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# Noxopharm to expedite Veyonda® Clinical Program

- **Internal strategic review triggered by growing confidence in Veyonda® becoming a major new anti-cancer drug and the need to confirm commercial and clinical strategies**
- **Confirmed aim to develop Veyonda® as a first-in-class effective and well-tolerated enhancer of all forms of radiotherapy, delivering meaningful pain relief and survival benefits in late-stage cancers**
- **Primary focus to be on prostate cancer based on large unmet need and significant current industry M&A activity with the need to expedite LuPIN and DARRT programs**
- **Potential secondary listing on a US securities exchange to be considered after the forthcoming release of interim LuPIN and DARRT clinical data**
- **Focus on maximising shareholder value in shortest possible time.**

**SYDNEY, February 21, 2019:** Noxopharm Ltd (NOX: ASX) (**Noxopharm** or the **Company**) today releases the key outcomes of a recently-completed internal strategic review.

The goal of the review was to set the platform for the Company's clinical strategy and commercial objectives over the next 2 years.

The review was triggered by recent clinical developments, underpinning the Company's confidence in its primary pipeline drug, Veyonda®, becoming a major opportunity in the field of radiotherapy. The need for a drug that enhances the anti-cancer effect of radiotherapy in a well-tolerated way, shifting radiotherapy in late-stage cancer from predominantly palliative outcomes to more curative outcomes, has long been identified as a major need. To date, no such drug has come to market.

NOX believes that it has established a strong position in the field with the opportunity to develop a radio-enhancer with the potential to become a key companion therapy to multiple forms of radiotherapy. The strategic review considered the steps the Company needed to take to realise that opportunity.

The three headline outcomes of the review are:

1. to prioritise use in late-stage prostate cancer, with LuPIN and DARRT programs to be run in parallel;
2. to adopt a commercial strategy that seeks to realise shareholder value in the shortest possible time;
3. to raise the profile of the Company in the U.S., including considering seeking a potential secondary listing of the Company's ordinary shares (**Shares**) on a U.S. securities exchange.

**Prostate Cancer and Radio-enhancement**

The review found that a focus on prostate cancer and radio-enhancement is justified by the following statistics:

- 31,500 men are expected to die from prostate cancer this year in the U.S.;
- an estimated 400,000 men in the U.S. this year will receive radiotherapy for prostate cancer;
- one estimate of the need for radiotherapy in first- and second-world countries across all forms of cancer is 4.2M cases each year;
- on that basis, the potential global market for a successful radio-enhancer in first- and second-world countries can be estimated to be US$84 billion for each US$20K cost of a course of radio-enhancer treatment.

(a) **LuPIN Program**. The review identified the LuPIN program in particular as a potential major commercial opportunity, given the emerging interest in radiopharmaceuticals in the treatment of a number of cancer types, particularly prostate cancer. In 2018, Novartis acquired Advanced Accelerator Applications SA for US$3.9 billion, and Endocyte Inc for US$2.1 billion, in both cases gaining access to their respective $^{177}$lutetium-PSMA technologies that are used in the treatment of late-stage prostate cancer.

The Company's current LuPIN program is aiming to show that Veyonda® boosts the current modest anti-cancer effect of $^{177}$lutetium-PSMA, with higher response rates and a greater depth of response. The first read-out of the current fully-recruited Phase 1b/2a study will be made public in June 2019.

The Novartis $^{177}$lutetium-PSMA agent is expected to receive marketing approval in about 2021, with a key strategic imperative for NOX to have confirmed the benefit of a Veyonda®/$^{177}$lutetium-PSMA combination by then.

**DARRT Program.** The aim of the DARRT treatment regimen is to use Veyonda to amplify the effect of palliative doses of external beam radiotherapy, applied to single lesions, such that a generalised anticancer effect is generated that enables patients to live longer.

