

Date: 5 March 2019

### Sydney, Australia

### ASX: NOX

#### Noxopharm Limited

ABN 50 608 966 123

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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

### **NEW CORPORATE PRESENTATION RELEASED**

**SYDNEY, 5 March 2019:** Noxopharm (NOX: ASX) today releases an updated corporate presentation ahead of non-deal roadshow presentations planned over the coming month in the U.S., Hong Kong and China. This is part of the Company's efforts to raise its profile in the global investment community ahead of planned release of key clinical data over the next 5 months.

#### 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 an flavonoid chemical structure, with Veyonda<sup>®</sup> the first pipeline product. Three other drug candidates for non-oncology indications are under development in a subsidiary company (Nyrada Inc).

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# We have a single objective: To make Veyonda<sup>®</sup> (a <u>radio-enhancing/immune-enhancing drug</u>)

a standard companion drug

- $\rightarrow\,$  for all forms of radiotherapy
- ightarrow across most forms of solid cancer

in order to deliver

- $\rightarrow$  more potent and more curative responses to radiotherapy
- $\rightarrow$  at lower, better tolerated dosages of radiotherapy

and in so doing

 $\rightarrow$  provide a transformative leap forward in the treatment of many cancers



# **Veyonda<sup>®</sup> - A New Improved Formulation of Idronoxil**

**Veyonda**<sup>®</sup> delivers a proprietary <u>pro-drug</u> form of idronoxil\* that delivers continuous anti-cancer activity for 12 hours

Veyonda<sup>®</sup> provides clinical benefit where earlier formulations did not

**Veyonda**<sup>®</sup> is a convenient-to-use, self-administered dosage form given twice daily to provide continuous 24-hour cover

\* Patents pending





### Examples of how a radio-enhancer might be used in prostate cancer



NOXOPHARM

## How radiotherapy works









# Veyonda<sup>®</sup> + Radiotherapy

### Potential use across broad range of radiotherapy practice



## Externally-delivered radiotherapy



## Internally-delivered radiopharmaceuticals



## Clinical Programs

DARRT Direct and Abscopal Response to Radio-Therapy

### LuPIN

<sup>177</sup>Lutetium-PSMA In Combination With VeyoNda

## Initial focus on late-stage prostate cancer

- Metastatic, castrate-resistant disease
- Post-docetaxel and abiraterone/enzalutamide
- No remaining standard treatment options
- Progressive disease
- Anticipated survival of > 3 months
- Patient eligible for palliative treatment



# DARRT

### Direct and Abscopal Response to Radio-Therapy

Rationale

1. Use of palliative (low) dose of radiation minimizes damage to innate immune cells within the irradiated lesion.

- 2. Veyonda<sup>®</sup> amplifies radiation-induced DNA damage in cancer cell by:
- blocking cell division, thereby exposing the DNA to greater damage, and
- blocking the ability of the cancer cell to repair that damage
- 3. Amplified radiation-induced DNA damage then:
- Increases likelihood of irradiated cancer cell dying
- Enhances response of local innate immune cells

### Objectives

Local effect. Greater shrinkage of the irradiated target lesion (DIRECT RESPONSE)

<u>Systemic effect</u>. An anti-cancer response in non-target, non-irradiated lesions stemming from enhanced innate immune and epigenetic responses in the irradiated lesion (ABSCOPAL RESPONSE)



# DARRT

### **Direct and Abscopal Response to Radio-Therapy**



**External Beam RT** or **Stereotactic Body RT** 

- Patients with multiple lesions and at least 2 measurable lesions
- Irradiate 1 lesion\* (20-25 Gy in 5 fractionated doses)
- > Veyonda<sup>®</sup> (600 mg bid) 10 days beginning Day -5
- Assessments at 6 , 12 and 24 weeks
  - PSA
  - Pain Score
  - **QoL** Score
  - Time to progression
  - RECIST\* (where possible)



\*Only patients in part 1 needed to have one measurable lesion as per RECIST v1.1

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# DARRT

### Direct and Abscopal Response to Radio-Therapy

### **DIRECT RESPONSE**

At a minimum, Veyonda<sup>®</sup> is expected to lead to better **DIRECT response** to radiotherapy by functioning as a **radio-enhancer** 



### **ABSCOPAL RESPONSE**

The best expected outcome would be an improved DIRECT response, plus shrinkage of non-targeted lesions



