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ST VINCENT'S HOSPITAL STUDY PASSES FIRST MILESTONE

- **Combination NOX66 + ^{177}Lutetium-PSMA radionuclide therapy in late-stage prostate cancer**
- **Treatment well tolerated in first cohort of 4 patients; second cohort now to start treatment**
- **Promising clinical response in 3 of 4 patients on lowest NOX66 dosage.**

Sydney, 17 April 2018: Noxopharm (ASX: NOX) is pleased to announce that the LUPIN clinical study being conducted at St Vincent's Hospital in Sydney has received approval to enrol the second cohort of patients following a safety review of the first cohort that showed absence of any adverse events.

The LUPIN study represents an entirely new approach to the treatment of late-stage prostate cancer, involving a combination of a radio-enhancing drug (NOX66) with intravenous radiotherapy (^{177}lutetium-PSMA-617). Unlike the great majority of clinical studies that involve testing a single experimental drug, both therapies being used in LUPIN are experimental therapies, requiring the investigators to adopt a cautious approach.

The study ultimately will enrol 16 patients, divided into 4 cohorts each of 4 patients. Each cohort starts when the 4 patients in the preceding cohort have undergone 2 months of therapy without significant toxicity. Cohorts 1 and 2 are receiving a 400 mg dosage of NOX66; cohorts 3 and 4, an 800 mg dosage of NOX66.

^{177}Lutetium-PSMA-617 (Lu-PSMA) is an emerging and promising form of treatment for late-stage, metastatic prostate cancer. Known as theranostic radionuclide therapy, it involves delivering radiation directly to prostate cancer cells through an intravenous injection. St Vincent's Hospital has been at the forefront globally in evaluating this technology.

Study Co-Principal Investigator, Associate Professor Louise Emmett, explained, "Clinical experience with Lu-PSMA is limited. It appears to work well in about 60% of patients, but the benefit appears of limited duration in some men. The hope is that NOX66 will boost the anti-cancer effect of Lu-PSMA to the extent that a higher proportion of men respond, to a greater degree, and for much longer. If we can achieve that, then this form of therapy becomes a realistic proposition for a high proportion of the several thousand Australian men each year facing end-stage prostate cancer."

LUPIN is a sighting study evaluating whether a combination of NOX66 and Lu-PSMA will prolong the life of patients with late-stage prostate cancer. The treatment course is 6 months (6 x monthly injections), with efficacy being determined at 3 and 12 months on the basis of scans (to measure number and size of tumours) and pain scores.

Blood PSA levels are measured monthly. Increased PSA (prostate-specific antigen) levels are an indicator of prostate cancer cell activity and thus are an indicator of tumour activity. The results of the first cohort are encouraging, with 3 of the 4 patients showing a fall in PSA levels of between 78-85%. The 4th patient has progressed despite therapy.

The study is expected to complete enrolment by August 2018 and to complete the 12-month follow-up by August 2019.

Noxopharm CEO, Dr Graham Kelly, said, "We see NOX66 as a unique anti-cancer drug, capable of enhancing the anti-cancer effect of radiotherapy regardless of how it is delivered and in a proportion of patients capable of producing an abscopal response leading to the complete eradication of cancer cells in the body. With both DARRT and the LUPIN programs now underway, we are giving ourselves the opportunity of comparing which form of radiotherapy + NOX66 combination works best in men with prostate cancer – that is, radiation delivered either externally or internally."

"We are encouraged to see good PSA responses in 3 of the first 4 men treated, particularly when we note that this is with a low dosage of NOX66. We look forward to seeing the outcome over the coming months when the hospital doubles that dosage to what we expect to be a more therapeutic dosage of 800 mg."

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About LUPIN

LUPIN is LuPSMA in Combination with NOX66 Study. The study design is a prospective, open label, single arm, non-randomised Phase 1 pilot study. LuPSMA is administered in six 1x monthly cycles, each cycle comprising a single intravenous injection of LuPSMA followed by 10 days of NOX66 treatment. Patients are examined for tumour response using ^{68}gallium-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, time to disease progression, progression-free survival and overall survival. LUPIN is an investigator-initiated study for which Noxopharm is providing financial support. The Principal Investigators are A/Prof Anthony Joshua and A/Prof Louise Emmett.

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 prosurvival mechanisms including resistance mechanisms, sensitizing the cancer cell to the cytotoxic effects of chemotherapy drugs and radiotherapies.

About Lu-PSMA

LuPSMA is ^{177}lutetium-PSMA-617. PSMA-617 is a peptide fragment of an antibody against PSMA, a protein expressed by a range of tissues in the body, with prostate cancer cells having the highest expression. Following intravenous injection, PSMA-617 binds overwhelmingly to prostate cancer cells throughout the body of a patient with metastatic prostate cancer. Attaching the radionuclide, ^{177}lutetium, a beta-emitter, to the PSMA-617 prior to injection, results in the PSMA delivering a radioactive payload to clusters of prostate cancer cells in most parts of the body. The rationale is that this provides a means of delivering radiotherapy to prostate cancer cells scattered throughout the body in a highly selective way, where standard radiotherapy delivered externally is limited to a small number of specific areas of the body.

About late-stage prostate cancer

The number of men estimated in 2018 to die from prostate cancer is 3,500 in Australia and 27,000 in the US. Globally, prostate cancer is the second most common cause of cancer-related deaths in men after lung cancer. Standard treatments of prostate cancer include surgery (prostatectomy), radiotherapy, chemotherapy and hormone (anti-androgen) therapy. Prostate cancer metastasises mainly to the skeleton and lymph nodes, and

to a lesser extent to the lungs, liver and brain. Externally-delivered radiotherapy typically is used on a palliative basis to attempt shrinkage of a small number (1-2) of the larger lesions in order to provide pain relief. However, late-stage prostate cancer typically involves multiple secondary lesions throughout the body, meaning that standard radiotherapy is limited to a small proportion of the lesions.

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 sensitise cancer cells to radiotherapy and chemotherapy. NOX66 is the first pipeline product, with later generation drug candidates under development.

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