept has been achieved for the drug candidate.

Phase IIb clinical trials are typically performed on a larger patient population and during a longer time period compared to Phase IIa. The main objective is to establish a correct dosing of the drug candidate in order to achive desired efficacy without undesired side effects.

Phase III clinical trials are performed to establish the long-term efficacy and safety of the drug candidate in its final dose and formulation. These studies may involve thousands of patients who are treated during one to two years.

Upon completion of the Phase III studies, the drug candidate dossier is submitted to the appropriate regulatory authorities for review and approval for launch.