



Date: 10 April 2019

Sydney, Australia

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

Board of Directors

Mr Peter Marks

Chairman

Non-Executive

Director

Dr Graham Kelly

Chief Executive Officer

Managing Director

Dr Ian Dixon

Non-Executive

Director

Mr John Moore

Non-Executive

Director

ASX Limited
20 Bridge Street
SYDNEY NSW 2000

Veyonda[®] Chemotherapy Enhancement Program to be Expanded

- **Expansion based on Final Report for Phase 1b CEP-1 study confirming positive efficacy signals in late-stage cancers**
- **U.S. study to investigate Veyonda[®] + doxorubicin in sarcomas**
- **CEP-2 target start Q4 2019**
- **Comprehensive plan on track to establish Veyonda[®] as key, versatile cancer drug**

SYDNEY, April 10, 2019: Noxopharm Ltd (ASX: NOX) (Noxopharm or the 'Company') provides an update on the progress of its Veyonda[®] chemotherapy enhancement program (CEP) which is being run in parallel to the Company's two radio-enhancing programs (DARRT and LuPIN). The three programs collectively are investigating the unique dual cytotoxic and immuno-oncologic properties of Veyonda[®], with CEP exploring using these properties in combination with standard chemotherapy to achieve anti-cancer effects in patients with end-stage, metastatic solid cancers. Together these programs aim to cement Veyonda[®] as a key, versatile treatment in the multi-billion dollar cancer market.

The Company's overriding commercial and regulatory approval objectives remain to establish Veyonda[®] as an essential adjunct to all forms of radiotherapy in the treatment of prostate cancer, both late-stage and early-stage prostate cancer. CEP-2 falls under the Company's secondary objective which is to broaden the clinical uptake and value of Veyonda[®] once it reaches market, by demonstrating broad clinical benefits beyond a single approved marketing indication. The 3 ways that is being done are by demonstrating (i) a radio-enhancing effect of Veyonda[®] in cancer types other than prostate cancer, (ii) an ability to enhance the effect of other immuno-oncology agents such as checkpoint inhibitors, and (iii) an ability to enhance the effect of standard chemotherapies.

The strategic decision to expand CEP was confirmed by the positive data in Final Report of the CEP-1 Phase 1b study, recently received by the Company. This study enrolled 19 patients with late-stage metastatic, solid cancers (breast, lung, ovarian, prostate). Patients had undergone multiple lines of chemotherapy and their cancers had stopped responding to standard therapies. The cancers were considered unlikely to respond to any additional standard chemotherapy (including carboplatin), and even less likely to respond to the lower-than-normal dose of carboplatin that was used in this study (50-75% of standard dose).

As previously disclosed, this study demonstrated encouraging efficacy signals for the combination of Veyonda® and carboplatin.

Dose cohort	Assessment time point*	Count n	Partial response	Stable disease	Progressive disease
Cohort 1 NOX66 400mg, n (%)	Cycle 3	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 6	2	0 (0.0)	1 (50.0)	1 (50.0)
Cohort 2 NOX66 800mg, n (%)	Cycle 3	9	0 (0.0)	7 (77.8)	2 (22.2)
	Cycle 6	6	1 (16.7)	4 (66.7)	1 (16.7)

RECIST 1.1 Data for evaluable patients after 3 and 6 cycles

Of the 9 patients allocated to the higher dosage (800 mg) of Veyonda®, 5/9 (56%) showed stable disease (no tumour growth and no new tumours) or a partial response (up to 99% shrinkage of measurable lesions) over the 8-month term of the study. The Company and its medical advisors regard this outcome as significant, given that all patients were heavily-pretreated and with extensive and progressive Stage 4 chemo-resistant disease.

Greg van Wyk, M.D., CEO of Noxopharm, said, “Along with the positive signals emerging from our DARRT-1 study and the excellent progress being made in the LuPIN trial, both of which are being studied in prostate cancer, the CEP-1 data gives us confidence that we can bring Veyonda® to market as a versatile treatment for a range of cancers.”

CEP will now focus on a combination of Veyonda® and doxorubicin in sarcomas, based on the following:

- pre-clinical data showing a strong anti-cancer effect of idronoxil (the active ingredient in Veyonda®) against a broad range of subtypes of sarcoma (cancers of the connective tissues);
- previously published *in vitro* and *in vivo* data demonstrating a synergistic effect between idronoxil and doxorubicin in osteosarcoma (Yao C, Wub S, Lia D, et al. (2012). *Co-administration phenoxodiol with doxorubicin synergistically inhibit the activity of sphingosine kinase-1 (SphK1), a potential oncogene of osteosarcoma, to suppress osteosarcoma cell growth both in vivo and in vitro. Mol Onc, 6, 392-404*);
- the generally poor response rates of sarcomas to chemotherapy and radiotherapy, marking sarcomas as a cancer of high unmet need and few competing clinical studies;
- the commercial incentives associated with sarcomas including accelerated approval pathways, access to the U.S. Food and Drug Administration (FDA) Orphan Drug and Rare Pediatric Disease Priority Review Voucher programs, and prolonged market exclusivity and extended patent life.

Noxopharm continues to advance plans for a Phase 1b clinical trial in sarcoma in the U.S. Through a collaboration with George Clinical, the Company has engaged a group of high calibre US-based medical oncologists with deep expertise in sarcoma research and treatment. These experts will help design and execute the study which is aimed at determining the tolerability, safety and efficacy of Veyonda® in combination with doxorubicin, the standard of care chemotherapy for many sarcomas. The Company currently is in dialogue with the FDA with the aim of commencing the study during Q4 2019.

About Veyonda®

Veyonda® (previously known as NOX66) is an innovative dosage formulation of the experimental anti-cancer drug, 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 both radiotherapy and cytotoxic chemotherapy, in turn triggering up-regulation of the body’s innate immune system.

About Sarcoma

Sarcomas are a group of rare cancers that develop from cells in the body’s connective tissues. They are complex malignancies for which no cure exists once metastasis has occurred. They are categorised either as ‘soft tissue sarcomas’ e.g. cancer of fat and fibrous tissues (liposarcoma, fibrosarcoma) and cancer of muscle (rhabdomyosarcoma, leiomyosarcoma), or ‘hard tissue sarcomas’ eg. cancers of bone and cartilage (osteosarcoma, chondrosarcoma, Ewing’s sarcoma). Over the last few decades, traditional treatment with surgery and/or chemotherapy and/or radiotherapy has not significantly improved outcomes for most sarcoma

types. Sarcomas account for about 1% of all cancers in adults and about 20% of all cancers in children and adolescents. The American Cancer Society estimates that 5,270 Americans will die of soft tissue sarcomas in 2019.

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).

About George Clinical

George Clinical is a leading contract research organization with approximately 300 global staff providing the full range of clinical trial services to pharmaceutical, medical device, and diagnostic customers, for all trial phases, registration, and post-marketing trials.

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:

Cherilyn Cecchini, M.D.

LifeSci Public Relations

T: +1 646 876 5196

E: ccecchini@lifescipublicrelations.com

www.noxopharm.com

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.