2 December 2019 Sydney, Australia

ASX Ltd
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Positive DARRT-1 Data in Late-Stage Prostate Cancer

- **Clinical responses point to the NOX66 DARRT treatment regimen as a potentially major new treatment option for men with late-stage prostate cancer**
- **Positive results trigger planning for proposed pivotal (registration) DARRT-2/DARRT-3 study to commence 2020**
- **Combination NOX66 (Veyonda®) + palliative radiotherapy achieves durable anti-cancer response in high proportion of late-stage prostate cancer patients with no other standard treatment options**
- **10 of 15 patients (66%) scanned at 6-months had responded to treatment with stable disease or better**
- **Major reduction in pain levels in 10 of 16 (62%) of patients including achieving pain-free state**
- **Favourable safety profile. Treatment well tolerated with no new adverse safety signals**
- **Primary and Secondary End-Points met**

Sydney, 2 December 2019: Noxopharm (ASX: NOX), an Australian drug development company, reports positive end-of-study data from its DARRT-1 Phase 1b trial.

Commentary: Noxopharm Executive Chairman and CEO, Graham Kelly PhD
"This is exciting data that validates our confidence in the future of the NOX66 DARRT treatment regimen. NOX66 DARRT has delivered a very meaningful anti-cancer effect in a high proportion of men, halting progression of their disease and providing an average 80% reduction in their pain levels, including some men becoming pain-free."

The context here is that men in DARRT-1 had late-stage, progressive disease and had exhausted all available treatment options. In general, they were experiencing considerable pain, had poor quality of life, and had a life expectancy of about 6-8 months. In this trial, 10 of 15 (66%) men at the conclusion of the study had responded to treatment with stable disease or better at 6-months following start of treatment (as determined radiographically) and with significantly lower pain levels.

"A 66% response rate is a substantial response rate for such late-stage disease, putting NOX66 DARRT right at the top end of response rates in late-stage cancer," Kelly added.

Currently 360,000 men globally are estimated to die from prostate cancer each year,[1] with 100,000-plus of those men in Australia, U.S. and Europe.[1-3] That is a substantial global unmet need and multi-billion dollar market opportunity that the Company intends to pursue with all vigour.

"The combination of Veyonda® and low-dose radiotherapy has proven to be very well tolerated and minimally intrusive, important factors for patients with advanced cancer and generally poor health

when considering their future. Another positive is that NOX66 DARRT uses external beam radiotherapy, a relatively inexpensive and readily-available source of radiotherapy around the world, supporting wide uptake," Kelly concluded.

Trial data

Patients enrolled in DARRT-1 were eligible for low-dose (palliative) radiotherapy for relief of symptoms such as pain, with little or no expectation of it changing the course of the disease.

The data shows that adding Veyonda® (NOX66) to low-dose (20Gy) palliative radiotherapy applied to a single lesion changed the course of disease to a considerable degree in at least 66% of men, with a halt to disease progression and high levels of pain relief lasting at least for the 6-months of observation.

The study treated 25 men. At the end of study at 6-months:

- 9 had withdrawn, died or been lost to follow-up
- 16 completed the study of whom 15 were measurable radiographically.

Across all 3 Veyonda® dosages (400, 800, 1200 mg):

- 1/15 patient had a partial response, 9/15 had stable disease and 5/15 had progressive disease, giving an overall tumour response rate of 66%
- 5/16 patients (31%) had a PSA Response (>50% fall from baseline), with PSA reductions ranging from 61-98%
- 10/16 patients (62%) had a Pain Response (>30% fall from baseline), with falls ranging from 43-100% (pain-free).

The trial's primary end-point of safety was met with no significant or dose-limiting toxicities.

The secondary end-point of efficacy very clearly was achieved based on rates of PSA Response, Pain Response and Tumour Response (RECIST) in a high proportion of men.

