PRESS RELEASE

NOXXON Spiegelmer® receives FDA Orphan Drug Designation for Glioblastoma Treatment

Berlin, Germany and Boston, USA - 23 September 2014 - NOXXON Pharma announced today that one of its Spiegelmer® therapeutics, olaptesed pegol (NOX-A12), received orphan drug designation from the U.S. Food and Drug Administration (FDA) for treatment of glioblastoma in conjunction with radiotherapy.

Glioblastoma is the most common and most aggressive primary malignant brain tumor, associated with poor outcomes and low survival times. Standard treatments comprise chemotherapy, radiation and surgery, but treatment is very difficult due to resistance of tumor cells, an almost inevitable relapse following initial treatment and the risk of damaging the brain with conventional therapies.

Olaptesed pegol is a PEGylated mirror-image (L-)oligonucleotide that binds and neutralizes the chemokine CXCL12/SDF-1, preventing interaction with its receptors CXCR4 & CXCR7. The CXCL12/CXCR4/CXCR7 pathway directly affects tumor progression by controlling cancer cell survival, proliferation and migration, and also has indirect effects through angiogenesis and recruitment of immune cells.

Neutralization of CXCL12 with olaptesed pegol results in increased susceptibility of tumors to the effects of chemotherapy and radiotherapy. Anti-cancer efficacy is further enhanced in olaptesed pegol treatment by inhibition of tumor repair mechanisms driven by CXCL12-recruited bone marrow-derived cells. In animal models of glioblastoma, olaptesed pegol therapy resulted in a significant increase in the anti-cancer activity of radiotherapy (Liu et al., Neuro Oncol. 2014).

Currently, olaptesed pegol is under investigation in Phase IIa studies in two hematological cancers: multiple myeloma (MM) and chronic lymphocytic leukemia (CLL). The FDA's orphan drug designation will support NOXXON's further development of olaptesed pegol for the treatment of glioblastoma.

Chief Medical Officer Dr. Matthias Baumann, NOXXON Pharma, said: "The FDA orphan drug designation for olaptesed pegol in the US is a significant regulatory milestone for NOXXON. In conjunction with interim results of our ongoing Phase IIa studies in multiple myeloma and chronic lymphocytic leukemia, the preclinical glioblastoma findings further support the broad therapeutic potential of olaptesed pegol."

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Notes for Editors:

About Orphan Drug Designation
Orphan Drug Designation provides regulatory support for development activities for drugs that have the potential to provide significant benefit to patients suffering from rare, life-threatening diseases. The designation provides companies with access to protocol assistance and reduced regulatory fees, as well as tax incentives and market exclusivity following drug approval.

About NOXXON Pharma
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 being tested in Phase IIa studies in two hematological cancers, multiple myeloma (MM) and chronic lymphocytic leukemia (CLL). Studies for treatment of glioblastoma have also 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.

For more information, please visit: www.noxxon.com

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