



Date: 17 September 2019

Sydney, Australia

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VEYONDA® AND RADIOTHERAPY PROFILED AT KEY ONCOLOGY MEETING

- Research relating to Veyonda® in the treatment of advanced prostate cancer is to be included in a key Australian oncology meeting
 - Both Noxopharm and independent investigators have abstracts accepted
 - DARRT-1 interim data showing high incidence of a durable anti-cancer effect at 6 months
 - Retrospective review by investigators showing Veyonda® significantly increasing the anti-cancer response to experimental radionuclide, ¹⁷⁷lutetium-PSMA-617
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Sydney, 17 September 2019:

Noxopharm (ASX: NOX) (**'Noxopharm'** or the **'Company'**) is pleased to announce that Australian clinicians will be presented updates on research relating to the use of Veyonda® (idronoxil) with radiotherapy for the treatment of prostate cancer at the Clinical Oncology Society of Australia (COSA) annual scientific meeting in November this year. This is the key meeting for oncologists in Australia and this year there is a program focus on urological cancer. The Company is releasing details of the presentations now as the meeting organisers have released the scientific abstracts earlier than expected via the meeting website.

An abstract on DARRT-1 interim results (as released on 2 May 2019) has been accepted at this conference. These results showed that patients who were treated with the Company's proprietary treatment Veyonda® combined with externally-delivered radiotherapy had a durable anti-cancer response rate lasting at least 6 months (the length of the study) in a high proportion of men with end-stage, metastatic, castration-resistant prostate cancer (mCRCP). <http://cosa-2019.p.asnevents.com.au/days/2019-11-13/abstract/67209>

There also is underway an investigator-led study, the LuPIN study, looking at the effect of Veyonda® in combination with intravenously-delivered radioactivity (¹⁷⁷LuPSMA-617), also in men with late-stage mCRPC. This study is independent work from researchers at St Vincent's Hospital Sydney, the Garvan Institute of Medical Research and St Vincent's Clinical School who have also chosen to present their data at COSA.

<http://cosa-2019.p.asnevents.com.au/days/2019-11-12/abstract/66985>



In the abstract, the researchers are comparing two pieces of work that have both previously been made public. In the first study, patients were treated solely with the radioactive substance ¹⁷⁷lutetium-PSMA-617; in the second, patients were treated with ¹⁷⁷lutetium-PSMA-617 in combination with Veyonda® (as released on 26 June 2019). The important aspect of this abstract is that the two sets of data have been put together, and the finding to date is that the combination treatment with Veyonda® has resulted in a significantly better clinical response. Statistically significant differences were seen in

- the ability of patients to stay on treatment longer (*potentially meaning that they are responding more favourably to treatment or are tolerating treatment better*)
- a reduction in PSA (*prostate specific antigen*) levels
- longer progression-free survival (*the amount of time these patients with advanced disease had improvement of, or no worsening of, their symptoms*)

The summary of the two sets of data is contained in the EGM corporate presentation on the Noxopharm website and is re-presented here.

	¹⁷⁷ lutetium-PSMA-617	¹⁷⁷ lutetium-PSMA-617 + Veyonda®
Number of patients	14	16
Median starting PSA (ng/ml)	88	147
PSA response*	36%	69%
PFS**	2.0 months	8.4 months
Able to complete 4 cycles	21%	69%

* >50% decline in PSA levels from starting level

** Progression-free survival = time to disease progression

Dr Greg van Wyk, Noxopharm CEO and Chief Medical Officer, said: ‘Inclusion of studies relating to Veyonda® at this peak oncology conference is validation of the work we have underway. The abstracts have been peer-reviewed and found to be of value to specialists working with cancer patients in Australia and beyond.’

Dr Graham Kelly, Noxopharm Executive Chairman, said, ‘These data support the Company’s strategy in developing two potential transformative treatments for men who find themselves with late-stage prostate cancer and no remaining standard treatment options. The DARRT program is our major focus because of its potential ability to be deployed across both early- and late-stage prostate cancer. Also, the LuPIN data being presented suggests that Veyonda® has



the ability to increase significantly the value of ^{177}Lu lutetium-PSMA-617 as a treatment option for late-stage prostate cancer.'

Both Veyonda[®] studies continue. The DARRT-1 patients will continue to be monitored and the results of the final group of patients 24 weeks post-treatment will be available in late November 2019. The combined data from the trial will be presented at an international scientific congress and will be submitted to a peer reviewed journal in H1 2020. The LuPIN study also continues in total 56 men with late-stage mCRPC and final results are expected in late-2020.

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 signalling via sphingosine-1-phosphate. Idronoxil also promotes the STING mechanism, thereby activating the body's innate immune system.

About the DARRT program

The Company's DARRT (Direct and Abscopal Response to Radiotherapy) Program is testing the ability of Veyonda[®] to increase tumour response to radiotherapy. The rationale of DARRT is to take advantage of the radio-enhancing properties of Veyonda[®] that stem from its inhibition of sphingosine-1-phosphate pro-survival functions, combined with its ability to stimulate the body's first line immune defence cells against cancer. The clinical outcome being sought is PSA and pain reductions as well as greater shrinkage of irradiated tumours and shrinkage of non-irradiated tumours (abscopal response). The DARRT treatment regimen is being tested initially in prostate cancer, but in due course is to be extended into other forms of solid cancer that the Company believes will assist the Veyonda[®] marketing approval process.

About DARRT-1

DARRT-1 is a Phase 1b 26-subject study being conducted in Georgia and Australia. The study is in 2 arms, with 14 subjects in the first arm and 12 in the second. The first arm is for dose-finding entailing 3 cohorts receiving 400 mg, 800 mg and 1200 mg Veyonda[®] respectively. In the second arm, all subjects are receiving the 1200 mg Veyonda[®] dose. The DARRT treatment regimen entails a 5-day course of radiotherapy (20 Gy) with Veyonda[®] administered daily for up to 2 weeks. The subjects are being assessed clinically at 6-, 12- and 24- weeks.



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 177 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 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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