Next steps

1. The Company expects to receive the final Statistical Report in March 2020 which will contain specific details of the radiographic analysis, including the extent of any partial responses and detailed responses of both irradiated and non-irradiated lesions.
2. Planning for the next stage of testing is underway in collaboration with the Company's Medical Advisory Boards. This will be a double-blind, control-arm, multi-national, Phase 2/Phase 3 adaptive study that the Company hopes will be the final step to obtaining marketing approval. DARRT-2/DARRT-3 will use 6 repeated cycles of treatment with Veyonda®, compared to the single treatment cycle used in DARRT-1. The Company anticipates that this could provide an additional anti-cancer effect and with it, the potential for an increase in the all-important overall survival endpoint.
3. Upcoming milestones include the lodgement of an IND application for DARRT-2/DARRT-3 to the U.S. FDA, as well as applications to a range of other regulatory bodies including the EMA and TGA.
4. The family of PCT patents relating to NOX66 DARRT have proceeded into the national examination phase in upwards of 80 countries.

Refs: 1. Rawla P (2019) World J Oncol 10, 63-89; 2. Cancer Australia; 3. American Cancer Society

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About DARRT-1

DARRT-1 is an open-label Phase 1b trial evaluating the safety and tolerability of the Company's lead product candidate, Veyonda® (NOX66), in combination with low-dose palliative radiotherapy in 25 patients with late-stage metastatic castration-resistant prostate cancer (mCRPC) who had exhausted available standard treatment options.

The primary objective of the study was to investigate the safety and tolerability of a combination of Veyonda® and a palliative dose of external beam radiotherapy and to confirm the appropriate dose of Veyonda® for the next stage of clinical trialling. To determine the optimal dose, the first 3 cohorts of 4-6 patients (known as the dose escalation part) were treated with either 400mg, 800mg and 1200mg of NOX66 in combination with radiotherapy. Following the decision of the Safety Steering Committee in November 2018, an expansion cohort of the study was recruited involving 11 patients who received 1200mg of Veyonda®. The patients were treated with Veyonda® for 14 days and low-dose radiation treatment given on 5 days (5 fractionated doses) to between 1-2 measurable lesions during the Veyonda® administration. Patients then were followed up after 6, 12 and 24 weeks.

For more information, visit ClinicalTrials.gov, using identifier: NCT03307629

About the NOX66 DARRT program

The Company's NOX66 DARRT (Direct and Abscopal Response to Radiotherapy) clinical program is testing the ability of Veyonda® to augment an immunological response to palliative (non-ablative) dosages of radiotherapy. The principle of NOX66 DARRT is to use low-dose radiation to trigger local inflammatory and immune responses in a single irradiated tumour, with Veyonda® designed to boost that response and extend it to all tumours in the body via an ability to increase trafficking of the body's innate and adaptive immune cells. The clinical outcome being sought is shrinkage of both irradiated tumours (direct effect) and non-irradiated tumours (abscopal response), resulting in reduced pain, extended progression-free survival, and improved survival.

The DARRT treatment regimen is being tested initially in late-stage prostate cancer, but given that the active ingredient in Veyonda®, idronoxil, targets an oncogene common to most forms of cancer, the Company is confident that the NOX66 DARRT treatment principle should be applicable to most if not all forms of solid cancer including breast, lung, ovarian and colorectal cancers.

About Veyonda®

Veyonda® (NOX66) is an innovative suppository dosage formulation of the experimental anticancer drug, idronoxil. Idronoxil inhibits the oncogene, Ecto-NOX disulfide-thiol exchanger type 2, leading indirectly to inhibition of the key secondary pro-survival messenger, sphingosine-1-phosphate. This enhances the DNA-damaging effects of radiotherapy, as well as promoting trafficking of the body's innate and adaptive immune systems.

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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Forward Looking Statements

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as “aim”, “anticipate”, “assume”, “believe”, “continue”, “could”, “estimate”, “expect”, “intend”, “may”, “plan”, “predict”, “project”, “plan”, “should”, “target”, “will” or “would” or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections and assumptions made by Noxopharm about circumstances and events that have not yet taken place. Although Noxopharm believes the forward-looking statements to be reasonable, they are not certain. Forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond the Company’s control that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement. No representation, warranty or assurance (express or implied) is given or made by Noxopharm that the forward-looking statements contained in this announcement are accurate and undue reliance should not be placed upon such statements.