



NOXXON ANNOUNCES PLANNED EXPANSION OF PHASE 1/2 NOX-A12 BRAIN CANCER TRIAL

Berlin, Germany, October 19, 2021, 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 expansion plans of its ongoing Phase 1/2 study of NOX-A12 in combination with radiotherapy in patients with brain cancer (glioblastoma, GBM).

The company plans to expand the ongoing GLORIA study to include additional patients in three new arms in the first-line chemotherapy resistant population (unmethylated MGMT promoter) at the highest 600 mg/week dose of NOX-A12 combined with radiotherapy:

- 6 patients with fully resected tumor will receive radiotherapy and NOX-A12;
- 6 patients with partially resected or unresected tumor will receive bevacizumab in combination with radiotherapy and NOX-A12;
- 6 patients with partially resected or unresected tumor will receive a PD-1 immune checkpoint inhibitor in combination with radiotherapy and NOX-A12.

These expansion arms come in addition to the ongoing Phase 1/2 trial evaluating three ascending doses of NOX-A12 (200, 400 and 600 mg/week), each combined with external-beam radiotherapy in newly diagnosed brain cancer patients. Positive data from the first two cohorts at 200 and 400 mg/week have already been reported and data from the third cohort at 600 mg/week for which patient recruitment has been completed will be reported in Q1 2022. A protocol amendment to expand the study with the first two arms above has been approved by the German Federal Institute for Drugs and Medical Devices (BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte), and another amendment for the third arm is being prepared. Once enrolled in the study, patients will be treated for 6 months.

"The expansion of our Phase 1/2 study of NOX-A12 in brain tumor patients will allow us to explore three further treatment configurations, all of which are supported by the clinical data emerging from the GLORIA trial. We will extend our safety data to the full surgical resection population, as we also plan to include this population of patients in our future pivotal glioblastoma study.

In addition, the extensions will assess the safety and potential synergistic benefit of NOX-A12 with anti-PD-1 and anti-VEGF combinations. Our interest in the anti-PD-1 combination is driven by the observation that NOX-A12 appears to drive infiltration of activated cytotoxic immune cells into the tumor tissue, and thus the combination with anti-PD-1 is expected to unlock a significantly stronger tumor response. We will also test a combination with anti-VEGF therapy which is commonly used in this patient population. We look forward to evaluating all these combinations," **commented Aram Mangasarian, CEO of NOXXON**.

NOX-A12 targets CXCL12, a crucial signal molecule that is used by malignant cells to form the tumor microenvironment to their favor, and is designed to (i) prevent tumor recurrence after radiotherapy by blocking the influx of tumor repair cells from the bone marrow and (ii) modify the tumor microenvironment in order to enable the action of anti-cancer immune cells, such as killer T-cells.

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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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