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**Sydney, Australia**

ASX Limited  
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SYDNEY NSW 2000

## **Conference Hears of Positive Interim Data from LuPIN Trial**

### **KEY HIGHLIGHTS**

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- LuPIN study enrolling heavily pre-treated men with **progressive late-stage prostate cancer (mCRPC)**
  - Clinical data shows combining **Veyonda® with radiopharmaceutical, <sup>177</sup>Lu-PSMA-617**, is **well tolerated** and with **early signals of anti-cancer activity**
  - **Overall 69% PSA response** rate (>50% reduction in PSA levels) with <sup>177</sup>Lu-PSMA-617 + Veyonda®
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**SYDNEY, 26 June, 2019:** Noxopharm Ltd (ASX: NOX) ('Noxopharm' or the 'Company') is pleased to report on positive interim clinical data from the ongoing LuPIN study of its lead drug candidate, Veyonda®, presented today at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2019 Annual Meeting, June 22-25, in Anaheim, California.

The data was presented by Associate Professor Emmett MB ChB, Director of Theranostics and Nuclear Medicine at St Vincent's Hospital, Sydney (Australia), and the Principal Investigator of the study.

The LuPIN study is a 56-patient Phase Ib/IIa study evaluating the efficacy and safety of a combination of two experimental drugs - Veyonda® and the radiopharmaceutical, <sup>177</sup>Lu-PSMA-617 – in men with progressive metastatic castration-resistant prostate cancer (mCRPC) following docetaxel, cabazitaxel and abiraterone and/or enzalutamide. At the time of enrolment, the median PSA level (ng/mL) was 148 (range 60-980) and 75% of the men had >20 metastases.

These data are from the first 16 men who have received at least two of an intended six cycles of study treatment. The 16 subjects were divided into two cohorts of 8. Cohort 1 received 400 mg Veyonda® and Cohort 2 received 800 mg Veyonda®.

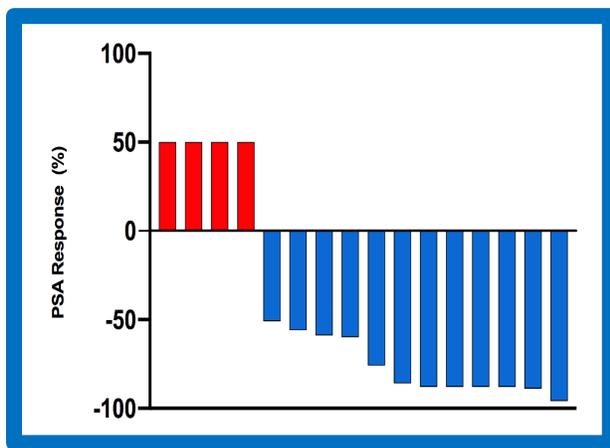
In announcing the interim data, Professor Emmett said, "These initial results show that the combination treatment was well tolerated with encouraging signs of efficacy."



**Safety:** The combination treatment generally was well tolerated. All Adverse Events were Grade 1 or 2 and included dry mouth (69%), anaemia (63%), fatigue (44%), anal irritation (19%), nausea (7%) and pneumonitis (7%).

**Efficacy:** Efficacy end-points in this study are PSA response (*>50% reduction in PSA level compared to baseline*), quality of life score, pain score, and duration of response. [Note that this part of the study was not powered to provide a statistical outcome].

The PSA response rate was 62.5% (Cohort 1) and 75% (Cohort 2), with an overall response rate of 69%. The following graph shows the % change in PSA plotted against starting PSA level.



Over the course of the study, 56% (9/16) were able to complete their full 6 cycles of treatment over 36 weeks; 44% (7/16) progressed before completing the full 6 cycles, with 25% (4/16) completing 3 cycles and 19% (3/16) completing 4-5 cycles.

Overall survival was 100% at 3 months and 93% at 6 months and at the time of reporting was 81% after a median follow-up duration of 12 months.

**Comments:** Graham Kelly PhD, Noxopharm Executive Chairman, said, “These results are particularly encouraging in light of the advanced stage of disease these men are in. Late-stage mCRPC typically is a progressive, debilitating disease associated with mounting pain from multiple secondary tumors growing in the skeleton. Treatment generally is palliative, such as pain relief, with no realistic expectation of stopping or even slowing the disease process. So being able to use this combination to deliver an anti-cancer effect as evidenced by PSA responses in such a high proportion of patients, and seeing over half of the men being able to complete their full course of treatment, all in a generally well-tolerated way, is a ground-breaking and a personally highly rewarding outcome.”

