

NOXXON Initiates Phase IIa Study of Anti-Hepcidin Spiegelmer[®] Lexaptepid Pegol (NOX-H94) in Dialysis Patients with EPOhyporesponsive Anemia

Berlin, Germany - 31 July 2014 - NOXXON Pharma today announced the treatment of a first patient with its anti-hepcidin Spiegelmer[®] lexaptepid pegol (NOX-H94) in a phase IIa proof-of-concept clinical trial to treat erythropoietin (EPO)-hyporesponsive anemia in dialysis patients. This is the fourth clinical trial with lexaptepid pegol. The multi-center, placebo-controlled study will examine the pharmacokinetics, pharmacodynamics, efficacy and safety of single and multiple doses of lexaptepid pegol in EPO-hyporesponsive dialysis patients with anemia.

Approximately 10% of the dialysis population has erythropoiesis-stimulating agent (ESA)-resistant anemia, an unmet medical need that NOXXON now addresses with this study. Anemic dialysis patients that do not respond adequately to an ESA could benefit from the inhibition of hepcidin by lexaptepid pegol. A recent study by NOXXON, presented at the AACR meeting and the EHA congress in 2014, has already shown significant increases in hemoglobin levels (>1 g/dL) in response to lexaptepid pegol monotherapy in a subset of anemic cancer patients.

Lexaptepid pegol is a Spiegelmer[®] that binds and neutralizes hepcidin, a peptide hormone that negatively regulates serum iron levels. High hepcidin levels, commonly found in dialysis patients, lead to iron restriction, also known as functional iron deficiency. This condition, in which iron is blocked inside its cellular stores and therefore unavailable for hemoglobin synthesis, ultimately results in anemia.

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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 chemically synthesized L-stereoisomer oligonucleotide aptamers, a non-immunogenic alternative to antibodies. NOXXON has a diversified portfolio of clinical-stage Spiegelmer[®] therapeutics:

- Emapticap pegol (NOX-E36), an anti-CCL2/MCP-1 (C-C chemokine ligand 2 / Monocyte Chemoattractant Protein-1) Spiegelmer[®], has completed a Phase IIa proof-of-concept study in patients with type 2 diabetes with albuminuria and a Phase IIb study is in the planning stages. CCL2 is a pro-inflammatory chemokine involved in the recruitment of immune cells to inflamed tissues.
- Olaptesed pegol (NOX-A12), an anti-CXCL12/SDF-1 (CXC chemokine ligand 12 / Stromal Cell-Derived Factor-1) Spiegelmer[®], is currently tested in Phase IIa studies in two hematological cancers, multiple myeloma (MM) and chronic lymphocytic leukemia (CLL). A study for treatment of glioblastoma has been designed. CXCL12 is a chemokine known to be involved in tumor invasion, metastasis, and resistance to therapy.
- Lexaptepid pegol (NOX-H94), an anti-hepcidin Spiegelmer[®], has completed a Phase IIa pilot study in cancer patients with anemia and is now being studied in EPO-hyporesponsive dialysis patients. Hepcidin 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 approximately 60 employees.

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: <u>NCT02079896</u>

For more information, please visit: <u>www.noxxon.com</u>

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