# DARRT-1 Study

### **Details:**

- Phase 1b multi-national study (Australia, NZ, Georgia)
- Open label, single-arm study
- 24 patients; metastatic, castrate-resistant prostate cancer
- Veyonda<sup>®</sup> + external beam RT to 1 lesion\*
- Part 1: Dose-finding (constant RT dose)
  - 400 mg Veyonda (4 patients)
  - 800 mg Veyonda (4 patients)\*\*
  - 1200 mg Veyonda (4 patients)\*\*\*
  - Part 2: 1200 mg Veyonda
    - 12 patients

\*Only patients in part 1 needed to have one measurable lesion

as per RECIST v1.1

\*\*2 patients were replaced





# DARRT-1 Study

## 12-week data for Part 1 patients:

	<u>400 mg</u> n=4	<u>800 mg</u> n=4	<u>1200mg</u> n=4 (3 evaluable)
PSA response*	0	2	2
Pain response**	2	3	2
RECIST response***	4 SD	1 PR 2 SD 1 PD	3SD
<ul> <li>* &gt; 50% decline</li> <li>** &gt; 30% decline</li> <li>*** aggregate of all measurable lesions</li> </ul>			
24-week data Part 1 patients – late Ma 12-week data Part 2 patients – July 201 24-week data Part 2 patients – Q1 202	L9 1		NOXOPHARM

# DARRT-1 Study

### Interim conclusions:

- Veyonda<sup>®</sup> + palliative dosages of radiotherapy well tolerated
- 400 mg dose of Veyonda<sup>®</sup> sub-therapeutic
- No notable difference between 800 and 1200 mg doses
- In the 7 evaluable patients in the 800 and 1200 mg cohorts\*
  - 4/7 achieved PSA falls >50%
  - 5/7 achieved decrease in pain levels >30%
  - 1/7 showed partial response (RECIST) and 5/7 showed stable disease

The significant reductions in PSA, pain levels and halt in tumour growth suggests potential off-target responses at 3 months in men with advanced mCRPC.



LuPIN

### <sup>177</sup>Lutetium-PSMA-617 In Combination With VeyoNda



Aim of <sup>177</sup>lutetium-PSMA-617 therapy is to deliver a low dose of radiation to all cancer cells within the body



LuPIN

### <sup>177</sup>Lutetium-PSMA-617 In Combination With VeyoNda

### Rationale

1. Use of radiopharmaceutical maximises interaction between **Veyonda**<sup>®</sup> and radiation in the broad spread of cancer cells throughout the body.

- 2. Veyonda<sup>®</sup> amplifies radiation-induced DNA damage in cancer cell by:
- blocking cell division, thereby exposing the DNA to greater damage, and
- blocking the ability of the cancer cell to repair that damage
- 3. Amplified radiation-induced DNA damage then:
- Increases likelihood of irradiated cancer cell dying
- Enhances response of local innate immune cells

### Objectives

- 1. To achieve higher response rates, with more patients able to complete the 6-course Lu-PSMA treatment without relapsing
- 2. To achieve greater depth of response as measured by PSA levels
- 3. To achieve more durable responses as measured by improved time to progression and overall survival.





# LuPIN-1 Study

- Phase 1/2 study; investigator-initiated; Australia
- > Open label, single arm
- PSMA-positive, late-stage mCRPC patients
- 6 courses of <sup>177</sup> lutetium-PSMA-617 administered intravenously every 6 weeks
- Veyonda<sup>®</sup> administered for 10 days starting Day-2 each course
- > 8 patients 400 mg Veyonda<sup>®</sup>; 24 patients 800 mg Veyonda<sup>®</sup>
- > 30/32 patients enrolled 1 March 2019\*

\*Clinical data from first 8 patients (400 mg dose cohort) to be presented at SNMMI Conference, Anaheim, June 2019.





# **External radiotherapy in cancer (all forms) treatment\***

	Africa	Asia Pacific	Europe	Latin America	North America	
Population	1070	4108	893	601	350	
No. radiation centres	140	2590	1430	620	2790	
No. radiotherapy courses	0.4M	3.3M	1.9M	0.6M	0.9M	
Cost per course (US\$)	1,300	2,120	3,490	2,080	7,050	
RADIO-ENHANCER OPPORTUNITYTotal 7.1 M courses of radiotherapy = U\$\$70 billion (U\$\$10K per course)						
* Zubizaretta E et al. C	linical Oncology	(2017) 29, 84-92	22 2019 Noxopharm		NOXOPH	ARM

# **Key metrics**

Number of Shares	<b>121.9M</b> : Free float 66.8%
Market Cap (1 March 2019)	AU\$53M
IPO price	20 cents
12 month high/low	\$1.64/0.36
Cash position	AU\$ 9.6M (31 Dec 2018)





