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ST VINCENT'S HOSPITAL SYDNEY CANCER STUDY TO COMMENCE WITH NOX66 + RADIOTHERAPY

- **Combination of NOX66 + pioneering form of radiotherapy**
- **Late-stage prostate cancer patients**
- **Safety and efficacy study**

29 May, Sydney: Noxopharm (ASX: NOX) today announces the involvement of its experimental drug, NOX66, in a clinical study looking at the ability of a pioneering form of radiotherapy to boost survival prospects in men with late-stage prostate cancer.

Study summary
The Phase 1 Investigator-Initiated study is being run at St Vincent's Hospital, Sydney, with nuclear medicine specialist, Dr Louise Emmett, as Principal Investigator.

The study will test the safety and efficacy of NOX66 in combination with an experimental form of radiotherapy in men with metastatic, castrate-resistant prostate cancer that has failed to respond to all standard therapies and who have limited survival prospects.

Radiotherapy is a standard first-line therapy in early-stage prostate cancer, but generally only used for symptom relief in late-stage prostate cancer. Noxopharm is developing NOX66 as a radio-sensitising drug intended to convert a palliative effect of radiotherapy in most forms of late-stage cancer into a meaningful clinical effect providing a significant survival advantage.

This study will involve 30 men and recruitment is expected to commence in mid-June.

Rationale
NOX66 is a first-in-class sensitiser of both chemotherapy and radiotherapy in cancer cells only. The active ingredient, idronoxil, sensitises cancer cells to radiation by blocking their ability to repair the

DNA damage caused by the radiation. That DNA repair process continues for about 1 week following radiotherapy, with cancer cells either dying or recovering depending on their capacity to repair the damage. The purpose of idronoxil is to block that repair capacity, resulting in cancer cells with even minor DNA damage being killed.

Noxopharm is undertaking a clinical program of 3 clinical trials evaluating the radio-sensitising capacity of NOX66 across the 3 main forms of radiotherapy used in the treatment of late-stage prostate cancer – (i) standard external beam radiotherapy, (ii) stereotactic body radiotherapy, and (iii) brachytherapy. The current study is the first of these 3 to commence and involves brachytherapy, or where the source of radiation is placed internally within the body either inside or near to the cancer.

Radiotherapy brachytherapy

The St Vincent's Hospital study is using an experimental radioactive drug known as ^{177}lutetium-PSMA peptide complex (LuPSMA). LuPSMA is injected intravenously and has been shown to be effective at locating pockets of prostate cancer cells throughout the body, including clusters of cancer cells too small to be seen by standard methods of scanning. The drug serves as a Trojan Horse, delivering small doses of a radioactive emitter directly to the prostate cancer cells.

The new study is an extension of a pilot study conducted recently by St Vincent's Hospital in conjunction with the Peter MacCallum Cancer Centre, Melbourne. That earlier study was successful in providing proof-of-concept of the ability of LuPSMA to attack lesions in men with late-stage prostate cancer, with most men showing a clinical response in terms of a reduction in both the size and number of cancer lesions. However, that response in most men was incomplete and relatively short-lasting. The objective of the new study is to use NOX66 to achieve a more complete and a longer-lasting response.

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About PSMA

Prostate specific membrane antigen (PSMA), also known as folate hydrolase I, or glutamate carboxypeptidase II, is a glycoprotein expressed in normal human prostate epithelium. PSMA is over-expressed in virtually all-prostate cancers and its expression is increased in poorly differentiated, metastatic and castration-resistant carcinomas. PSMA also is expressed by new blood vessels in many solid tumours. The expression of PSMA in non-prostate tissues is predominantly within the small intestine, proximal renal tubules and salivary glands. However, in these tissues it is expressed at levels 100-1000 times less than in the prostate.

About Radionuclide-associated PSMA

The discovery of PSMA is providing advances in both the diagnosis and treatment of prostate cancer. An antibody fragment (peptide) developed against PSMA is providing a means to deliver radioactive isotopes (radionuclides) such as ^{68}gallium and ^{177}lutetium directly to prostate cancer cells throughout the body. ^{68}gallium-PSMA peptide is a diagnostic drug used in conjunction with PET/CT scanning to stage prostate cancer; ^{177}lutetium-PSMA peptide is an experimental drug being tested as a therapeutic of prostate cancer.

About the Study
The study design is a prospective, open label, single arm, non-randomised Phase 1 pilot study. Treatment will be administered in four 1x monthly cycles, each cycle comprising a single intravenous injection of LuPSMA followed by 10 days of NOX66 treatment. Patients will be examined for tumour response after each cycle and then at 12 months.
Efficacy outcomes will be serum PSA levels, tumour load (imaging), quality of life, pain scores, progression-free survival and overall survival.

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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Forward Looking Statements

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