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ASX: NOX

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FIRST PATIENT TREATED IN LUPIN STUDY AT ST VINCENT'S HOSPITAL, SYDNEY

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

16 November 2017, Sydney: Noxopharm (ASX: NOX) today announces the treatment of the first patient in the LUPIN study.

The LUPIN Study is an Investigator-Initiated clinical trial being run at St Vincent's Hospital, Sydney, with Dr Louise Emmett as the Principal Investigator.

The study is testing the safety and efficacy of NOX66 in combination with ¹⁷⁷lutetium-PSMA-617 (LuPSMA) in men with metastatic, castrate-resistant prostate cancer that has failed to respond to all standard therapies and who have limited survival prospects.

LuPSMA has emerged as a highly promising experimental treatment for late-stage prostate cancer with clinical studies showing about 50% of patients responding to treatment. A response to LuPSMA rarely is complete and the response typically lasts < 12 months. There is a need to find a way of making the response more complete, of longer duration, and occurring in a higher proportion of patients.

LuPSMA is a radionuclide-peptide complex that is administered intravenously. The peptide seeks out prostate cancer cells throughout the body, with the attached ¹⁷⁷lutetium then delivering radioactive damage to the cancer cell.

Response to LuPSMA treatment includes shrinkage and even complete remission of metastases throughout the body, although responses in most men are relatively short-lived.

The LUPIN study is evaluating whether NOX66 can sensitise the prostate cancer cells to radioactive damage to the extent that the combination therapy delivers a higher rate of response and a more durable response, without causing any additional side effects.

St Vincent's Hospital, Sydney, is at the forefront globally of work with LuPSMA.

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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 more pronounced 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 PSMA-617

An antibody has been developed against PSMA, with the active peptide fraction of the whole antibody then isolated. PSMA-617 is a proprietary form of the peptide developed by the German Cancer Research Centre, Heidelberg, Germany.

About Radionuclide-Associated PSMA-617

PSMA-617 was developed initially as a diagnostic tool to stage the extent of metastatic prostate cancer. The radionuclide, ⁶⁸gallium, was attached to PSMA-617 and injected intravenously, with PET/CT scanning then being used to identify metastatic cancers, including those too small to be seen by standard scanning methods. Replacing the non-destructive ⁶⁸gallium with the destructive ¹⁷⁷lutetium changes the product from a diagnostic to a therapeutic.

About the LUPIN Study

LUPIN Study is LuPSMA in Combination with NOX66 Study. The study design is a prospective, open label, single arm, non-randomised Phase 1 pilot study. Treatment (¹⁷⁷lutetium-PSMA-617) 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 (⁶⁸gallium-PSMA-617) after cycle 3 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. The study aims to recruit up to 30 participants.

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 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 that are held by subsidiary company, Nyrada, Inc.

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Forward Looking Statements

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as “aim”, “anticipate”, “assume”, “believe”, “continue”, “could”, “estimate”, “expect”, “intend”, “may”, “plan”, “predict”, “project”, “plan”, “should”, “target”, “will” or “would” or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections and assumptions made by Noxopharm about circumstances and events that have not yet taken place. Although Noxopharm believes the forward-looking statements to be reasonable, they are not certain. Forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond the Company’s control that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement. No representation, warranty or assurance (express or implied) is given or made by Noxopharm that the forward-looking statements contained in this announcement are accurate and undue reliance should not be placed upon such statements.