

## **NOXXON TO LAUNCH NOX-A12 WITH RADIOTHERAPY CLINICAL TRIAL IN PATIENTS WITH BRAIN CANCER**

**New therapeutic combination is expected to be generally applicable to many solid tumors with high unmet medical need**

**Berlin, Germany, November 21, 2018, 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 Company is preparing a new clinical trial combining NOX-A12 with radiotherapy for the treatment of patients with newly diagnosed brain tumors. The combination of NOX-A12 and radiotherapy has the potential for wide application as a cancer therapy.

NOXXON plans to perform a dose escalation trial of NOX-A12 plus radiotherapy in primary brain cancer patients who would not benefit medically from standard of care chemotherapy. The aim of this study is to establish the safety and tolerability profile and define the recommended Phase 2 dose of NOX-A12 in combination with radiotherapy as well as assess signals of efficacy including changes in tumor vascularization, progression-free and overall survival.

“It is known that radiotherapy kills blood vessels supplying tumors. The problem is that the tumor regrows vessels rapidly thanks to cells recruited from the bone marrow in a process called vasculogenesis, but we can block the recruitment of these “repair” cells with NOX-A12,” said Dr. Jarl Ulf Jungnelius, CMO of NOXXON Pharma. “With the clinicians who will run this dose-escalation trial, we are convinced that this approach will provide significant benefit for patients once the dose and therapy duration are optimized. We aim to initiate the trial in the second quarter of 2019.”

Aram Mangasarian, CEO of NOXXON Pharma, added, “there is growing interest from the clinical community for testing a NOX-A12 and radiotherapy combination in rare pediatric brain cancers where radiotherapy alone is currently the standard of care. Approval in one of these pediatric brain cancer indications could allow NOXXON to obtain a priority review voucher from the US FDA.”

See “About Brain Cancer” and “About Priority Review Vouchers” for more information

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**About Brain Cancer**

Over 33,000 people in the European Union including more than 700 children under 15 die each year from cancers of the brain and central nervous system (Eurostat database - [Link](#)). Only a small number of pharmaceuticals have been approved for the treatment of brain cancers including everolimus, bevacizumab, carmustine, lomustine and temozolomide (US National Cancer Institute- [Link](#)). The high unmet medical need in brain cancers results in significant commercial potential for agents which demonstrate beneficial activity in patients. Temozolomid (Temodar<sup>®</sup>, Merck), which is approved for glioblastoma multiforme and anaplastic astrocytoma achieved revenues of over one billion dollars per year in peak sales.

**About the Rare Pediatric Disease Priority Review Voucher Program**

Under the rare pediatric disease priority voucher program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product from the US Food and Drug Administration ([Link](#)). The pediatric program, which is part of a larger program for neglected or rare diseases, currently runs to 2020 (2022 approval deadline for drugs with rare pediatric designations in 2020 or earlier) and would require reauthorization for issuance of vouchers thereafter. The vouchers may be used by the company receiving them for accelerated review of another one of their own drugs, or sold to another drug development company. Vouchers have been sold for prices ranging from US\$ 68 to 350 million each. [Link](#).

**About NOXXON**

NOXXON's oncology-focused pipeline acts on the tumor microenvironment (TME) and the cancer immunity cycle by breaking the tumor protection barrier, blocking tumor repair and exposing hidden tumor cells. Through 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 will deliver top-line data from a Keytruda<sup>®</sup> combination trial in metastatic colorectal and pancreatic cancer patients in 2018. The company plans to initiate further studies with NOX-A12 in brain cancer in combination with radiotherapy, for which an orphan drug status has been

granted in the US and EU. The company's second asset, NOX-E36 is a Phase 2 TME asset targeting the innate immune system. NOXXON plans to test NOX-E36 in pancreatic cancer patients both as a monotherapy and in combination. Further information can be found at: [www.noxxon.com](http://www.noxxon.com)

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