

Date: 29th January 2020 Sydney, Australia

#### **Noxopharm Non-Deal Roadshow Presentation**

**Sydney, 29**<sup>th</sup> **January 2020:** Noxopharm (ASX: NOX) is pleased to provide shareholders and the market the attached Noxopharm corporate presentation "Non-Deal Roadshow Presentation".

This document is being used by Noxopharm for presentation during a non-deal roadshow by the company in Melbourne and Sydney on the 29<sup>th</sup> and 30<sup>th</sup> January 2020.

The presentation can be found at www.noxopharm.com

#### **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 Nyrada Inc.

www.noxopharm.com

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Graham Kelly, CEO and Chairman of Noxopharm has approved the release of this document to the market.

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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,



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## **Noxopharm Limited**

**Veyonda**®

**Non-Deal Roadshow Presentation** 



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#### **Non-Deal Roadshow Presentation**



1

Dr Gisela Mautner Medical Overview



2

Mr Alex Hunter Corporate Overview



Noxopharm is seeking to bring Veyonda® to market as a first-in-class drug that combines with radiotherapy to provide a potent anti-cancer effect in prostate cancer



# Dr Gisela Mautner MD-PHD, MPH, MBA Medical Overview

Drug development process

Prostate cancer

Veyonda<sup>®</sup>

**DARRT** 

LuPIN

Veyonda® market potential

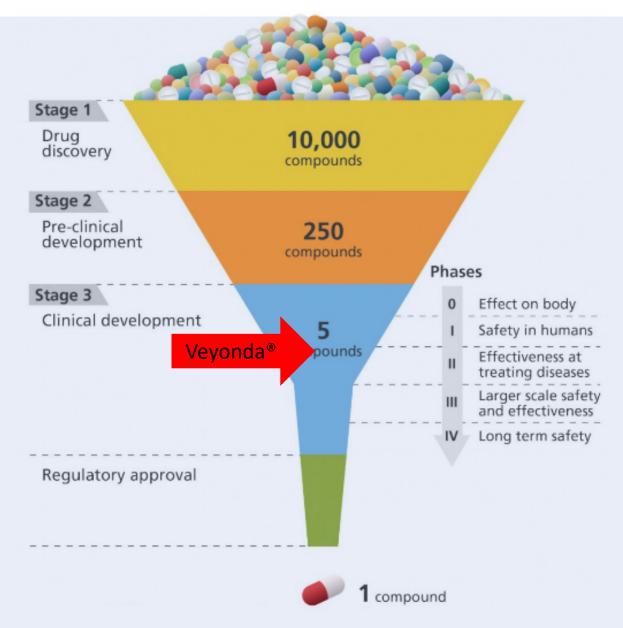
Indicative clinical program timing



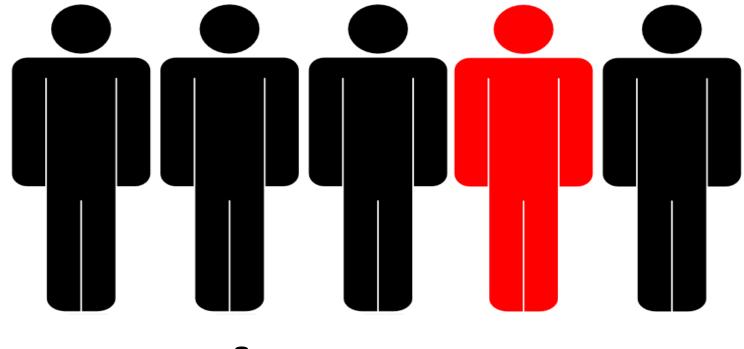


### **Drug Development Process**









# 1 in 5 men

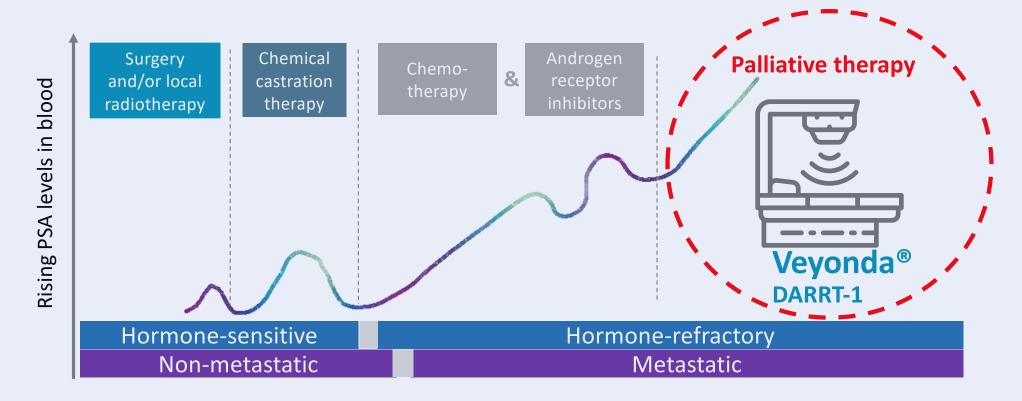
develop prostate cancer before they turn 85



