

Date: 11 February 2020 Sydney, Australia

# LuPIN interim trial data to be presented at ASCO GU 2020

**Sydney, 11 February 2020:** Noxopharm (ASX: NOX) announces that more mature interim data from the investigator-initiated LuPIN phase I/II clinical trial will be presented at the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium 2020 in San Francisco on Thursday 13 February at 11.30am PST (Friday 14 February, 6:30am AEST).

The LuPIN study is being conducted by St Vincent's Hospital Sydney and is evaluating NOX lead product candidate, Veyonda® in combination with <sup>177</sup>Lu-PSMA-617 in 56 patients with late-stage metastatic castration-resistant prostate cancer (mCRPC).

The presentation was granted on the basis of earlier data, but the full interim data, including the all-important overall survival data for the first 32 study participants, will be announced on 14 February 2020. The aim of combining Veyonda® with <sup>177</sup>Lu-PSMA-617 is to achieve a greater survival outcome than with <sup>177</sup>Lu-PSMA-617 alone in men with Stage 4 mCRPC that has progressed following all available lines of therapy.

The ASCO Genitourinary Cancers Symposium is a world-renowned multidisciplinary conference focused on treatments, research and patient care of genitourinary malignancies.

#### **About LuPIN-1**

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<sup>®</sup> (NOX66) in combination with <sup>177</sup>Lu-PSMA-617.

The Phase I part of the study was 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<sup>®</sup> 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  $^{177}$  Lu-PSMA 617 at 6-weekly intervals and NOX66 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). 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 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 Chairman of Noxopharm has approved the release of this document to the market.

#### **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.