



**Date: 12 November 2019**

**Sydney, Australia**

ASX Limited  
20 Bridge Street  
SYDNEY NSW 2000

### **LuPIN DATA BEING PRESENTED TO CONFERENCE**

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- LuPIN: Evidence that NOX66 enhances the anti-cancer effect of <sup>177</sup>Lu-PSMA-617 therapy
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**Sydney, 12 November 2019:** Noxopharm (ASX: NOX) confirms the presentation of clinical data concerning NOX66 (Veyonda®) to the 46<sup>th</sup> Annual Scientific Meeting of the Clinical Oncology Society of Australia (12<sup>th</sup>-14<sup>th</sup> November 2019).

The data concerns LuPIN trial data and is being presented by a team of researchers at St Vincent's Hospital, Sydney and the Garvan Institute of Medical Research. This data has been reported on earlier (30 September 2019) and involves a comparison of the results of the first 16 men treated with NOX66 + <sup>177</sup>Lu-PSMA-617 (combination therapy) compared to 14 men receiving <sup>177</sup>Lu-PSMA-617 alone (monotherapy).

Within the limits of comparing data sets from different studies, combination therapy was superior to monotherapy in terms of:

- men able to undergo a 4<sup>th</sup> treatment cycle (69% vs 21%)
- a PSA reduction of >50% (69% vs 36%)
- overall progression-free survival based on PSA levels (7.8 vs 3.4 months).

The LuPIN study involves men with late-stage prostate cancer (metastatic castrate-resistant disease) that have progressed after 2 lines of taxane therapy (docetaxel and cabazitaxel) and either abiraterone or enzalutamide.

The data is contained in the attached PDF file.

#### **About Noxopharm**

Noxopharm is a clinical-stage Australian 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 Nyrada Inc, a spin-off company developing a pipeline of non-oncology drugs.

[www.noxopharm.com](http://www.noxopharm.com)



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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.

**<sup>177</sup>Lu-PSMA-617 as monotherapy or in combination with NOX66 for the treatment of men with late-stage metastatic castrate resistant prostate cancer (mCRPC): An exploratory analysis.** (66985)

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**Aims:** <sup>177</sup>Lu-PSMA-617 is an emerging targeted therapy that has shown good efficacy and safety in mCRPC. Idronoxil is an inhibitor of external NADH oxidase type 2 that possesses downstream pro-apoptotic actions that confer radio-sensitivity to cancer cells. We aimed to evaluate the efficacy of <sup>177</sup>Lu-PSMA-617 monotherapy versus combination <sup>177</sup>Lu-PSMA-617/NOX-66 (Veyondra) therapy.

**Methods:** 30 men with progressive mCRPC despite docetaxel, cabazitaxel and either abiraterone or enzalutamide were enrolled across two therapeutic studies. The first with <sup>177</sup>Lu-PSMA-617 alone (14 men) and the second <sup>177</sup>Lu-PSMA-617 + NOX66 (16 men; 8 receiving 400mg and 8 receiving 800mg daily for 10 days per cycle). Both studies required PSMA uptake on PSMA PET of greater than liver activity with no discordant disease compared with FDG-PET. Each man received <sup>177</sup>Lu-PSMA-617 at 6-weekly intervals.

**Results:** Baseline PSA distributions were similar in the combination and monotherapy trials (median PSA level 147ng/mL [IQR 67-443] versus 88ng/mL [IQR 54-293] respectively). Significantly more patients in the combination trial initiated a fourth treatment cycle compared to the monotherapy trial (69% vs 21%;  $P < 0.001$ ). PFS was significantly longer in the combination group 8.4 months (IQR 3.6-10.9) versus the monotherapy group 2 months (IQR 0.2-5.0; mean PSA PFS 7.8 vs 3.4 months [ $p=0.023$ ]). A PSA reduction of  $\geq 50\%$  occurred in 69% (11/16) versus 36% (5/14) of patients treated with combination and monotherapy respectively ( $P=0.073$ ). Kaplan-Meier survival estimation revealed a significant benefit to combination therapy ( $p=0.014$ ). Cox regression further revealed that combination treatment and increasing SUVmax were significant predictors of PSA PFS (HR 0.239 [95%CI 0.92-0.623] and HR 0.945 [95%CI 0.93-0.977] respectively). No significant treatment related adverse effects were reported in either study.

**Conclusions:** Within the limits of a comparison of two separate phase 1 trials, the efficacy of PSMA targeted treatments may be significantly improved through patient selection and use of combination treatments.