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ASX: NOX

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AUSTRALIAN NOX66 - RADIOTHERAPY STUDY OPENS

- **late-stage prostate cancer**
- **novel attempt to sensitise cancers to low-dose radiation**
- **aim to achieve shrinkage of both irradiated and non-irradiated tumours**
- **5 radiation oncology clinics in QLD and NSW.**

Sydney, 27 September 2017: Noxopharm (ASX: NOX) is pleased to announce that the third clinical trial of its lead product, NOX66, is approved to commence recruitment.

The study is to be conducted in men with metastatic castrate-resistant prostate cancer who have no remaining standard therapeutic options. NOX66 is being used in these men as a radio-sensitiser. The objective is to sensitise the cancer cells to radiation to the extent that even a low (palliative) dose of radiotherapy will lead to better tumour responses and increased patient survival. Of particular interest is whether the effect of NOX66 is limited to providing more potent responses in tumours directly exposed to radiation, or whether that anti-cancer effect extends to all other tumours in the body that are not exposed to radiation.

This is a Noxopharm-initiated, Phase 1b study involving 24 men. It is being conducted at 5 radiation oncology clinics in Queensland and New South Wales under the oversight of TROG (Trans-Tasman Radiation Oncology Group) Cancer Research Australia.

Patients must have multiple tumours, some of which will receive radiotherapy at a dosage normally intended to deliver no more than partial shrinkage for short-term symptomatic (pain) relief. Some tumours deliberately will be left unirradiated in order to determine their response to treatment.

The radiotherapy will be delivered over a 7-day period. Patients will receive NOX66 daily for approximately 2 weeks from the time of the radiotherapy.

The first patient is expected to commence treatment in late-October 2017, with recruitment of the first 12 patients anticipated by late-December 2017. Following a safety review, the remaining 12 patients are expected to be enrolled by the end of Q1 2018.

Patients will be scanned at 3 and 6 months to determine the extent of any response in both irradiated and non-irradiated tumours, and the durability of any response. Determining the safety of the combined treatment is a primary objective.

Dr Graham Kelly, Noxopharm CEO, said, "This study is breaking new ground in the field of cancer therapy in the two potential outcomes we are pursuing. The first potential outcome is to make tumours more responsive to direct radiotherapy. Currently, in patients with late-stage cancer such as prostate cancer where the cancer can be widely spread throughout the body, radiotherapy commonly is used to shrink some of the larger tumours, mostly just to provide relief from pain or pressure. The first question we are asking in this study is whether NOX66 can make those tumours exposed to radiotherapy go from a typical partial response of short-term shrinkage, to a more significant response involving longer-term complete remission."

"The second question we are asking is whether NOX66 can go beyond that direct radio-sensitising effect to an indirect radiosensisiting effect where all those other cancers in parts of the body not exposed to radiotherapy, also respond. This is known as an abscopal response, a rare phenomenon that we are hoping that NOX66 has the ability to induce, and which if achieved, has the potential to herald in a new era in cancer therapy."

This study joins 2 other studies, all involving patients with late-stage prostate cancer being treated with NOX66 + radiotherapy, that have received ethical approval from their respective hospitals to commence patient recruitment. Each of these 3 studies is investigating a different method of combining NOX66 with radiotherapy to treat late-stage prostate cancer, the indication considered by the Company to be the most likely indication for a Phase 3 registration study.

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About Study NOX66-002A
Phase 1b open label study involving men with metastatic castrate-resistant prostate cancer with no remaining standard treatment options. Patients must have at least two measurable metastatic lesions, one of which is amenable to radiotherapy (RT). Treatment involves RT (20 Gy) in 5 fractionated doses (Days 2-9) to 1-4 tumours and NOX66 daily (Days 1-16). NOX66 will be dose-escalated involving 3 cohorts of 12 patients (n=4 per cohort) of 400, 800 and 1200 mg NOX66., followed after a safety review by an expansion cohort of an additional 12 patients.

Safety will be determined by standard medical examinations.

Efficacy will be determined by RECIST criteria (CT/MRI scans pre-study and at 12 and 24 weeks), pain score and well-being (ECOG) score.

About NOX66
NOX66 is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to preserve the anti-cancer activity of idronoxil in the body and to enhance its drug-like behaviour.
Idronoxil is a kinase inhibitor that works by inhibiting a range of enzymes including sphingosine kinase and PI3 kinase that regulate cell pro-survival mechanisms and which are over-expressed in cancer cells, as well as inhibiting external NADH oxidase Type 2 (ENOX 2) which is responsible for maintaining the transmembrane electron potential (TMEP) in the plasma membrane of cancer cells and whose expression is limited to cancer cells. Inhibition of these enzymes results in disruption of key downstream pro-survival mechanisms including resistance mechanisms, sensitizing the cancer cell to the cytotoxic effects of chemotherapy drugs and radiotherapy.

About Noxopharm
Noxopharm is an Australian drug development company with offices in Sydney, Melbourne and Hong Kong. The Company has a primary focus on the development of drugs to address the problem of drug-resistance in cancer cells, the major hurdle facing improved survival prospects for cancer patients. NOX66 is the first pipeline product, with later generation drug candidates under development. The Company also has initiated a pipeline of non-oncology drugs.

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