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ASX: NOX

Noxopharm Limited

ABN 50 608 966 123

Registered Office and Operational Office:
Suite 3, Level 4
828 Pacific Highway
Gordon NSW 2072
Australia

ASX Limited
20 Bridge Street
SYDNEY NSW 2000

Combination of Veyonda® + Radiotherapy Delivers Clinical Benefits

- **Interim (12-week) DARRT-1 readout**
- **Combination Veyonda® + low-dose radiotherapy well tolerated**
- **PSA, pain and tumour responses at higher doses**
- **24-week readout to indicate longevity of response.**

SYDNEY, February 6, 2019: Noxopharm (ASX: NOX) announces interim (12-week) results from the dose-ranging component of the DARRT-1 study.

1. Key findings:

→ combining Veyonda® with low-dose radiotherapy applied to a single metastasis (lesion) is able to produce an anti-cancer response in both the irradiated and non-irradiated lesions as evidenced by PSA response, pain reduction, and/or tumour measurements

→ a dose-response was observed, with the 1200 mg dose confirmed as the therapeutic dose

→ clinical responses were achieved with no serious side-effects related to Veyonda®.

2. Rationale: The DARRT treatment regimen involves using Veyonda® to trigger a generalised anti-cancer response to radiotherapy against cancer cells throughout the body. This is known as an abscopal response and is thought to involve a generalised immune response. Veyonda® has been shown to activate the body's innate immune system, an action that the company believes will provide a transformative approach to the use of radiotherapy in oncology, enabling low dosages of focused radiation to be used to create a generalised anti-cancer effect.

3. DARRT and prostate cancer: 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. The DARRT-1 study is the starting point in this program involving end-stage prostate cancer.

Prostate cancer preferentially spreads to bone and lymph nodes. Late-stage (metastatic castrate-resistant) prostate cancer typically involves multiple secondary lesions in the skeleton (vertebrae, ribs, pelvis, hips, skull, long bones) and pelvic lymph nodes; secondary lesions in soft tissues such as the lungs, liver and brain are less common. The tumour burden in Stage IV prostate cancer generally is greatest in the skeleton and is associated with significant pain. Treatment in these men nearing end

of life is palliative, with pain relief a major objective through the use of radiotherapy and pain medications.

NOX is developing the DARRT regimen in advanced prostate cancer with the dual objectives of providing better palliation (pain relief) and extending survival and doing so in a well-tolerated way.

4. Interim data: The DARRT-1 study has two stages. Stage 1 involving 12 patients was designed to provide an indication of the benefit:risk profile of three different doses of Veyonda® (400, 800, 1200 mg daily) including four patient per dose. Patients included in this phase were required to have at least one soft tissue lesion that was amenable to accurate radiographic measurement (according to RECIST 1.1).

Stage 2 involved expansion into an additional 12 patients at a dose selected by an independent data safety monitoring board (DSMB). As previously announced, Stage 2 of the trial was initiated at the 1200 mg dose following DSMB review of the 6-week data. Stage 2 includes patients who lack a soft tissue lesion and whose lesion requiring radiatherapy is located in the bone, which often cannot be accurately measured (according to RECIST 1.1). Determination of a generalised (abscopal) response in such patients will be on the basis of PSA and pain responses. The final 4 patients in this stage have been screened and the study is expected to be fully enrolled within 2 weeks.

Today's announcement concerns the 12-week data on the 12 patients in Stage 1.

4.1 Safety: All three doses were well tolerated and no serious side-effects were reported as being related to Veyonda®. For patients with advanced disease receiving palliative therapy, not doing any harm is a key factor in any new treatment to be introduced, and Veyonda® is looking increasingly as meeting this fundamental need.

4.2 Efficacy: Efficacy analyses include reported changes from baseline (Day 1 of the study) at 12- and 24-weeks following radiotherapy on three key measures: PSA (prostate specific antigen) levels, pain levels, and aggregate lesion sizes.

- PSA is a standard surrogate measure of response in prostate cancer trials;
- pain relief is a key endpoint in palliative trials (particularly in prostate cancer trials);
- a change in aggregate (total) tumour diameter (length) gives a strong indication of anti-cancer effect (shrinkage of tumours).

Falls in PSA of > 50% compared to baseline and reductions in pain severity of > 30% compared to baseline are considered to be significant biochemical/tumour and pain responses respectively.

