

## PRESS RELEASE



### **NOXXON initiates Phase I of NOX-H94 for Anemia of Chronic Disease**

*First-in-man for third Spiegelmer® product*

**Berlin, Germany- 6 September 2011-** NOXXON Pharma today announced the initiation of a Phase I clinical trial for NOX-H94, the Company's third compound to enter the clinic. NOX-H94 is a Spiegelmer® designed to treat anemia of chronic disease by targeting the peptide hormone hepcidin, the key regulator of iron metabolism. Hepcidin is up-regulated by acute and chronic inflammatory reactions resulting in "iron restriction", which means that iron is blocked inside cellular stores and not available for hemoglobin synthesis<sup>1</sup>. This is in contrast to "iron deficiency", in which iron stores are depleted.

Subjects will first be administered escalating single doses of NOX-H94 and will then be tested with multiple doses. Both the intravenous and sub-cutaneous routes of administration will be tested. The primary objective of the study is to assess the safety and tolerability of NOX-H94 with a secondary objective to test pharmacokinetic/pharmacodynamic responses to the compound.

Mr. Iain Buchanan, Chief Executive Officer of NOXXON, commented: "The recent entry of NOX-H94 into human trials marks the third Spiegelmer® product in clinical development and underlines the transition that NOXXON has made to a company with clinical-stage assets. Preliminary data arising from this study suggest that NOX-H94 is safe, well tolerated and acts in a manner as predicted by preclinical studies. NOXXON will provide further updates on the progress of NOX-H94 and other compounds in its pipeline later in the year."

The underlying causes of anemia of chronic disease are mainly infections, cancer, autoimmune diseases and chronic kidney disease. Estimated prevalence reaches approximately 70% in certain cancers and autoimmune diseases and constitutes an area of significant medical need. In this US, more than 1 million people are estimated to have anemia of chronic disease<sup>2</sup>.

- ends -

#### **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 targets the pro-inflammatory chemokine MCP-1 (CCL2) and is currently in Phase Ib for complications of type 2 diabetes such as nephropathy.
- NOX-A12 targets SDF-1 (CXCL12), a chemokine mediator of metastasis and resistance to chemotherapy in cancer, and is currently in Phase I.
- NOX-H94 targets hepcidin, the key regulator of iron metabolism and mediator of iron restriction in anemia of chronic disease, and is currently in Phase I.

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, approx. 60 employees and a highly experienced management team.

For more information, please visit: [www.noxxon.com](http://www.noxxon.com)

**Notes for editors:**

**NOX-H94**

NOX-H94 is a Spiegelmer compound targeted at the iron-regulating protein hepcidin. Hepcidin 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 inflammation by limiting the availability of iron for erythroid progenitor cells. Patients with anemia of inflammation display an impaired response to erythropoietin (EPO). The 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 and has similar pharmacokinetics to other Spiegelmer® compounds. The compound can be administered intravenously or subcutaneously. NOXXON receives grant support within the program KMU-innovativ from the German Federal Ministry of Education and Research (BMBF) for the preclinical development and the first-in-human clinical trial with NOX-H94.

**References**

- 1) Guenter Weiss, M.D., and Lawrence T. Goodnough, M.D., (2005) **Anemia of Chronic Disease**, N Engl J Med 2005; 352:1011-1023.
- 2) Gary J. Vanasse and Nancy Berliner (2010) **Anemia in Elderly Patients: An Emerging Problem for the 21<sup>st</sup> Century**, Hematology, 2010:271-5).

**Contact:**

NOXXON Pharma AG	College Hill Life Sciences
Emmanuelle Delabre T: +49-30-726247-100 edelabre@noxxon.com	Dr. Robert Mayer T: +49 (0)89 57001806 robert.mayer@collegehill.com