

NOXXON ENROLLS FIRST PATIENT IN THE PHASE 1/2 CLINICAL TRIAL COMBINING NOX-A12 WITH RADIOTHERAPY IN NEWLY DIAGNOSED BRAIN CANCER

Berlin, Germany, October 16, 2019, 08.00 a.m. CEST - NOXXON Pharma N.V. (Euronext Growth Paris: ALNOX), a biotechnology company focused on improving cancer treatments by targeting the tumor microenvironment (TME), announced today the enrollment and first treatment of a patient with newly diagnosed brain cancer in a phase 1/2 clinical trial. The study investigates a combined therapy of increasing doses of the CXCL12 inhibitor, NOX-A12, and external-beam radiotherapy. Within this study, NOX-A12 administration is planned for up to six months. The anticipated mode of action of NOX-A12 is the inhibition of the unwanted influx of bone marrow-derived “repair cells” to the tumor following radiotherapy-induced breakdown of the vasculature in the tumor. These “repair cells” act by replacing the tumor’s blood vessels that were destroyed by the irradiation, which ultimately results in disease recurrence.

The study is designed to deliver safety and first efficacy data to support the definition of a Recommended Phase 2 Dose (RP2D) for this new treatment approach. In addition, the noninvasive assessment of the changes in tumor vascularization is expected to confirm the predicted mechanism of action for the combination of NOX-A12 and radiotherapy.

“The trial represents a new option for very difficult-to-treat patients. The candidate drug should block the influx of two distinct types of cells that the damaged brain tumor tries to recruit to help repair itself and survive. A plethora of pre-clinical studies as well as a recent clinical trial at Stanford yielded promising results with interventions targeting the CXCL12 pathway. We learnt some lessons from these data, and we are very optimistic that blocking both cell types for a longer duration will be even more effective,” commented Dr. Frank Giordano, Interim Director of the Department of Radiation Oncology at the University Medical Center Mannheim.

“Based on promising preclinical data in rat and mouse models, we are excited to evaluate NOX-A12 in this indication. It is a unique and promising approach with the potential to effectively treat brain cancer patients for whom there are currently no optimal therapies. The demand from the clinical community to test this combination has been very strong and we are pleased that the dosing of patients has been initiated. We expect data from the first cohort of patients to be available in mid-2020,” added Dr. Jarl Ulf Jungnelius, Chief Medical Officer of NOXXON.

The trial is being conducted at three hospitals in Germany. Up to three escalating doses of NOX-A12 will be administered in combination with standard radiotherapy as a first line treatment to newly diagnosed patients with brain tumors who would not benefit from the current standard of care of chemotherapy and whose tumors cannot be fully resected by surgery. The main objective of the study is to assess the safety and tolerability of this combination. Secondary endpoints include activity of the therapy, assessed through the monitoring of tumor vascularization by MRI scans, progression-free survival, overall survival and rates of response.

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About NOXXON

NOXXON's oncology-focused pipeline acts on the tumor microenvironment (TME) and the cancer immunity cycle by breaking the tumor protection barrier and blocking tumor repair. By neutralizing chemokines in the tumor microenvironment, NOXXON's approach works in combination with other forms of treatment to weaken tumor defenses against the immune system and enable greater therapeutic impact. Building on extensive clinical experience and safety data, the lead program NOX-A12 has delivered top-line data from a Keytruda® combination trial in metastatic colorectal and pancreatic cancer patients in December 2018 and further studies are being planned in these indications. In September 2019 the company initiated an additional trial with NOX-A12 in brain cancer in combination with radiotherapy. The combination of NOX-A12 and radiotherapy has been granted orphan drug status in the US and EU for the treatment of certain brain cancers. The company's second clinical-stage asset NOX-E36 is a Phase 2 TME asset targeting the innate immune system. NOXXON plans to test NOX-E36 in patients with solid tumors both as a monotherapy and in combination. Further information can be found at: www.noxxon.com

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