



## **NOXXON Announces Initiation of First-in-Human Clinical Trial with Hematopoietic Stem Cell Mobilizing Spiegelmer® NOX-A12**

**Berlin, Germany, November 02, 2009** – NOXXON Pharma AG, the biopharmaceutical company focusing on the development of novel drugs based on its unique proprietary Spiegelmer® technology, announced today the successful initial dosing of healthy volunteers in a first-in-human clinical trial with Spiegelmer® NOX-A12. NOX-A12 is NOXXON's second drug candidate entering the clinical stage of development within only five months.

The Phase I program is currently being conducted in Germany following review and approval of the Clinical Trial Application by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). This single center study is designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics in up to 42 individuals, following intravenous administration of the hematopoietic stem cell (HSC) mobilizing Spiegelmer® NOX-A12. Further information about this clinical trial is available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (ID: NCT00976378).

Dr. Frank Morich, Chief Executive Officer of NOXXON, commented: “Based on exceptionally positive pre-clinical data, we strongly believe that, NOX-A12 has the potential to become an improved alternative for hematopoietic stem cell mobilization. Our goal is to have NOX-A12 approved by 2014. In this ongoing trial we are expecting to see a good safety profile and to gain initial efficacy data that will further validate the value of the Spiegelmer® technology for the drug development in areas with high unmet medical need.”

NOX-A12 binds and neutralizes the chemokine Stromal Cell-Derived Factor-1 (SDF-1, also known as CXCL12), a key regulatory element in the homing and retention of HSCs in the bone marrow. Mobilized HSCs can be collected by leukapheresis, a process that is generally preferred to invasive bone marrow harvesting. NOXXON's pre-clinical data indicate that the efficacy and pharmacokinetic properties of NOX-A12 may lead to a simpler and more effective HSC mobilization procedure compared to current practice.

The results obtained in this Phase I clinical trial will form the basis for the Phase II program to be conducted by mid 2010 in patients with Multiple Myeloma or non-Hodgkin's Lymphoma undergoing autologous stem cell transplantation.

### **About NOX-A12**

NOX-A12 mobilizes hematopoietic stem cells from the bone marrow by disrupting the SDF-1 gradient that normally attracts them to their niches. Studies in animal models demonstrate that treatment with a single dose of Spiegelmer® NOX-A12 significantly mobilizes hematopoietic progenitor cells in a dose dependent manner. NOXXON receives grant support 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 Hematopoietic Stem Cell Transplantation**

Hematopoietic stem cell transplantation is considered the treatment of choice for many patients with severe malignant or non-malignant, acquired or congenital disorders of the hematopoietic

system or for patients with chemosensitive, radiosensitive or immunosensitive tumors. Better management of the patients, improved supportive care, increased donor pools and novel conditioning regimes have extended its use to new patient categories and new disease conditions.

### **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, 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 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), Sevenure Partners, Dow Venture Capital, Dieckell Group, FCP OP MEDICAL BioHealth- Trends, IBG Risikokapitalfonds, VC Fonds Berlin, and others.

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