Apart from pain relief in 2 patients in the 400 mg cohort, this dose did not appear to have any significant anti-cancer effect in this small number of patients.

Encouraging efficacy signals were demonstrated in the 800 and 1200 mg cohorts at 12 weeks. Two patients in each cohort had PSA falls > 50% (51-78%). 3/4 patients in the 800 mg cohort and 2/4 patients in the 1200 mg cohort had a pain response of > 30% (52-92%). One patient in the 800 mg cohort had a reduction in aggregate tumour diameter of > 30% (RECIST 1.1 partial response); the other three 800 mg patients and 3 of the 1200 mg patients were classified by RECIST 1.1 as having stable disease at 12-weeks.

The changes in PSA levels and total tumour lengths, relative to starting (baseline) levels across all 11 evaluable Stage 1 patients are shown below in Figures 1 and 2, respectively.

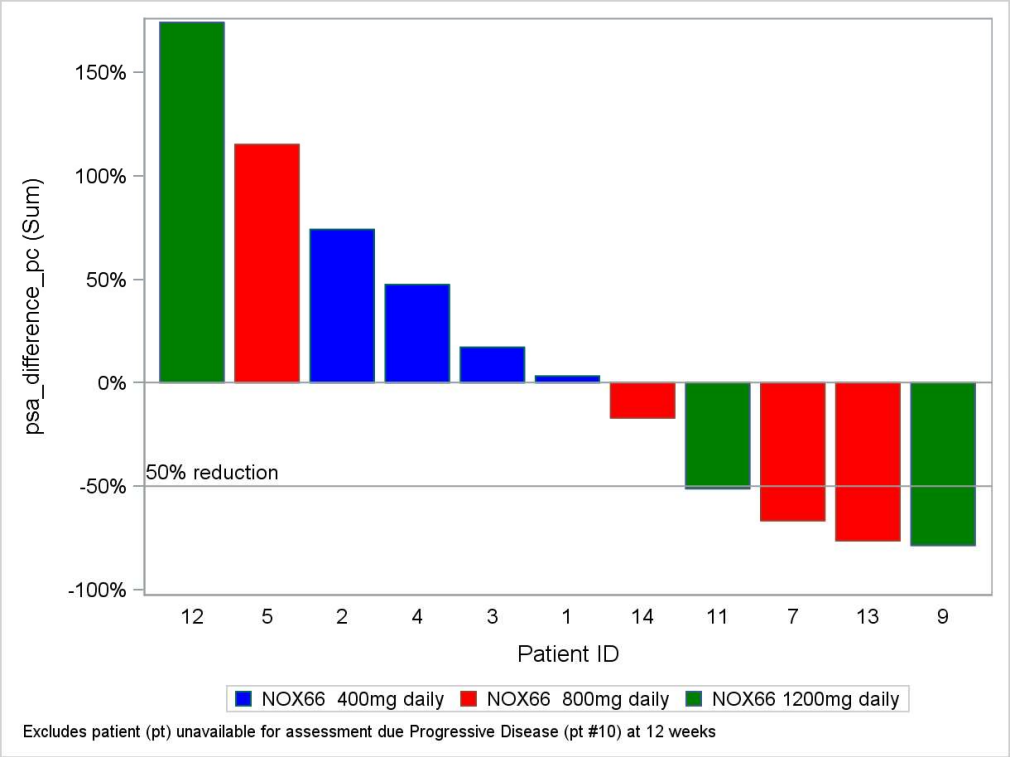

Figure 1: Percentage change in prostate specific antigen, from baseline to 12-weeks, by patient.