The review noted that prostate cancer is a field of considerable M&A activity:

- Pfizer paid US$14 Billion in 2016 for Medivation Inc, acquiring Xtandi (enzalutamide), a US$2.2B p.a. treatment used in late-stage prostate cancer;
- Boston Scientific acquired Augmenix Inc in 2018 for US$500M for a product intended to protect the rectum from radiation damage during radiotherapy for early-stage prostate cancer.

The DARRT treatment regimen is being used in men following failure on androgen-ablation therapy with drugs such as enzalutamide, with the Medivation acquisition quantifying the need and value of providing even modest extension of life in late-stage prostate cancer. The Augmenix acquisition identifies the value of a therapy that spares radiation damage to healthy tissue, something that Veyonda® is intended to do through its use with low dosages of radiation.

The Company aims to progress its DARRT program in late-stage prostate cancer into a larger study, with planning underway. This work is expected to be conducted globally, including in the United States.

The review determined the importance of running both LuPIN and DARRT programs in parallel, because although the LuPIN program has the potential to reach a commercialisation stage before the DARRT program, the DARRT program offers considerably greater potential commercial value in its ability to be used in early-stage prostate cancer, along with its potential to be applied to a much broader range of cancer types than radiopharmaceuticals such as $^{177}$lutetium-PSMA provide.

**Expedited Time To Value Capture**

The review noted that bringing a drug through the clinical trialling and regulatory approval processes is a necessarily lengthy and very expensive exercise. For companies without revenue, that means that the further into that process a company proceeds, the more dilutionary it becomes for shareholders. The review considered the options in maximising return on shareholder funds and the risk:reward aspects.

The review concluded that the Company needed to continue to proceed with the development of Veyonda® on the basis of taking it through to filing for marketing approval. The review also concluded that in light of (i) the widely acknowledged need for a radio-enhancer in cancer therapy, (ii) the current climate of M&A activity in the oncology field and in prostate cancer in particular, and (iii) the pending release of LuPIN and DARRT data, that the Company should be prepared to receive and consider commercial offers as a way of maximising shareholder value.

**Executive Appointments**

Dr Graham Kelly moves to Group CEO, with overall responsibility for Noxopharm and its subsidiary, Nyrada Inc., ahead of anticipated growing interest in both companies in both the Australian and U.S. investment markets and the global pharmaceutical industry.

Dr Greg van Wyk, previously the chief medical officer of Noxopharm, assumes the CEO role in addition to CMO duties.

Dr Gisela Mautner MD PhD MPH MBA FACPE has been appointed Global Medical Director focusing on the global Veyonda® clinical trial program.

**U.S. Profile and Listing**

The goal is to raise the profile of the Company in the U.S. investment community on the back of the scheduled release of LuPIN-1 in June and DARRT-1 clinical data over the course of the next 6 months.

The Company also will consider a secondary listing on a U.S. securities exchange (**Potential Secondary Listing**) in H2, 2019 to facilitate the ability of U.S. investors to invest in the Company. Any Potential Secondary Listing would be a compliance listing and involve American Depositary Receipts.

Shareholders and potential investors should be aware that the implementation of any Potential Secondary Listing is subject to, amongst other things, the granting of the necessary approvals by the U.S. Securities and Exchange Commission (**SEC**) and the relevant U.S. securities exchange. There is no

assurance that approval or permission will be obtained from the SEC or the relevant U.S. securities exchange for any Potential Secondary Listing. Accordingly, any Potential Secondary Listing may or may not proceed. Shareholders and potential investors should exercise caution when dealing in Shares.

As at the date of this announcement, no Registration Statement has been lodged with the SEC. Further, no application has been made to a U.S. securities exchange in respect of any Potential Secondary Listing.

The Company will make further announcements as appropriate and necessary to keep shareholders updated on any material developments.

**About Veyonda®**

Veyonda® (previously known as NOX66) is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil. Idronoxil specifically inhibits the ability of a cancer cell to respond to stress such as that induced by radiation, leading to loss of pro-survival signaling via sphingosine-1-phosphate. Idronoxil also activates the body's innate immune system.

**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 Veyonda® as a dual-acting radio-enhancer and stimulator of innate immune cell function.


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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.