1 June 2020 **Sydney, Australia**

ASCO 2020 Highlights NOX66 Potential in Late-Stage Cancer

Highlights:

- **NOX66 (Veyonda®) clinical data released to world-wide audience**
- **Anti-cancer responses (tumor size and pain responses) observed in approximately two-thirds of men with end-stage prostate cancer**
- **Abscopal responses in approximately one-quarter of men with end-stage prostate cancer**
- **Industry data presented at ASCO supports NOX confidence in prominent position of NOX66**
- **Data to be discussed in a Webcast later this week**

Sydney, 1 June 2020: Noxopharm (ASX: NOX) today reports on the public release at a global oncology conference of 2 sets of clinical data relating to the development of NOX66 (Veyonda®) as a treatment of end-stage cancer.

The data was presented to the 2020 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting. ASCO is the premier annual scientific event in the oncology field globally, providing an opportunity for Noxopharm, the pharmaceutical industry and the investment market to yardstick NOX66 against competitive therapies in end-stage prostate cancer.

Graham Kelly PhD, Noxopharm CEO and Executive Chairman, said, "Industry reports at this year's ASCO conference confirm the Company's confidence in NOX66 being poised to make a significant contribution to cancer therapy. ASCO annual conferences provide a valuable snapshot of emerging cancer therapies and this year there are 120 clinical presentations relating to prostate cancer. The conference take-out message continues to be that prostate cancer, once it becomes metastatic and hormone-insensitive, remains poorly responsive to further therapy. That end-stage condition is what we are developing NOX66 for."

"We have been unaware for some time of any therapies under development that come close to offering an anti-cancer effect to anything like the same degree that we are seeing with NOX66, and in particular delivering this level of benefit in a well-tolerated, minimally invasive and cost-effective manner. In the context of what has been reported at ASCO 2020, the high response rates we are seeing with NOX66 in both the DARRT and LuPIN programs mark NOX66 as a major drug prospect."

An estimated 300,000 men die each year worldwide from prostate cancer after exhausting available treatment options and that is a number that looks set to rise with increasing longevity. Add to that the generally high pain levels associated with the typical spread of prostate cancer to bone, and the need for a last-line treatment offering a meaningful effect once everything else has failed becomes compelling.

Presentations

The data was presented in the form of two posters. Details of the DARRT-1 Phase 1b clinical study and details on the interim data from the Phase 1b/2a LuPIN clinical trial have been reported before (30 April 2020 and 14 February 2020 respectively). The significance of re-presenting these data to this conference is that it has allowed the Company to reference the Veyonda clinical data against that of other technologies.

DARRT-1 Study

- 67% of patients (10/15) scanned at 6-months had responded to treatment with stable disease or better
- 27% of patients (4/15) reported an abscopal response (abscopal responses in non-irradiated lesions varied from approximately 50% shrinkage of the abscopal lesion to almost complete resolution)
- 63% of patients (10/16) reported a major reduction in pain levels in including 4 patients achieving a pain-free state
- 31% of patients (5/16) had a clinically significant PSA response
- Combination (Veyonda + external beam radiotherapy) treatment had a favourable safety profile, was well tolerated and had no new adverse safety signals.

LuPIN Study

- Median Overall Survival in 32 men was 17.1 months, an encouraging outcome for end-stage prostate cancer patients
- 62.5% of patients (20/32) had an anti-cancer effect as evidenced by a PSA response greater than 50%
- 50% (12/24) of patients who had severe pain at the beginning of the study experienced a significant pain reduction
- 47% of patients (15/32) were able to complete the full 6 courses of treatment
- Combination treatment (Veyonda + ^{177}Lu-PSMA-617) was safe and well tolerated.

Dr Gisela Mautner, Noxopharm Chief Medical Officer, said: "ASCO is the world's premier annual scientific event in the oncology field. Having two key sets of results presented on this world stage to oncology professionals, patient advocates and industry representatives confers strong validation of our work in prostate cancer. ASCO sets a very high scientific bar and we are very proud that our poster presentations

stood up to its rigorous scientific peer review process as well a strong peer competition on a worldwide scale."

"We are delighted to present the results of our DARRT-1 study to ASCO and discuss the remarkable achievement of 4 patients having achieved abscopal responses, where the combination therapy of NOX66 and low-dose radiation has not only shrunk irradiated lesions, but also lesions outside of the radiation field. Abscopal responses are exceptionally rare and this result is highly encouraging."

"The interim data from LuPIN also is highly encouraging, showing a pronounced survival benefit for patients with late-stage prostate cancer. These patients often have a limited survival expectancy and poor quality of life. However, the LuPIN trial is reporting a median Overall Survival of 17.1 months which is a great clinical achievement, offering new hope."

Future

The DARRT program remains the Company's major focus and it plans to conduct an expanded version of DARRT-1 in 2021. DARRT-2 will be a multi-national Phase 2 study in men with metastatic castrate-resistant prostate cancer post two rounds of taxane therapy and novel anti-androgen therapies. A key difference between DARRT-1 and DARRT-2 will be the use of repeat cycles of NOX66 in order to maximise its monotherapy anti-cancer effect. The planning for this study is underway, including an imminent lodgement of an IND with the U.S. FDA.

The LuPIN study is fully recruited and will continue to be monitored with the objective of using NOX66 to enhance the efficacy of the experimental radiopharmaceutical, ^{177}lutetium-PSMA-617.

Webcast

A webcast recording of Drs Mautner and Kelly discussing the 2020 ASCO poster presentations is planned to be made available later this week. Details will announced via the Noxopharm ASX portal.

Glossary

Abscopal response	An anti-cancer response in tumours in response to radiotherapy where the responding tumours are outside of the field of irradiation. Believed to be associated with an immune response triggered by the radiation
ASCO	American Society of Clinical Oncology
DARRT	Direct and Abscopal Response to Radiotherapy. Combination of NOX66 and low-dose external beam radiotherapy
IND	Investigational New Drug
LuPIN	^{177}Lutetium-PSMA-617 in Combination with NOX66
NOX66	Suppository dosage formulation of idronoxil (Veyonda)
PSA	Prostate Specific Antigen

About DARRT-1

DARRT-1 was 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 14days 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.

About LuPIN

LuPIN is an Investigator-Initiated Phase 1/2, single-arm, open label study enrolling 56 men with mCRPC whose disease was 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) Veyonda in combination with ^{177}Lu-PSMA-617.

The Phase 1 part of the study is intended to establish the safety of the combination treatment. The Phase 2 expansion part is intended to establish the dose-response effect of increasing Veyonda® levels in combination treatment.

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 and Veyonda every cycle on days 1-10.

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

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 the drug development company, Nyrada Inc. (ASX:NYR).

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The release of this announcement has been authorised by the Noxopharm Board of Directors

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