“There is growing interest in using <sup>177</sup>Lu-PSMA-617 in late-stage prostate cancer with a recent multi-billion dollar series of acquisitions confirming that interest. But this treatment doesn’t



provide a durable benefit in the majority of men, which is why we and the investigators are looking to add Veyonda<sup>®</sup> to improve the outcome.”

“Today’s data complement the positive interim results we have reported from the DARRT-1 study, also involving men with late-stage mCRPC, and provides additional evidence for the radio-enhancing and immunological activities of Veyonda<sup>®</sup>. The Company is in the unique position of being involved in two novel clinical studies involving the same type of patients but using Veyonda<sup>®</sup> with two different types of radiotherapy. Should Veyonda<sup>®</sup> achieve separate indications in combination with either low-dose, external-beam radiotherapy or intravenous, radionuclide radiotherapy, then it will be well on the way to becoming an essential adjunct to radiotherapy in prostate cancer,” Kelly added.

A video recording of Professor Emmett’s presentation at SNMMI is expected to be available in coming days on [www.noxopharm.com](http://www.noxopharm.com).

#### **About Veyonda<sup>®</sup>**

Veyonda<sup>®</sup> (previously known as NOX66) is a suppository dosage formulation of the experimental anti-cancer drug, idronoxil, that leads in the body to the formation of a proprietary pro-drug form. Idronoxil specifically inhibits the ability of cancer cells to respond to stress, such as that induced by radiation, leading to loss of pro-survival signaling via sphingosine-1-phosphate. Idronoxil also is a STING agonist, activating the body’s innate immune system.

#### **About <sup>177</sup>Lu-PSMA-617**

PSMA-617 is a peptide targeting prostate membrane surface antigen, a protein expressed predominantly by prostate cancer cells. The peptide is linked to the radionuclide, <sup>177</sup>lutetium. The advantage of <sup>177</sup>Lu-PSMA-617 therapy is that following intravenous injection, it is able to reach prostate cancer cells throughout the body and to deliver radiotherapy (beta-radiation) in a highly targeted way. PSMA-617 is licensed to Endocyte Inc (a subsidiary of Novartis).

<sup>177</sup>Lu-PSMA-617 therapy has been used in over 3,000 men to date on an experimental basis mainly in Germany and Australia. Endocyte (a subsidiary of Novartis) is conducting a Phase 3 registration study of <sup>177</sup>Lu-PSMA-617 in men with progressive mCRPC (VISION Study) in the U.S., Canada and Europe in approximately 750 men.

Standard use of <sup>177</sup>Lu-PSMA-617 is intravenous administration once weekly every six weeks for 30 weeks. The reported general outcome is that less than 50% of men complete the full course of 6 injections before suffering relapse.

#### **About LuPIN**

LuPIN is an Investigator-Initiated Phase Ib/IIa, single-arm, open label study enrolling 56 men with mCRPC that is 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) NOX66.

The Phase Ib arm of the study is intended to establish the safety of the combination treatment. The Phase IIa expansion arm is intended to establish the dose-response effect of increasing NOX66 levels on combination treatment safety and efficacy.

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; the first 8 men received 400mg idronoxil (suppository) daily cycle days 1-10.

Following safety data review of the first cohort (400 mg NOX66), the dose for patients 9-16 was escalated to 800mg NOX66 daily. The study then was expanded to recruit a third cohort of 16 patients to receive 800 mg NOX66. With



further evidence of efficacy and good tolerability, the study was expanded to include a fourth patient cohort (1200 mg NOX66).

#### **About this data**

This research was originally published in an earlier form in the Journal of Nuclear Medicine. *Emmett L et al. Interim results of a Phase I/II prospective dose escalation trial evaluation safety and efficacy of combination <sup>177</sup>Lu-PSMA-617 and NOX66 in men with mCRPC post androgen signaling inhibition and 2 lines of taxane chemotherapy (LuPIN trial)*. The publication is available at the following link:  
[http://jnm.snmjournals.org/content/60/supplement\\_1/465.abstract?sid=77766228-dd3b-4ab5-b471-4dfa2257985c](http://jnm.snmjournals.org/content/60/supplement_1/465.abstract?sid=77766228-dd3b-4ab5-b471-4dfa2257985c)

#### **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<sup>®</sup> 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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