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Sydney, Australia

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FURTHER DATA REVIEW SHOWS MAJOR CLINICAL BENEFITS FROM VEYONDA®

- Comparative data shows Veyonda® significantly boosts the effectiveness of a promising new form of radiation therapy (¹⁷⁷LuPSMA) in advanced prostate cancer
 - ¹⁷⁷LuPSMA therapy is the subject of a recent US\$6 billion series of acquisitions
 - Veyonda® improves three key measures of response to ¹⁷⁷LuPSMA therapy – falls in PSA levels (doubled), progression-free survival (quadrupled) and treatment duration rates (tripled)
 - Noxopharm foresees Veyonda® as standard companion drug for ¹⁷⁷LuPSMA therapy
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Sydney, 30 September 2019: Noxopharm (ASX:NOX) further describes the upcoming release of clinical data concerning its lead drug candidate, Veyonda®. On further review of the interim data, Noxopharm now sees an important and exciting story emerging that it considers needs to be brought to market attention.

Noxopharm is developing Veyonda® as a drug to boost the effectiveness of two forms of radiation therapy in prostate cancer with the aim of relieving pain, decreasing the activity of the cancer and extending life. In one form, the radiation is delivered externally (DARRT study). In the other, the radiation is injected intravenously (LuPIN study). Today's announcement concerns the LuPIN study.

A review of recent clinical data presents compelling evidence that Veyonda® boosts the anti-cancer effect of the intravenous radiopharmaceutical, ¹⁷⁷lutetium-PSMA-617 (or ¹⁷⁷Lu-PSMA), in men with late-stage prostate cancer.

¹⁷⁷Lu-PSMA is an experimental radioactive drug that was the subject of a US\$6 billion series of acquisitions by Novartis in 2018 and currently is in a Phase 3 registration study expected to finish in 2020.

A major aim of the LuPIN study is to see if Veyonda® can boost the effectiveness of ¹⁷⁷Lu-PSMA radiation therapy so that more men are able to complete their full course of radiation treatment before their cancer progresses and they need to stop treatment.



Graham Kelly, Noxopharm Executive Chairman, said, “This is exciting data because anti-cancer drug trials rarely deliver such significant improvements in response rates. Veyonda® has more than tripled the number of men able to stay on this kind of radiation treatment, and we would expect that to translate into longer survival times, which is supported by the data showing Veyonda® providing an overall quadrupling of the time until the cancer resumed growing.”

The data comes from two separate clinical studies involving the same hospital and the same clinicians, as well as similar patient selection criteria and treatment protocols. Hence the validity in comparing the two sets of data.

In the first study, 14 patients were treated with ¹⁷⁷Lu-PSMA alone. In the second study, patients were treated with ¹⁷⁷Lu-PSMA in combination with Veyonda®.

	<u>¹⁷⁷Lu-PSMA</u>	<u>¹⁷⁷Lu-PSMA + Veyonda®</u>
Number of patients	14	16
Median starting PSA (ng/ml)	88	147
PSA response	36%	69%
Progression-free survival (months)	2.0	8.4
Able to start the 4th cycle	21%	69%

The group receiving the combination therapy started with a higher overall PSA (Prostate-Specific Antigen) level, suggesting that the cancer was more progressed in this group at the start of treatment.

The three endpoints used to measure anti-cancer effect all showed a benefit from combining Veyonda® with ¹⁷⁷Lu-PSMA therapy.

- (i) PSA response refers to a fall in PSA levels in blood of greater than 50%. This is accepted by oncologists as a surrogate marker of disease activity. **Adding Veyonda® to ¹⁷⁷Lu-PSMA therapy almost doubled the PSA response (69% with Veyonda® vs 36% with ¹⁷⁷Lu-PSMA alone).**
- (ii) Progression-free survival (PFS). PFS is a measure of the time from the start of treatment until the disease progresses. **PFS quadrupled through the addition of Veyonda® (8.4 months vs 2.0 months with ¹⁷⁷Lu-PSMA alone).**
- (iii) Treatment duration. The addition of Veyonda® meant that **the number of men able to start the 4th treatment cycle tripled to 69% from 21% with ¹⁷⁷Lu-PSMA alone.**



The combination therapy also was well tolerated, pointing to Veyonda® as being safe to use in combination with radiation therapy.

In summary, combination therapy of Veyonda® and ¹⁷⁷Lu-PSMA therapy shows benefits to patients well above that with ¹⁷⁷Lu-PSMA therapy alone and underscores the Company's confidence in Veyonda® eventually becoming a standard drug in the management of prostate cancer.

About Veyonda®

Veyonda® (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 promotes the STING mechanism, thereby activating the body's immune system.

About LuPIN

LuPIN is an Investigator-Initiated Phase Ib/IIa, single-arm, open label study being conducted by clinicians at St Vincent's Hospital Sydney. The study is enrolling 56 men with metastatic castrate-resistant prostate cancer 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) Veyonda®. 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 Veyonda® 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 ¹⁷⁷Lu-PSMA 617 at 6-weekly intervals; the first 8 men received 400mg Veyonda® days 1-10. Following safety data review of the first cohort (400 mg Veyonda®), the dose for patients 9-16 was escalated to 800mg Veyonda® for 10 days. The study then was expanded to recruit a third cohort of 16 patients to receive 800 mg Veyonda®. With further evidence of efficacy and good tolerability, the study was expanded to include a fourth patient cohort (1200 mg Veyonda®).

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.

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