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NOX TO SUPPORT EXPANDED LuPIN STUDY

- **St Vincent's Hospital, Sydney Phase 1 study in late-stage prostate cancer.**
- **Combination Veyonda® and Lu-PSMA-617 therapy**
- **Safety acceptable to date**
- **Patient numbers increased from 16 to 32**
- **Purpose to create a more meaningful data set.**

Sydney, 5 September 2018: Noxopharm (ASX: NOX) today announces that its Phase 1 LuPIN study at St Vincents Hospital, Sydney has been granted approval to double the number of treated patients.

The LuPIN sudy is being conducted in men with metastatic castrate-resistant prostate cancer who have no remaining standard treatment options and who are eligible to receive treatment with the experimental drug, ^{177}lutetium-PSMA-617 (Lu-PSMA). The men are receiving a combination of Lu-PSMA and Veyonda® with safety and PSA responses the main end-points.

The first cohort of 8 men are receiving Lu-PSMA and 400 mg Veyonda®. Three of these men have completed their course of treatment and 5 are nearing the end of treatment. Six men in a second cohort of 8 patients have commenced treatment with Lu-PSMA and 800 mg Veyonda®. Both treatment regimens have proved to be well tolerated.

In the absence of any serious safety issues, the study's investigators sought permission to increase the number of patients to 32 in order to provide a larger study size capable of delivering meaningful safety and efficacy endpoints.

Lu-PSMA
Lu-PSMA (^{177}lutetium-PSMA-617) is an experimental intravenous therapy based on the principle of using a peptide (PSMA-617) as a delivery vehicle to carry a radioactive payload (^{177}lutetium) directly to prostate cancer cells scattered throughout the body. The ^{177}lutetium remains attached to the cancer cells via the peptide, inflicting damage to the cancer cells over 6 weeks as the radionuclide gradually decays. A typical treatment course involves 6 injections, each injection 6 weeks apart for a total of 36 weeks.

Compared to traditional radiotherapy, this form of intravenous radiotherapy enables radiation to reach prostate cancer cells in both bone and soft tissues throughout the body. Approximately 80% of cases of prostate cancer are thought to be PSMA-positive and therefore eligible for this treatment.

PSMA-617 is licensed to US company, Endocyte Inc, who currently is conducting a Phase 3 registration study of Lu-PSMA in 750 men with metastatic castrate-resistant prostate cancer (VISION Study) in 80 centres in the US, Canada and Europe.

Aim of LuPIN Study

The primary objective of this Phase 1 study is to see if using Veyonda® in conjunction with Lu-PSMA is safe.

The LuPIN study is testing whether Veyonda® is able to boost the cancer-killing effect of current dosages of Lu-PSMA without increasing safety risks such as an enhanced risk of radiation sickness and local toxicity.

The additional 16 patients are expected to be recruited over the coming 6 months.

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About LuPIN Study

The study design is a prospective, open label, single arm, non-randomised Phase 1 pilot study. Lu-PSMA is administered in six 6-weekly cycles, each cycle comprising a single intravenous injection of LuPSMA followed by 10 days of Veyonda® treatment at 400mg or 800mg per day. Patients are examined by PET scan 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 Veyonda®

Veyonda® (previously known as NOX66) is an experimental anti-cancer drug being developed as a radio-enhancer (both externally delivered and intravenously delivered radiation). Veyonda® has 4 primary functions: (i) cytotoxic to cancer cells, including prostate cancer cells; (ii) cytostatic to cancer cells, generally blocking in G_2M phase of mitosis, when DNA is most sensitive to radiation-induced damage; (iii) blocking enzymes (PI3 kinase. PARP-1, topoisomerase 1 and 2) responsible for DNA repair mechanisms; (iv) an immuno-oncology effect through up-regulation of natural killer (NK) cell activity.

About Noxopharm

Noxopharm is a clinical-stage 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. Veyonda® is the first pipeline product, with later generation drug candidates under development.

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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.