Media Statement
Veyonda® Enhances Radiotherapy in Prostate Cancer Treatment
Further Promising Results

28 Aug 2019

Noxopharm (ASX: NOX) ('**Noxopharm'** or the '**Company'**) today announced the interim three month results from the second part of the DARRT-1 study on its proprietary treatment Veyonda® combined with radiotherapy which resulted in reductions in tumour size; reductions in pain for 45% of the men; and reductions in PSA levels for 55% of these men.

The Company's DARRT (Direct and Abscopal Response to Radiotherapy) Program is testing the ability of Veyonda® to increase tumour response to low-dose radiotherapy in prostate cancer. The effect of this treatment combination on tumours in animals was reported in last week's announcement on 23 Aug 2019. The Company previously reported on the patients in the dose-escalation or first part of the study on 2 May 2019.

Dr Greg van Wyk, Noxopharm CEO and Chief Medical Officer, said: 'Today's data builds positively on the previously released figures obtained from the first group of patients living with end-stage metastatic castration-resistant prostate cancer (mCRPC).

'Particularly exciting is the fact that at this stage, two men in particular, appear to have had a marked improvement in their condition, based on reduced tumour size, lowered PSA levels, and reduction in pain. This kind of response in men with terminal disease is very encouraging, as palliative radiotherapy is not generally expected to deliver benefits beyond symptom reduction such as pain relief.

'Similarly, the overall PSA response rate observed is very promising. We know from published scientific data that only 5-9%[1][2] of end-stage mCRPC patients achieve a PSA response at any point following low-dose radiotherapy treatment alone, so it is particularly encouraging to see that 55% of patients in this group have shown a PSA response in the first 12 weeks after treatment with Veyonda® and low-dose radiotherapy.

'The men participating in the trial have what is known as 'end-stage' disease; it is not curable, and the cancer has spread, usually to other parts of the body including the bones, which can be

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[1] Din, O. S., Thanvi, N., Ferguson, C. J., & Kirkbride, P. (2009). Palliative prostate radiotherapy for symptomatic advanced prostate cancer. Radiotherapy and Oncology, 192-196.

[2] Kwon, E. D., & al, S. H. (2015). Ipilimumab versus placebo after radiotherapy in patients with metastatic castration-resistant prostate cancer that had progressed after docetaxel chemotherapy (CA184-043): a multicentre, randomised, double-blind, phase 3 trial. Lancet Oncology, 700-712.

extremely painful. They have few treatment options, and those that are available are intended to provide palliative care - to decrease pain and maintain or improve quality of life. A well tolerated treatment that could reduce pain, improve quality of life and possibly even prolong life would be welcomed by the over 350,000 men who will die of prostate cancer worldwide each year, as well as their families and their doctors.'

Dr Anne Capp, Radiation Oncologist from GenesisCare and Principal Investigator on the DARRT-1 trial confirmed 'Currently the therapeutic options for patients with advanced metastatic prostate cancer are very sparse. These men generally have a limited life expectancy and are living with high levels of pain. A medication that could improve the response to radiation therapy for a number of these patients would be welcomed by clinicians and patients alike.'

The DARRT-1 patients will continue to be monitored, with the next key point of data collection being at 24 weeks, in late Nov 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. Publication represents an important validation from the medical / scientific community and will build confidence in the pathway to registration and commercialisation. Completion of the DARRT-1 study will lay the foundation for the next stage in the drug development pathway required by regulators, that is, Phase II clinical trials.

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MORE EVIDENCE THAT VEYONDA® ENHANCES RT IN PROSTATE CANCER

- More, positive responses observed with Veyonda® + low-dose radiotherapy (RT)
- 45% of patients with end-stage prostate cancer had significant pain reduction at 12 weeks
- 55% of patients achieved a prostate specific antigen (PSA) response during the first 12 weeks
- 2 of 11 patients demonstrated a significant reduction in their overall tumour size (RECIST partial response)

Sydney, 28 Aug 2019: Noxopharm (ASX: NOX) ('**Noxopharm'** or the '**Company'**) is pleased to announce additional data from the DARRT-1 (Direct and Abscopal Response to RadioTherapy) study.

The Company previously reported on the patients in the dose-escalation (first) part of the study (2 May 2019). Today's announcement concerns the next group of patients enrolled in the dose-expansion (second) part of the study, 12 weeks post-treatment with Veyonda® and radiotherapy for palliative care in end-stage prostate cancer.

Topline findings:
12[3] men with late-stage prostate cancer, that is, progressive, metastatic and without any remaining standard treatment options were enrolled into the second part of the study. Patients were treated with a single 15-day course of Veyonda® 1200 mg daily combined with low-dose radiotherapy.

- **Tumour size:** 8 men had tumours suitable for radiographic assessment under the study design. Two men had a reduction in aggregate tumour size of at least 30% (partial responders), the remaining six men had tumours classified as stable (progression free)
- **PSA:** 55% of patients (6/11) achieved a PSA response (≥50% fall) at any point during follow up. The expected reduction with low-dose radiotherapy alone is only 5% to 9%
- **Pain:** 45% (5/11) of patients reported considerably reduced pain levels (≥ 30% falls) at 3 months

[3] 11 men underwent study treatment, with one participant withdrawing prior to treatment, for personal reasons

- Safety profile of Veyonda® + RT continues to be encouraging, with few adverse events noted.

This study is ongoing and 6-month data will be released in late Nov 2019.

Conclusion: A short, easily administered and well-tolerated treatment regimen of Veyonda® with low-dose radiotherapy produced an anti-cancer response in a high proportion of men. 55% had a PSA response, 45% had clinically meaningful reduction in pain and aggregate tumour size change was graded as stable or better in all evaluable patients. Two of these men were partial responders experiencing significant tumour shrinkage – a very positive outcome for patients in a palliative setting.

Future results from DARRT-1:
Publication represents an important validation from the medical / scientific community and builds confidence in the pathway to registration and commercialisation. The Company's goal is to publish its results via peer-reviewed media, wherever possible.
Anticipated reports and publications include:

- The DARRT-1 patients will continue to be monitored, with the next key point of data collection being at 24 weeks, in Nov 2019. The combined data from this cohort of men and those in the first part of the trial will be presented at an international scientific congress and will be submitted to a peer reviewed journal in H1 2020.

- Finalisation of the DARRT-1 study will be followed by an independent expert committee review of the radiographic results to fully characterise the reductions in the sizes of non-irradiated tumours - abscopal effects. These findings are also expected to be published in H1 2020.

- Finally, DARRT-1 is also investigating longer-term data on the participants, including overall survival. These are expected be reported in late 2020.

Future Studies:
Planning is also currently underway for the next step in the DARRT program in prostate cancer, with a multi-national study targeted to start in 2020. The Company's ultimate goal in prostate cancer is to become an essential adjunct to radiotherapy at multiple stages of the disease continuum. The DARRT program is a core component of that goal.

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 (20-30 Gy) with Veyonda® administered daily for up to 2 weeks. The subjects are being assessed clinically at 6-, 12- and 24- weeks.

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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