

PRESS RELEASE



## **NOXXON presents Positive Results from Emapticap Pegol Phase IIa Diabetic Nephropathy Study**

*Anti-CCL2 /MCP-1 Spiegelmer<sup>®</sup> emapticap pegol (NOX-E36) shows beneficial and lasting effects on albuminuria and glycemic control*

**Berlin, Germany - 4 April 2014** - NOXXON Pharma AG announced that Phase IIa proof-of-concept data from the emapticap pegol (NOX-E36) trial in diabetic nephropathy were presented at the ISN Nexus Symposium in Bergamo, Italy earlier today.

Emapticap pegol is a Spiegelmer<sup>®</sup> that binds and neutralizes CCL2/MCP-1 (C-C Chemokine Ligand / Monocyte Chemoattractant Protein-1), a pro-inflammatory chemokine that plays an important role in diabetic kidney disease, the most common single cause of chronic kidney failure and end-stage renal disease.

The objective of this randomized, double-blind placebo-controlled multi-center international study was to evaluate the efficacy, pharmacokinetics, safety and tolerability of treatment with emapticap pegol. Seventy-five type 2 diabetic patients with albuminuria on current standard of care to control hypertension, hyperglycemia and dyslipidemia were treated for 12 weeks with twice-weekly subcutaneous emapticap pegol or placebo. This treatment period was followed by a 12 week observational period to study the long-term effect of emapticap pegol treatment on albuminuria. Importantly, the underlying standard of care mandatorily included stable renin-angiotensin system (RAS) blockade, which has been demonstrated to reduce albuminuria and to slow progression of diabetic nephropathy. Emapticap pegol was found to be safe and well tolerated with no treatment-related serious adverse events. For the primary efficacy analysis, patients with major protocol violations, on dual RAS blockade, or with concomitant hematuria and leukocyturia were excluded.

Results showed relevant, statistically significant reductions in urinary albumin excretion and improved glycemic control. Importantly, these effects were independent of hemodynamic changes and maintained after cessation of treatment, suggesting that emapticap pegol interferes with the underlying pathophysiology of diabetic nephropathy. Long-lasting effects on urinary albumin after cessation of treatment are not seen with agents currently approved to treat diabetic nephropathy (ACE inhibitors and ARBs<sup>1</sup>) or with other agents that act primarily via a hemodynamic mechanism of action such as endothelin A receptor antagonists.

Professor Dr. Hermann Haller, Director of the Department of Nephrology and Hypertension at Hannover Medical School and lead investigator of the study commented: "This Phase IIa study clearly shows that emapticap pegol is exceptionally safe and well tolerated in the target population and produces significant

and clinically relevant beneficial effects on albuminuria and glycemic control after only three months of treatment. The observation that these effects are maintained even after cessation of treatment suggests that emapticap pegol interferes with the underlying pathophysiology and may be the first disease-modifying drug for this indication.”

Dr. George Bakris, Professor of Medicine and Director of the ASH Comprehensive Hypertension Center at the University of Chicago Medicine remarked: “From the data I’ve seen, I’m particularly impressed by the dissociation of emapticap pegol’s albuminuria lowering effect from hemodynamics. The fact that this beneficial effect is accompanied by an additional benefit on glycemic control is a unique feature that differentiates this drug from other compounds in development.”

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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<sup>®</sup> therapeutics:

- Emapticap pegol (NOX-E36), an anti-CCL2/MCP-1 (C-C chemokine ligand 2 / Monocyte Chemoattractant Protein-1) Spiegelmer<sup>®</sup>, has completed 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.
- Olaptosed pegol (NOX-A12), an anti-CXCL12/SDF-1 (CXC chemokine ligand 12 / Stromal Cell-Derived Factor-1) Spiegelmer<sup>®</sup>, 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.
- Lexaptepid pegol (NOX-H94), an anti-hepcidin Spiegelmer<sup>®</sup>, has completed a Phase IIa pilot study in cancer patients with anemia and will soon begin a study in EPO-hyporesponsive dialysis patients. Heparin is the key regulator of iron metabolism and responsible for the iron restriction leading to anemia of chronic disease.

The Spiegelmer<sup>®</sup> 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.

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

**Contact:**

<b>NOXXON Pharma AG</b>	<b>Instinctif Partners</b>
Emmanuelle Delabre T: +49-30-726247-0 edelabre@noxxon.com	Robert Mayer / Cora Kaiser T: +49-89-30905189-13 noxxon@instinctif.com

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<sup>i</sup> ACE – Angiotensin Converting Enzyme, ARB – Angiotensin Receptor Blocker