



NOXXON Initiates Phase IIa of anti-CXCL12/SDF-1 Spiegelmer® NOX-A12 for Treatment of Chronic Lymphocytic Leukemia

Berlin, Germany- 11 July 2012- NOXXON Pharma today announced the treatment of the first cohort of three chronic lymphocytic leukemia (CLL) patients in a Phase IIa clinical trial of its NOX-A12 anti-CXCL12/SDF-1 (CXC Chemokine Ligand 12 / Stromal Cell-Derived Factor-1) Spiegelmer®. CXCL12 signaling has been shown to play an important role in the pathophysiology of CLL, especially in the interaction of leukemic cells with the tissue microenvironment. The therapeutic concept of NOX-A12 is to inhibit such tumor-supporting interactions and thereby sensitize CLL cells to chemotherapy.

NOXXON's multi-center, open-label, uncontrolled study will be conducted on 33 relapsed CLL patients, all of whom were previously treated for CLL. The patients will receive NOX-A12 in combination with a background therapy of bendamustine and rituximab (BR). Combination treatment with NOX-A12 and BR will occur in 6 cycles of 28 days, with a follow-up period of 30 months. Each patient will receive up to three different doses of NOX-A12 as part of an individualized dose titration. The primary efficacy endpoint of the study will be complete remission (CR) rate. NOXXON expects interim results to be available at the upcoming American Society of Hematology Annual Meeting in Atlanta, Georgia which will be held from 8-11 December, 2012.

Although BR is one of the established therapies for CLL, there remains significant need for improved therapy in relapsed patients. Recent publications indicate that the complete remission rate for BR therapy of relapsed CLL is approximately 15%¹.

NOX-A12 is the only anti-cancer agent in active clinical development that neutralizes the CXCL12 ligand, thereby resulting in a complete block of CXCL12 signaling through its two receptors, CXCR4 and CXCR7. Competing agents act at the receptor level and only inhibit one of the two CXCL12 receptors.

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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 is an anti-CCL2/MCP-1 (C-C Chemokine Ligand 2 / Monocyte Chemoattractant Protein-1) Spiegelmer® currently in a Phase IIa study in diabetics with albuminuria. CCL2 is a pro-inflammatory chemokine involved in recruitment of immune cells to inflamed tissues.
- NOX-A12 is an anti-CXCL12/SDF-1 (CXC Chemokine Ligand 12 / Stromal Cell-Derived Factor-1) Spiegelmer® that has completed Phase I. Phase IIa studies in two hematological cancers, multiple myeloma (MM) and chronic lymphocytic leukemia (CLL), have begun recruiting patients. CXCL12 is a chemokine mediator of tumor invasion, metastasis and resistance to chemotherapy.
- NOX-H94 is an anti-hepcidin Spiegelmer® that has completed a comprehensive single and multiple ascending dose Phase I study and a Phase I endotoxin challenge study, designed to test the ability of NOX-H94 to block hepcidin-mediated hypoferrremia in healthy volunteers. A Phase IIa study of NOX-H94 in myeloma and lymphoma patients with anemia is planned to start mid-2012. Heparin is the key regulator of iron metabolism and a mediator of iron restriction in anemia of chronic disease.

¹ Fischer K (2011) J Clin Oncol. 29(26):3559-66 & Waldthaler C (2011) Wien Klin Wochenschr, 123(9-10):269-75

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

Notes for editors:

About NOX-A12

NOX-A12 specifically antagonizes CXCL12/SDF-1 (CXC Chemokine Ligand 12 / Stromal Cell-Derived Factor-1), a chemokine which attracts and activates immune and non-immune cells including stem cells from the bone marrow. CXCL12 binds with high affinity to two chemokine receptors, CXCR4 and CXCR7. The CXCL12 / CXCR4 / CXCR7 axis has been shown to play a role in stem cell mobilization, vasculogenesis, tumor growth and metastasis. Inhibition of the CXCL12 binding to its receptors sensitizes tumor cells to chemotherapy and in some solid tumors, prevents invasion and metastasis, suggesting that NOX-A12 in combination with chemotherapy could be beneficial in the treatment of various cancers.

NOX-A12 has shown promising activity in models of both solid and hematological tumors in addition to models of stem cell mobilization. Preclinical data from NOXXON's collaborators has shown that in an animal model of glioblastoma, NOX-A12 resulted in a significant extension of lifespan of animals when used in combination with radiation therapy². NOX-A12 has also been shown to inhibit chemotaxis of primary patient CLL cells down a CXCL12 gradient and to have distinct properties from CXCR4 antagonists³. In multiple myeloma models NOX-A12 detached myeloma cells from stromal cells and sensitized them to killing by Velcade[®]/Bortezomib both *in vitro* and *in vivo*⁴.

In Phase I studies with healthy volunteers, single doses of NOXXON's CXCL12 inhibitor, NOX-A12, up to 10.8 mg/kg and daily doses up to 2 mg/kg for five days were found to be safe and well tolerated and resulted in dose-dependent mobilization of white blood cells and CD34+ hematopoietic stem cells as predicted by preclinical studies.

NOXXON received grant support within the program "KMU-innovativ" from the German Federal Ministry of Education and Research (BMBF) for the preclinical program and the Phase I clinical trials with NOX-A12.

Further information about the ongoing clinical trial in relapsed CLL patients is available at ClinicalTrials.gov (ID: NCT01486797).

About CLL

Chronic lymphocytic leukemia (CLL) is the most common leukemia in Western countries accounting for approximately 30% of all leukemias. CLL is generally incurable due to post-therapeutic re-emergence of leukemic cell clones, although some patients treated with allogeneic stem cell transplantation have achieved prolonged disease-free survival. Based on information from the US National Cancer Institute, the American Cancer Society and the GLOBOCAN database, NOXXON estimates that there are approximately 130,000 CLL patients requiring treatment every year in the combined markets of the EU-5 (France, Germany, Italy, Spain and the United Kingdom), Japan and the United States.

² C. Liu (2012) AACR, Apr 3, 2012 (abstract # 4382)

³ Hoellenriegel J (2011) ASH 53rd Annual Meeting, poster 3878, Session 652

⁴ Roccaro AM (2011) ASH 53rd Annual Meeting, oral presentation 887, Session 652

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