NOXXON Pharma AG announces excellent preliminary phase I trial results for Spiegelmer® NOX-E36 – good safety and pharmacodynamic profile and additional good subcutaneous bioavailability

Berlin, Germany, 12 October – NOXXON Pharma AG, the biopharmaceutical company focusing on the development of novel drugs based on its unique proprietary Spiegelmer® technology, today announced successful completion of the first phase I trial with its anti-inflammatory Spiegelmer® NOX-E36. This drug candidate will be developed for the treatment of complications of type 2 diabetes, preferentially diabetic nephropathy, but also others.

The phase I study, conducted in the United Kingdom, was performed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of the chemokine inhibitor NOX-E36 in 72 healthy volunteers. A double-blind, placebo-controlled, single ascending dose study design was used to investigate escalating intravenous doses, the bioavailability of subcutaneous doses and potential gender differences.

Preliminary results show NOX-E36 to be safe and well tolerated at all dose levels in both the intravenous and subcutaneous groups. NOX-E36 showed dose-linear pharmacokinetics, leading to plasma concentrations well above those known to be effective in animal models. Pharmacodynamic evaluation indicates a dose-dependent decrease of peripheral blood monocytes, consistent with the mode of action of NOX-E36 – neutralization of chemokine monocyte chemoattractant protein-1 (MCP-1). This protein is a specific target in the inflammatory reaction cascade that causes recruitment of monocytes to sites of inflammation. It has recently been introduced as “adipokine” playing an important role in obesity and complications of type 2 diabetes. Its inhibition is thus anticipated to be of benefit for type 2 diabetes patients.

In addition, NOX-E36 showed excellent bioavailability after subcutaneous administration. This fact should make it possible to achieve a dosing regimen with at least once weekly administration. Final results and analysis for this phase I trial are expected by early 2010.

The results of this phase I study will be instrumental in the design of the upcoming multiple dose studies in healthy volunteers and non-insulin dependent diabetic patients with multiple complications. The recruitment phase for these studies will begin in early 2010.

Dr Frank Morich, CEO of NOXXON Pharma AG, commented: “The preliminary results of this phase I study are impressive and show that Spiegelmers® have the potential to become a novel class of broadly applicable therapeutic agents addressing large areas of unmet medical need. They also indicate that Spiegelmers® can be applied in convenient dosing regimens. In the meantime our other drug candidates are advancing rapidly towards clinical development.”

About NOXXON

Berlin-based NOXXON Pharma AG is a clinical stage biotechnology company focusing on the development of Spiegelmers® for the treatment of inflammatory diseases and haematological indications. NOXXON is in possession of a broad patent estate and a readily scalable GMP production. In addition to its in-house programs NOXXON discovers and develops Spiegelmers® in collaboration with partners from the pharmaceutical industry, including Eli Lilly, Hoffmann La-Roche and Pfizer. The business strategy of NOXXON is to broaden this range of collaborations through co-development and licensing agreements for the proprietary clinical and pre-clinical products as well as technology-based multi-target partnerships. Currently the company has one compound in clinical development. The declared goal of NOXXON is to establish the Spiegelmer® drug discovery platform as the leading scaffold technology to deliver non-polypeptide-based chemical entities with superior properties.

NOXXON’s main investors are TVM Capital, Sofinnova Partners, Edmond de Rothschild Investment Partners, Deutsche Effecten- und Wechsel-Beteiligungsgesellschaft (DEWB), Seventure Partners, Dow Venture Capital, Dieckell Group, FCP OP MEDICAL BioHealth-Trends, IBG Risikokapitalfonds, VC Fonds Berlin, and others.

About Spiegelmers®

Spiegelmers® (L-aptamers) are chemical entities based on synthetic mirror-image oligonucleotides which are highly selective for their pharmacological target and potent inhibitors of target function. They combine the benefits of small molecule drugs and biopharmaceuticals.

Due to their unique mirror image configuration Spiegelmers® are not metabolized and do not hybridize with native nucleic acids. Spiegelmers® also do not activate the innate immune response via toll-like receptors and showed an exceptionally favourable immunogenicity profile in pre-clinical testing.

About NOX-E36

NOX-E36 is a new therapeutic modality that specifically targets the pro-inflammatory chemokine monocyte chemoattractant protein-1 (MCP-1), which is also known as CCL2. Previously completed studies in various animal models demonstrate that treatment with Spiegelmer® MCP-1 antagonists significantly delays the decline in kidney function as well as disease progression. The preclinical profiling and first-in-human enabling studies were supported by a grant of the German Federal Ministry of Education and Research (BMBF).