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DARRT Treatment Has Lasting Disease Control at Six Months

- **Long-lasting responses with Veyonda® + low-dose radiotherapy in late-stage prostate cancer**
- **High proportion of disease control following a single, short course of treatment**
- **Complete resolution of pain achieved in some patients**

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SYDNEY, 2 May 2019: Noxopharm (ASX: NOX) ('**Noxopharm'** or the '**Company'**) is pleased to announce the 6-month interim results from the dose-escalation arm of the DARRT-1 (Direct and Abscopal Response to Radio-Therapy) study.

The Company previously (6 Feb 2019) reported on the interim 3-month results of these patients. Today's announcement concerns those same patients at 6 months.

Topline findings:

- The study involves 14 men with late-stage prostate cancer that is progressive, metastatic and without any remaining standard treatment options
- Patients were treated with a single 15-day course of Veyonda® + low-dose radiotherapy to a single lesion:
  - **Tumour size:** Disease control (tumour volume) was highly durable with 8/14 (57%) of patients remaining progression-free at 6 months
  - **PSA:** 36% of patients achieved a PSA response (≥50% fall) at any point during follow up
  - **Pain:** of 7 patients with reduced pain levels (≥ 30% falls) at 3 months, pain responses were maintained in 5/7 patients at 6 months, with two of these being pain-free.

Conclusion: A short, minimally intrusive and well-tolerated treatment regimen of Veyonda® + low-dose radiotherapy is able to produce a durable anti-cancer response rate lasting at least 6 months (the length of this study) in a high proportion (57%) of men with end-stage, metastatic, castrate-resistant prostate cancer.

Commentary:

Greg van Wyk MB BCh, Noxopharm chief executive officer and chief medical officer, said:

- "The DARRT treatment regimen showed a high rate of disease control at 3 months, and today's data shows that this treatment effect is durable. We now intend to find out how just durable this effect may be, and so we have amended the DARRT-1 protocol to obtain longer-term data for this cohort, including overall survival. These data will be reported in 2020."

- "We know from preclinical studies that the combination of Veyonda® + radiotherapy kills cancer cells, so we are confident that this effect is contributing to the initial response to treatment. But to see disease control out to at least 6 months in the absence of any ongoing treatment, suggests that the immuno-oncology effects of Veyonda® observed in our preclinical work may be occurring clinically."

- "What is particularly pleasing is the level of pain relief achieved in this study, with two patients reportedly being completely pain-free at 6 months. Bone pain is a major issue in late-stage prostate cancer and being able to reduce pain to the extent that we have, on its own should make a major contribution to the well-being of patients."

- "We believe that DARRT represents a potential paradigm change in the treatment of prostate cancer, and we look forward to providing additional updates as we continue to advance our Veyonda® development plan. We plan to present today's full data set at an upcoming medical conference."

Graham Kelly PhD, Noxopharm Executive Chairman, said, "It is important to see this achievement in the context of the usual fate of men with late-stage prostate cancer. Once prostate cancer stops responding to anti-androgen therapy and becomes known as castrate-resistant, cancer progression generally is relatively rapid with the cancer spreading predominantly to the skeleton, forming dozens to hundreds of secondaries which typically are associated with significant bone pain. At this point, the only available standard treatment is palliative radiotherapy, where we know only 5-9% of patients achieve a PSA response at any point following treatment."[1,2]

"So, the first context is that we have halted progression in the disease and provided significant pain relief in over half of the men with a combination of palliative radiotherapy and Veyonda®."

"The second context is that we have achieved this by irradiating a single lesion outside of the skeleton. Lack of disease progression and a significant reduction in pain levels point to anti-cancer responses in lesions in the skeleton where no radiation was delivered. We believe this is associated with an off-target response known as an abscopal response and likely is associated with the immuno-oncology effects of Veyonda®."

"The third context is that we have achieved this outcome with a short (15-day), minimally-intrusive, very well-tolerated treatment regimen that could be repeated if required, although we did not do so in this study. That is, the ongoing block of disease progression has occurred in the absence of any further treatment over the 6 months."

Future studies:

The second arm of the DARRT-1 study is continuing as planned, with anticipated 3- and 6-monthly clinical reports in July and October 2019 respectively.

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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.

Planning also currently is underway for the next step in the DARRT program in late-stage prostate cancer, with a multi-national study planned to start in 2020.

The Company's ultimate goal in prostate cancer is to evaluate the DARRT treatment regimen across the full spectrum of prostate cancer from early-stage to late-stage, with low-dose radiotherapy potentially replacing the high and potentially destructive levels of radiation currently used in cancer that has spread from the prostate gland in early- and mid-stage disease.

About Veyonda®

Veyonda® (previously known as NOX66) is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to enhance the anti-cancer activity of idronoxil. Idronoxil inhibits the oncogene, Ecto-NOX disulfide-thiol exchanger type 2, leading to inhibition of the key secondary pro-survival messenger, sphingosine-1-phosphate. This enhances the DNA-damaging effects of radiotherapy and cytotoxic chemotherapy, as well as 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 palliative dosages of radiotherapy. The DARRT treatment regimen entails a 5-day course of radiotherapy (20-30 Gy) in 5 fractionated dosages targeting a single tumour, with Veyonda® administered daily for up to 3 weeks. The rationale of DARRT is to combine 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 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 of 4 subjects receiving 400 mg, 800 mg and 1200 mg Veyonda® respectively. In the second arm, subjects are receiving the 1200 mg Veyonda® dose. 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, Hong Kong and New York. The Company has a primary focus on the development of drugs based on a phenolic chemical structure, with Veyonda® the first pipeline product. The pipeline includes a number of other drug candidates for both oncology (within NOX) and non-oncology indications (in subsidiary company, Nyrada Inc).

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