



**NOXXON Initiates Phase IIa of Anti-Hepcidin Spiegelmer® NOX-H94
Anemia of Chronic Disease Study is Fourth Phase II Initiated by NOXXON in 2012**

Berlin, Germany - 04 December 2012 - NOXXON Pharma today announced the treatment of the first patients in a Phase IIa clinical trial of its anti-hepcidin Spiegelmer® NOX-H94 to treat anemia associated with chronic disease. This Phase IIa study was initiated following the successful completion of the clinical Phase I program, data from which will be presented at the upcoming ASH (American Society of Hematology) meeting in Atlanta, Georgia, 8-11 Dec 2012. The Phase I program consisted of a comprehensive single and multiple ascending dose study in healthy volunteers and a subsequent human pharmacodynamic study to assess the ability of NOX-H94 to prevent endotoxin-induced hypoferraemia in healthy subjects. This endotoxemia study delivered the first clinical evidence that NOX-H94 is capable of neutralizing high levels of hepcidin in humans and maintaining higher serum iron concentrations relative to subjects receiving placebo.

NOX-H94 is the third Spiegelmer® to enter Phase II studies and this study is the fourth Phase IIa trial that NOXXON has started this year. The other Phase IIa studies initiated in 2012 include the NOX-E36 Phase IIa for the treatment of diabetic nephropathy, the NOX-A12 Phase IIa for the treatment of Chronic Lymphocytic Leukemia, and the NOX-A12 Phase IIa for the treatment of Multiple Myeloma.

Excessive concentrations of the peptide hormone hepcidin, which is also called the master regulator of iron homeostasis, occur in some chronic diseases such as cancer, renal disease, or inflammatory diseases. These high hepcidin levels lead to iron restriction, also known as functional iron deficiency: a condition in which iron is blocked inside its cellular stores and is thus unavailable for hemoglobin synthesis. This condition, over time, results in anemia of chronic disease. NOX-H94 inhibits this pathological mechanism by binding and inactivating hepcidin.

The NOX-H94 Phase IIa study is being conducted to investigate the hypothesis that inhibition of hepcidin can raise hemoglobin levels in patients with anemia of chronic disease. The four-week repeated-dose multi-center study will be conducted in Europe in anemic patients with cancer. An open-label pilot phase will be followed by a 3-arm randomized, double-blind, placebo-controlled main phase comparing two different dose-regimens of NOX-H94 with placebo.

Hepcidin inhibitors such as NOX-H94 offer the potential to provide a targeted treatment alternative for anemia of chronic disease and to avoid some of the disadvantages of the existing unspecific therapies which are often given at supra-physiological doses: erythropoiesis-stimulating agents (ESAs), i.v. iron, and blood transfusions:

- the potential risks of ESAs in the treatment of patients with cancer and chronic kidney disease are documented in the black box warning required by the US FDA and include increased risk of tumor progression or recurrence;
- use of i.v. iron has increased in response to concerns with ESAs; but this therapy is limited by the potential occurrence of iron overload, in addition administration of i.v. iron leads to a counter-productive increase in hepcidin;
- blood transfusions also add iron to the body and in addition bring the risks of transmissible diseases and immunosuppression.

NOX-H94 is the first hepcidin inhibitor to reach Phase II.

Based on information from the GLOBOCAN database and scientific publications on rates and types of anemia in cancer and chronic kidney disease (CKD) patients, NOXXON estimates that there are approximately 230,000 cancer patients and 3.6 million CKD patients requiring treatment for anemia of chronic disease every year that could potentially benefit from a hepcidin inhibitor in the combined markets of the EU-5 (France, Germany, Italy, Spain and the United Kingdom), Japan and the United States.

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Notes for editors:

About NOXXON Pharma AG

NOXXON Pharma is a biopharmaceutical company pioneering the development of a new class of proprietary therapeutics called Spiegelmers. Spiegelmers are the chemically synthesized, non-immunogenic alternative to antibodies. NOXXON has a diversified portfolio of clinical-stage Spiegelmer[®] therapeutics:

- NOX-E36, an anti-CCL2/MCP-1 (C-C chemokine ligand 2 / Monocyte Chemoattractant Protein-1) Spiegelmer[®], is currently in a Phase IIa study in patients with type 2 diabetes with albuminuria. CCL2 is a pro-inflammatory chemokine involved in the recruitment of immune cells to inflamed tissues.
- NOX-A12, an anti-CXCL12/SDF-1 (CXC chemokine ligand 12 / Stromal Cell-Derived Factor-1) Spiegelmer[®], is currently in Phase IIa studies in two hematological cancers, multiple myeloma (MM) and chronic lymphocytic leukemia (CLL). CXCL12 is a chemokine mediator of tumor invasion, metastasis, and resistance to therapy.
- NOX-H94, an anti-hepcidin Spiegelmer[®], is currently in a Phase IIa study in cancer patients with anemia. Heparidin is the key regulator of iron metabolism and responsible for the iron restriction leading to anemia of chronic disease.

The Spiegelmer[®] platform provides the company with powerful and unique discovery capabilities, which have generated a number of additional leads under preclinical investigation. Located in Berlin, Germany, NOXXON is a well-financed mature biotech company with a strong syndicate of international investors, and approx. 60 employees. For more information, please visit: www.noxxon.com

About NOX-H94 & Anemia of Chronic Disease

NOX-H94 is a Spiegelmer[®] compound targeting the iron-regulating protein hepcidin. Heparidin is the master regulator of iron homeostasis via its effect on ferroportin, the

only known iron export protein. Cytokine-induced synthesis of hepcidin plays a crucial role in macrophage iron retention, which underlies the anemia of chronic disease by limiting the availability of iron for erythroid progenitor cells. Patients with anemia of chronic disease display an impaired response to erythropoietin (EPO). The NOX-H94 compound is a 44-nucleotide L-RNA oligonucleotide linked to 40 kDa PEG. Preclinical studies have demonstrated that this compound inhibits IL-6 induced anemia in monkeys and has similar pharmacokinetics to other Spiegelmer® compounds. The compound can be administered intravenously or subcutaneously.

NOXXON received grant support within the program KMU-innovativ from the German Federal Ministry of Education and Research (BMBF) for the preclinical and early clinical development of NOX-H94.

Further information about the ongoing NOX-H94 Phase IIa clinical trial is available at ClinicalTrials.gov: ID: [NCT01691040](https://clinicaltrials.gov/ct2/show/study/NCT01691040).

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