### **Prostate Cancer and Treatment Options**



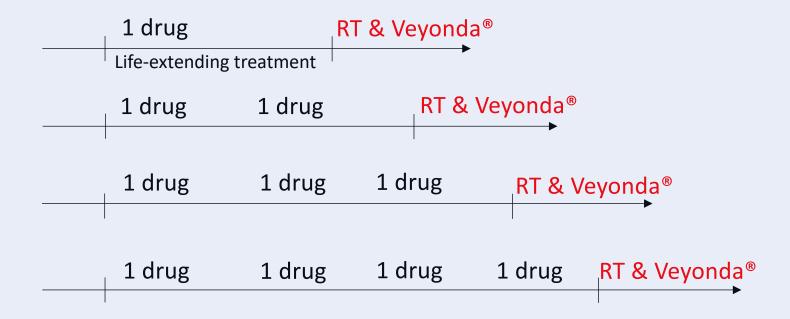
#### **Course of Disease and Treatment Journey for Stage I - IV Prostate Cancer**





### **Veyonda® Acts in a Unique Space**





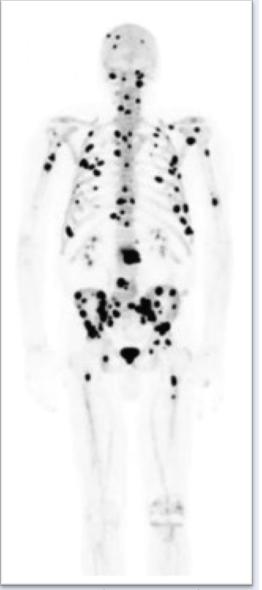
Irrespective of how many new drugs are coming to market, they will generally not affect Veyonda's space



### Veyonda® – Clinical Study DARRT-1



- 26 men enrolled with late-stage prostate cancer
- Metastatic castration-resistant prostate cancer (mCRPC)
- Progressive disease
- No remaining standard treatment options
- Eligible for palliative RT for symptomatic relief
- Treatment with low-dose RT (20Gy in 5 fractions) and 14 days of NOX66 (400, 800, 1200 mg)







### **DARRT-1: Safety and Tolerability**



- Primary end-point of acceptable safety and tolerability was met
- Treatment well tolerated with no serious side-effects due to Veyonda®
- No dose-limiting toxicities

✓ Veyonda® in combination with radiation therapy was reported to be safe and well-tolerated¹



### **DARRT-1: Efficacy – Tumour Response**



In the 15\* patients who were evaluable at 6 months¹

# The Tumours stopped growing or reduced in size in 10 patients

(1 patient achieved a partial response and 9 achieved stable disease at 6

months)

	First part	Expansion part	Overall		
6-months follow up	400mg, 800mg &	1200mg	All doses		
	1200mg				
	(Reported on 12		(Reported on 2		
	November 2019)		December 2019)		
Overall (RECIST1.1)	N=10	N=5	N=15		
Complete response	0	0	0		
Partial response	1	0	1		
	(10%)		(7%)		
Stable disease	7	2	9		
	(70%)	(40%)	(60%)		
Progressive disease	2	3	5		
	(20%)	(60%)	(33%)		

<sup>\* 10</sup> patients lost to follow-up, were not measurable, withdrew from study or died (unrelated to treatment)



1. Noxopharm. Data on file.

#### **DARRT-2** – In Planning



- Building on the experience and data of DAART-1
- Phase 2 trial
- Multinational
- Min. 60 patients
- Same patient population as in DARRT-1
- Radiation therapy plus repeated cycles of Veyonda®
- Medical Advisory Boards established
- Protocol synopsis being drafted
- Anticipated regulatory submissions late-2020
- Study expected to commence in early-2021
  - **✓** We are developing the most efficient and impactful study possible!



