NOXXON ANNOUNCES COMPLETION OF 6-MONTH THERAPY FOR LOW-DOSE COHORT IN PHASE 1/2 BRAIN CANCER STUDY OF NOX-A12 PLUS RADIOTHERAPY

NOXXON PROVIDES CLINICAL DEVELOPMENT STRATEGY UPDATE

Berlin, Germany, October 28, 2020, 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), announced today that the last patient in the low-dose cohort has completed six months of NOX-A12 therapy in the Phase 1/2 brain cancer clinical trial. The study investigates three dose regimens of NOX-A12 (200, 400 and 600 mg/week), each combined with external beam radiotherapy in newly diagnosed MGMT[1] promoter unmethylated glioblastoma patients, a difficult-to-treat brain cancer.

Patients participating in the study would not have benefitted clinically from the standard of care chemotherapy due to their MGMT promoter methylation status. They also all had tumor tissue remaining after surgical resection before being recruited into the study.

Tumor volume reductions were observed in two of three patients during the six-month treatment, and in the third patient in the period after a second surgery following continued NOX-A12 treatment. Maximum tumor volume reductions were 6% and 60% for the first two patients. The third patient experienced 23% tumor volume reduction relative to the post-second surgery baseline. Tumor volume reductions were reported as the average of two independent central MRI readers and results included unscheduled scans. Two of three patients had stable or decreasing tumor volumes for 16 weeks or longer (one following a second surgery) and both are currently in the treatment-free follow-up period. One patient deceased from tumor progression during the treatment period.

NOX-A12 steady-state plasma levels were in the targeted range following administration of 200 mg per week. With a data cutoff date of October 23, 2020, the adverse event profile was similar to that expected from radiotherapy alone in glioblastoma patients. Eighteen of 90 adverse events were noted as being potentially related to NOX-A12 and disease or radiotherapy. There were five adverse events potentially related only to NOX-A12 which were all mild or moderate (grade 1 or 2), confirming the manageable safety and tolerability profile for NOX-A12 in combination with radiotherapy.

"*It is encouraging to see that two of the first three patients are responding to treatment with shrinking tumor volumes, indicating early signs of clinical activity, especially considering that this is the lowest NOX-A12 dose being tested. Next, we need to follow up with the patients to understand how their condition will evolve over time, especially after the completion of therapy after six months,*" said Dr. Jarl Ulf Jungnelius, Senior Medical Advisor to NOXXON Pharma.

Going forward NOXXON's planned clinical development strategy for NOX-A12 will be focused on two indications: brain cancer and pancreatic cancer. Each indication will test a different combination strategy, thereby providing multiple possibilities to successfully advance the clinical development plan: NOX-A12 plus radiotherapy in brain cancer, and NOX-A12 plus immuno-/chemotherapy in pancreatic cancer.

In brain cancer, NOXXON plans to complete the ongoing Phase 1/2 study testing three doses of NOX-A12 combined with radiotherapy. The company is considering expanding the dose cohort, which is finally chosen for the planned pivotal trial, in order to gain experience in a larger group of patients for

[1] Methyl-Guanine MethylTransferase is an enzyme involved in DNA repair. In glioblastoma, the methylation status of the promoter region of DNA which controls the expression of this enzyme has been shown to predict the response of patients to standard of care chemotherapy (Hegi et al 2005, New Engl J Med 352:997).

discussions with regulatory agencies. The next planned trial will be a pivotal, randomized Phase 2 trial comparing NOX-A12 plus radiotherapy to standard of care in MGMT unmethylated first-line glioblastoma patients. MGMT unmethylated patients represent approximately 50% of all first-line glioblastoma patients, or approximately 6,000 patients per year in the EU and 5,000 patients per year in the US.

NOXXON's planned clinical development strategy for pancreatic cancer will initially involve a two-arm clinical trial testing the combination of NOX-A12 plus anti-PD-1 immunotherapy in second-line patients. In each arm, a different second-line standard of care chemotherapy regimen will be combined with NOX-A12 plus anti-PD1. This will allow NOXXON to choose the best combination therapy to move forward into a randomized, controlled pivotal trial.

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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 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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