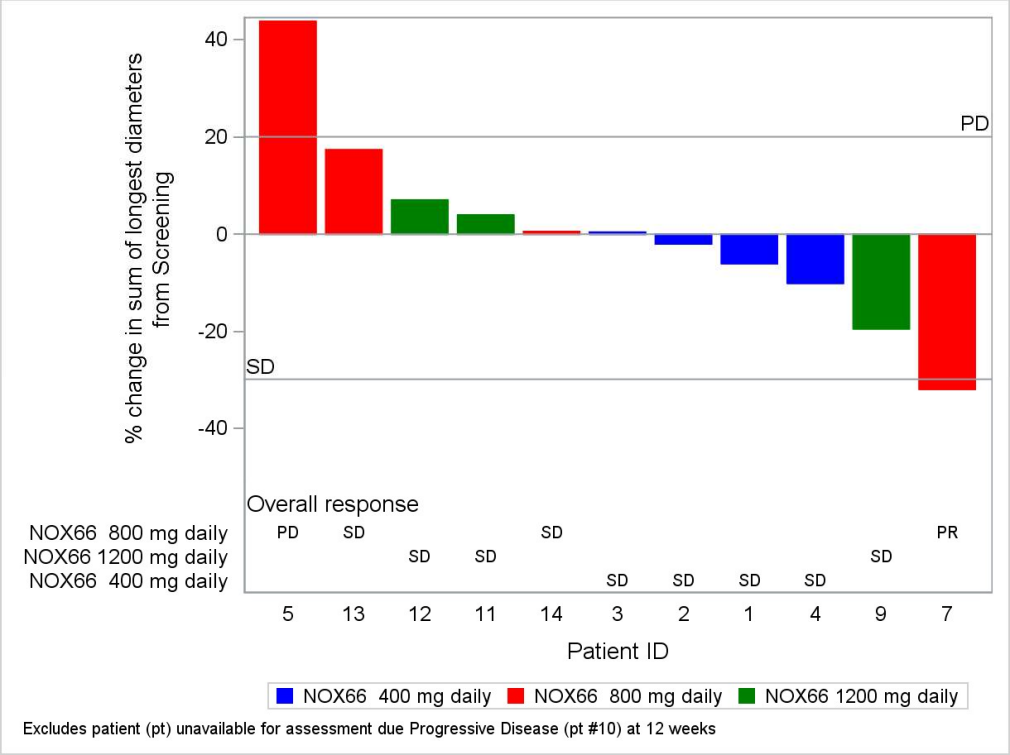

Figure 2: Percentage change in total tumour length, from baseline to 12-weeks, by patient (with RECIST 1.1 response designation)

In late-stage prostate cancer where a significant proportion of the tumour load can be in bones and where accurate measurement of tumour size by RECIST 1.1 criteria therefore is not possible, biochemical (PSA) response is a useful and well-accepted surrogate marker of anti-cancer response.

5. Comments: Greg van Wyk MD, Noxopharm Chief Medical Officer, said "We are very encouraged by these results as these men are right at the end of their treatment journey and are receiving radiotherapy principally to alleviate their pain and enhance their remaining quality of life. That a number of patients derived a meaningful clinical benefit in this trial in terms of pain relief and apparent reduction in tumour load gives us great hope that we can advance Veyonda to market to help many more men in this way."

Graham Kelly Ph.D., Noxopharm Chief Executive Officer, said, “Any interpretation of Phase 1 data always comes with the proviso that we are talking about small sample sizes. However, when you balance that with the advanced and rapidly progressive nature of the disease, plus the palliative, end-of-life nature of the treatment these men are receiving, to achieve any clinical benefit is a notable achievement. In broad terms, about half of the patients in the 800 and 1200 mg dosage cohorts reported significantly less bone pain combined with evidence of a reduction in the growth of their cancer through to a reduction in their tumour load.”

“The 24-week data is going to be even more important because we are seeing PSA levels in some men still falling at the 12-week point. The 24-week data will provide a much clearer picture of the full extent of the clinical benefit and be a strong pointer to just how beneficial the treatment is likely to have on survival times. But even before that point, the Company believes that this 12-week data justifies its belief that Veyonda® is a potentially transformative anti-cancer drug. ”

The end-of-study 24-week results for these cohorts are expected to be announced in early May. The 12-week and 24-week data for the 12 patients in the second phase of the trial are expected to be available in July and October, respectively.

About Veyonda®

Veyonda® (previously known as NOX66) is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to preserve the anti-cancer activity of idronoxil in the body and to enhance its drug-like behaviour. 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 DARRT

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, and the 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 all 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 24-subject study being conducted in Georgia and Australia. The study is in 2 stages, each of 12 subjects. Stage 1 is dose-finding entailing 3 cohorts of 4 subjects receiving 400 mg, 800 mg and 1200 mg Veyonda® respectively. In Stage 2, the 12 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, New York and Hong Kong. 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).

Investor & Corporate Enquiries:
Prue Kelly
M: 0459 022 445
E: info@noxopharm.com

Company Secretary:
David Franks
T: +61 2 9299 9690
E: David.Franks@automicgroup.com.au

Media Contact:
Allison Blum, Ph.D.
LifeSci Public Relations
T: +1 516 655 0842
E: allison@lifescipublicrelations.com

www.noxopharm.com

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