



3 March 2020

Sydney, Australia

## LuPIN Prostate Cancer Trial Fully Recruited

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- **LuPIN Phase I/II clinical trial fully recruited**
  - **Enrolment of all 56 patients with late-stage metastatic castration-resistant prostate cancer**
  - **Completion of recruitment significantly de-risks the study**
  - **Further interim data expected later this year**
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**Sydney, 3 March 2020:** Noxopharm (ASX: NOX) advises that the last patient has been enrolled and safely dosed in the ongoing LuPIN Phase I/II clinical trial being conducted by St Vincent's Hospital Sydney. This completes patient recruitment for the study, bringing the total number of participating patients to 56.

The LuPIN study is an investigator-initiated clinical trial evaluating Noxopharm lead product candidate, Veyonda®, in combination with radiopharmaceutical, <sup>177</sup>Lu-PSMA-617, in patients with late-stage metastatic castration-resistant prostate cancer (mCRPC) that have failed to respond to all standard therapies and have limited survival prospects.

**Dr Gisela Mautner, Noxopharm Chief Medical Officer, said:**

"We are extremely pleased that the last patient has been successfully dosed in the LuPIN trial. It is an important milestone that significantly de-risks the study. We sincerely thank the principal investigators at St Vincent's Hospital Sydney, the participating patients and their families for being part of this study.

"The LuPIN study recently has shown a pronounced survival benefit in an interim analysis of 32 patients, with a median Overall Survival of 17.1 months, and continues to report an excellent safety profile for the combination treatment. This is a remarkable outcome for end-stage prostate cancer patients."

**A/Prof Dr Louise Emmett of St Vincent's Hospital Sydney and Principal Investigator of LuPIN said:**

"It was a great pleasure to run the LuPIN trial and we were able to enrol patients into the study very quickly. Developing a new treatment option for late-stage prostate cancer patients is very important as their expected survival and quality of life can be very poor. I am glad we were able to help many men who had no further treatment options left."

Further interim data from the Phase I/II LuPIN study is expected later this year, with a final read-out anticipated in mid-2021.

**About LuPIN**

LuPIN is an Investigator-Initiated Phase I/II, single-arm, open label study enrolling 56 men with mCRPC whose disease was progressing despite docetaxel, cabazitaxel and either abiraterone and/or enzalutamide. The study is divided into 4 cohorts of 400 mg (8 patients), 800 mg (8 patients), 800 mg (16 patients) and 1200 mg (24 patients) Veyonda® in combination with <sup>177</sup>Lu-PSMA-617.



The Phase I part of the study is intended to establish the safety of the combination treatment. The Phase II expansion part is intended to establish the dose-response effect of increasing Veyonda® levels in combination treatment.

Imaging inclusion criteria include a PSMA PET/CT with uptake intensity in metastases more than twice the normal liver uptake and no discordant disease on FDG PET/CT. All men receive up to 6 doses of <sup>177</sup>Lu-PSMA-617 at 6-weekly intervals and Veyonda® every cycle on days 1-10.

#### **About Veyonda®**

Veyonda® is a suppository dosage form of idronoxil, a first-in-class inhibitor of sphingosine-1-phosphate (S1P) via inhibition of ENOX2. S1P is a key secondary messenger in cells, with dual roles of activating major pro-survival signalling pathways and regulating immune cell trafficking in tissues. Many solid cancers over-express S1P, supporting unregulated tumour growth and suppressing immune cell populations and activities in tumours. By inhibiting this over-expression, idronoxil acts as both a radio-sensitiser and chemo-sensitiser, and as an immunotherapy, intended to restore immune function to tumours.

#### **About Noxopharm**

Noxopharm is a clinical-stage Australian oncology drug development company with offices in Sydney and New York. The Company has a primary focus on the development of Veyonda® and is the major shareholder in the non-oncology drug development company, Nyrada Inc. (ASX:NYR)

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*Graham Kelly, CEO and Executive Chairman of Noxopharm, has approved the release of this document to the ASX.*

#### **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.