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EANS-News: DEWB Investment Holding NOXXON Announces the Completion of the First-in-Human Clinical Trial with Spiegelmer® NOX-A12

03.05.2010 - 12:25 Uhr, Deutsche Effecten- und Wechsel-Beteiligungsges. AG (DEWB)

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----- Company Information

Berlin, Germany, May 03, 2010 (euro adhoc) - NOXXON Pharma AG, the biopharmaceutical company focusing on the development of novel drugs based on its unique proprietary Spiegelmer® technology, announced today the successful completion of the first-in-human clinical trial with Spiegelmer® NOX-A12.

This Phase I study was designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics in healthy individuals following intravenous administration of the stromal cell-derived factor-1 (SDF-1) antagonizing Spiegelmer® NOX-A12. Final data analysis demonstrated an excellent safety and tolerability up to the highest tested dose of 10.8 mg/kg. In addition, analysis by flow cytometry revealed a long lasting and dose dependent mobilization of WBC and CD34 positive cells. The protocol also allowed that an additional group of volunteers would be dosed and be receiving a leukapheresis procedure if certain thresholds of circulating CD34 positive cells were reached, to further characterize the mobilized cells. This study goal was achieved, too. Further information about the clinical trial is available on www.clinicaltrials.gov (ID: NCT00976378).

Dr. Frank Morich, Chief Executive Officer of NOXXON, commented: "Based on exceptionally positive pre-clinical and clinical data, we strongly believe that NOX-A12 has the potential to be developed for acute as well as chronic indications in the area of hematological malignancies and/or solid tumors. NOX-A12 is scheduled to enter a multiple dose Phase I clinical trial by mid of 2010, and phase II clinical testing soon thereafter."

About NOX-A12 NOX-A12 specifically antagonizes stromal cell-derived factor-1 (SDF-1), a chemokine which attracts and activates immune- and non-immune cells. SDF-1 binds with high affinity to the chemokine receptors CXCR4 and CXCR7. The CXCR4/SDF-1 axis has been shown to play a role in stem cell mobilization, vasculogenesis, tumor growth and metastasis. Inhibition of the SDF-1 binding to CXCR4 sensitizes tumor cells to chemotherapy suggesting that NOX A12 in combination with chemotherapy could be beneficial in the treatment of various cancers.

NOX-A12 has been evaluated in models of stem cell mobilization, angiogenesis, inflammation and lung and kidney injury. In these models NOX-A12 reduced pathological angiogenesis and tissue remodeling. In preclinical safety and two weeks toxicology studies NOX-A12 was safe and did not show any organ toxicity. In particular NOX-A12 did not exert any immunotoxicity effects, such as Toll-like receptor activation or changes in cytokine levels.

NOXXON receives grant support (Grant no. 0315118) within the program "KMU-innovativ" from the German Federal Ministry of Education and Research (BMBF) for the preclinical program and the first-in-human clinical trial with NOX-A12.

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. Unlike conventional nucleic acids, Spiegelmers® do not activate the innate immune response via toll-like receptors and they showed an exceptionally favorable immunogenicity profile in pre-clinical testing.

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 is in possession of 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 as well as technology-based multi-target partnerships. Currently the company has two compounds in clinical development. The declared goal of NOXXON is to establish its oligonucleotide-based drug discovery platform (Spiegelmers®) as the leading 'scaffold' technology to create new chemical entities with superior properties.

NOXXON's 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.

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