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EANS-News: DEWB Investment Holding NOXXON to Initiate Phase Ib Clinical Trial of MCP-1 Inhibitor NOX-E36

07.07.2010 - 14:35 Uhr, Deutsche Effecten- und Wechsel-Beteiligungsges. AG (DEWB)

Study to include healthy volunteers and diabetic patients

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Subtitle: Study to include healthy volunteers and diabetic patients

Berlin, Germany, 7 July 2010 (euro adhoc) - NOXXON Pharma AG announced today that it has permission to commence a multiple ascending dose study of its Monocyte Chemoattractant Protein-1 (MCP-1) targeting anti-inflammatory Spiegelmer®, NOX-E36. NOXXON plans to develop NOX-E36 for the treatment of diabetic nephropathy and other diabetes related complications.

The double-blind, placebo controlled, Phase I study will evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of the MCP-1 inhibitor NOX-E36 in four groups of subjects. The first group, composed of healthy volunteers, will receive NOX-E36 i.v. every other day for 15 days. The three remaining groups, composed of type II diabetic patients, will receive ascending doses of NOX-E36 i.v. every other day for 27 days.

Dr Frank Morich, CEO of NOXXON Pharma AG, commented: "The pharmacokinetic and pharmacodynamic data from diabetic patients who will be enrolled in this NOX-E36 study will guide NOXXON in choosing the doses and endpoints most likely to reveal the therapeutic potential of NOX-E36 in a Phase II program. Given the absence of existing therapies in the indications targeted by NOX-E36 the inclusion of diabetic patients is a crucial step in defining the best path forward."

The NOX-E36 multiple ascending dose study is scheduled to begin treatment of the first group of subjects in August 2010. Further information about this clinical trial is available at www.clinicaltrials.gov (ID: NCT01085292).

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About Spiegelmers® Spiegelmers® (L-stereoisomer RNA oligonucleotides) 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 favorable immunogenicity profile in pre-clinical testing.

About NOX-E36 NOX-E36 is a new Spiegelmer®-based therapeutic that specifically binds to and inhibits the pro-inflammatory chemokine monocyte chemoattractant protein-1 (MCP-1), which is also known as CCL2. Previously completed studies in animal models of diabetes and lupus nephritis demonstrate that treatment with Spiegelmer® MCP-1 antagonists significantly delay decline in kidney function as well as disease progression. The Phase I single ascending dose trial demonstrated NOX-E36 to be safe and well tolerated in healthy volunteers at all employed dose levels after both intravenous and subcutaneous routes of administration. Subcutaneous bioavailability of NOX-E36 was greater than 50%. An overall comparison between NOX-E36 and placebo treated subjects did not reveal any safety related differences. There were no clinically relevant effects on vital signs, ECG and laboratory parameters. NOX-E36 exhibited dose-linear pharmacokinetics, and the pharmacokinetic profile after subcutaneous administration suggests the possibility to maintain clinically relevant plasma levels with a once or twice weekly dosing regimen. Pharmacodynamic data showed a significant and dose-dependent decrease in peripheral blood monocytes - the largest population of immune cells that carry the MCP-1 receptor. This effect is consistent with inhibition of MCP-1, the mode of action of NOX-E36. The preclinical profiling and first-in-human enabling studies were supported by a grant of the German Federal Ministry of Education and Research (BMBF, grant no. 01GU0703).

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 hematological indications. NOXXON possesses a broad patent estate and has access to 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 and Hoffmann La-Roche. 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. Currently the company has two compounds in clinical development. NOXXON's investors are NGN Capital, 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.

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inquiry note:

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