



NOXXON ANNOUNCES ENROLMENT OF FIRST PATIENT IN THE EXPANSION OF THE NOX-A12 PHASE 1/2 TRIAL IN BRAIN CANCER

Berlin, Germany, December 07, 2021, 08:00 a.m. CET - NOXXON Pharma N.V. (Euronext Growth Paris: ALNOX), a biotechnology company focused on improving cancer treatments by targeting the tumor microenvironment (TME), announces today that the first patient was enrolled in an expansion arm of the GLORIA clinical trial of NOX-A12 in MGMT unmethylated brain cancer (glioblastoma, GBM). The patient has received their first week of treatment of NOX-A12 (600 mg/week) and the VEGF inhibitor bevacizumab combined with radiotherapy.

The GLORIA Phase 1/2 clinical trial evaluates the safety and efficacy of NOX-A12 combined with radiotherapy. In three expansion arms, the synergistic benefit of NOX-A12 with other therapeutic settings will be evaluated:

Arm A: NOX-A12 with radiotherapy in patients with complete tumor resection

Arm B: NOX-A12 with radiotherapy and bevacizumab in patients with incomplete tumor resection

Arm C: NOX-A12 with radiotherapy and anti-PD-1 in patients with incomplete tumor resection.

Each expansion arm plans to evaluate 6 patients.

Aram Mangasarian, CEO of NOXXON, commented: "After the compelling results seen with NOX-A12 in glioblastoma patients in the GLORIA trial when combined only with radiotherapy, we are excited to move forward and explore additional treatment combinations that will potentially bring further benefits to these very difficult to treat patients. At this point, we are planning to prioritize recruitment to the bevacizumab and pembrolizumab arms and look forward to seeing the results."

Expansion arms A and B have already been approved by the German Federal Institute for Drugs and Medical Devices (BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte), while the third arm is still under review. The expansion arms aim at providing additional clinical data to support the design of the planned pivotal trial and discussions with the regulatory agencies.

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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 TME, NOXXON's approach works in combination with other forms of treatment to weaken tumor defenses against the immune system and enable greater therapeutic impact. NOXXON's lead program NOX-A12 has delivered final top-line data from a Keytruda® combination trial in metastatic colorectal and pancreatic cancer patients published at the ESMO conference in September 2020 and in July 2021 the company announced its Phase 2 study, OPTIMUS, to further evaluate safety and efficacy of NOX-A12 in combination with Merck's Keytruda® and two different chemotherapy regimens as secondline therapy in patients with metastatic pancreatic cancer. NOXXON is also studying NOX-A12 in brain cancer in combination with radiotherapy which has been granted orphan drug status in the US and EU for the treatment of certain brain cancers. GLORIA, a trial of NOX-A12 in combination with radiotherapy in newly diagnosed brain cancer patients who will not benefit clinically from standard chemotherapy has delivered interim data from the first two cohorts showing consistent tumor reductions and objective tumor responses. 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. Further information can be found at: www.noxxon.com.

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About the GLORIA Study

GLORIA (NCT04121455) is NOXXON's dose-escalation, phase 1/2 study of NOX-A12 in combination with irradiation in first-line glioblastoma (brain cancer) patients with unmethylated MGMT promoter (resistant to standard chemotherapy).

About the OPTIMUS Study

OPTIMUS (NCT04901741) is NOXXON's open-label two-arm phase 2 study of NOX-A12 combined with pembrolizumab and nanoliposomal irinotecan/5-FU/leucovorin or gemcitabine/nab-paclitaxel in microsatellite-stable metastatic pancreatic cancer patients.

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