NOXXON PROVIDES UPDATE ON NOX-A12 CLINICAL PROGRAMS

Berlin, Germany, August 5, 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), provided today an update on the clinical development and timelines of its lead asset NOX-A12.

As NOX-A12 recently reported promising data from the second cohort of patients with glioblastoma (brain cancer), NOXXON is advancing and broadening the clinical programs with the upcoming expansion of the ongoing GLORIA study in patients with brain cancer and the initiation of a Phase 2 study in pancreatic cancer patients over the coming 12 months:

Brain cancer:

- the ongoing Phase 1/2 GLORIA trial (NCT04121455), evaluating NOX-A12 in combination with radiotherapy in first-line MGMT unmethylated brain cancer patients, has already reported positive data from the first 2 cohorts of 3 patients each treated with weekly doses of 200 and 400 mg of NOX-A12. The third cohort of 3 patients dosed at 600 mg per week has been fully recruited with data expected in Q4 2021, but due to the drop out of one of the patients unrelated to NOX-A12, recruitment of a replacement patient has been initiated and the data from this third cohort are now expected in Q1 2022,
- the expansion of the Phase 1/2 GLORIA trial with NOX-A12 in MGMT unmethylated brain cancer patients is expected to be initiated in September 2021 at the 6 clinical sites in Germany which are already participating. First patients are expected to be recruited in Q4 2021. The trial will (i) expand the patient population to those with completely resected tumors for the combination of NOX-A12 with radiotherapy and (ii) evaluate a new NOX-A12 treatment combination in patients with incompletely resected tumors.

Pancreatic cancer:

- a new Phase 2 trial (OPTIMUS) with NOX-A12 in combination with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab), is now expected to start in Q2 2022, from the initial expected start in H2 2021. Although the collaboration with MSD was signed in July 2021, delays due to COVID-19 and other issues beyond NOXXON's control at raw materials and active ingredient services providers mean that the NOX-A12 batches needed to initiate the Phase 2 will only be available in Q1 2022 with first patients therefore expected to be dosed in Q2 2022.

Aram Mangasarian, CEO of NOXXON commented: *"The unexpected manufacturing delay affecting the pancreas cancer program is naturally disappointing, but we have worked tirelessly to address the issues to ensure the NOX-A12 batches are released as fast as possible while maintaining the highest standards in quality. We are very excited that Merck reiterated their trust in our collaboration by entering into a second collaboration with NOXXON and we look forward to delivering on our new expanded clinical program with NOX-A12. Recruitment of the brain cancer expansion cohort would be unaffected by these drug manufacturing and supply issues."*

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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 second-line 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.

Keytruda® is a registered trademark of Merck Sharp & Dohme Corp

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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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