#### **Additional Opportunity in Prostate Cancer**



#### **External Radiation**

- > Standard-of-Care
- Widely used





#### **Internal Radiation**

- Experimental
- Billion-dollar Acquisition by Novartis







## **LuPIN – Comparative Results**



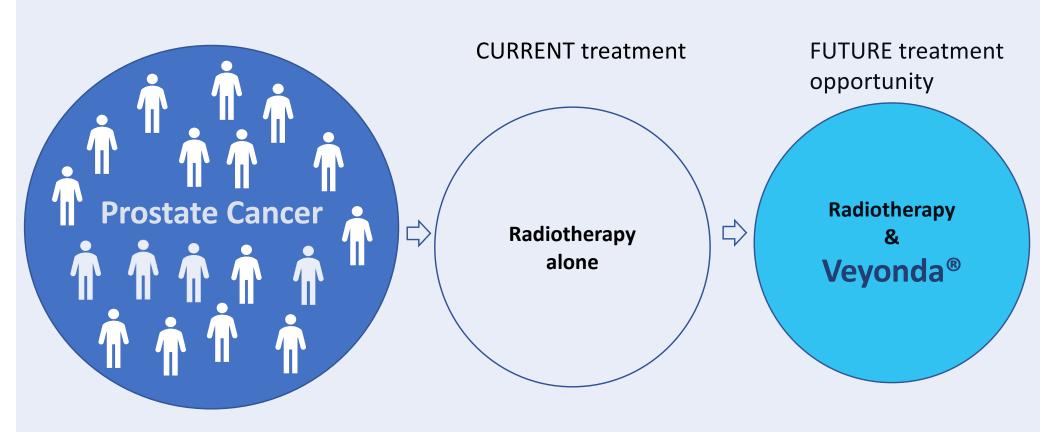
- Progression-free survival (PFS) is a measure of the time from the start of treatment until the disease progresses.
- ✓ Median PFS **quadrupled** through the addition of Veyonda® (8.4 months vs 2.0 months with ¹<sup>77</sup>Lu-PSMA alone)
- Treatment duration
- ✓ The addition of Veyonda® meant that the number of men able to start the 4th treatment cycle **tripled** to 69% from 21% with <sup>177</sup>Lu-PSMA alone
- ✓ The combination therapy also was well tolerated, pointing to Veyonda® being safe to use in combination with intravenous radiotherapy

In summary, combination therapy of Veyonda® and <sup>177</sup>Lu-PSMA-617 shows benefits to patients well above that achieved with <sup>177</sup>Lu-PSMA-617 therapy alone and underscores the Company's confidence in Veyonda® eventually becoming a standard drug in the management of prostate cancer



#### **Market Potential – Prostate Cancer**

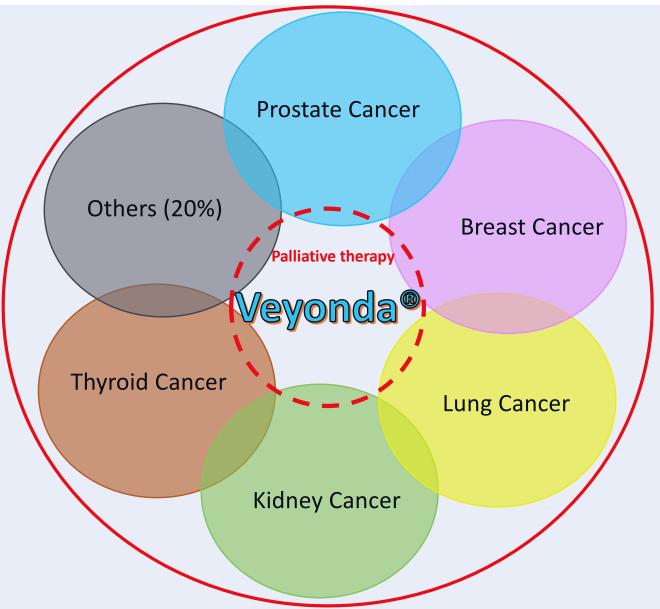






### **Market Opportunities – RT plus Veyonda®**







## **Indicative Clinical Program Timing**



DARRT -1 complete, final statistical results due March 2020

DARRT-2 protocol development under way

DARRT-2 clinical trial indicative commencement early 2021

Indicative Clinical Program Timing		DecQ2019	MarQ2020	JunQ2020	SepQ2020	DecQ2020	MarQ2021	JunQ2021	SepQ2021	DecQ2021	
DARRT-1											
Phase 1 clinical trial complete Phase 1 statistical report	Dec Q 2019 Mar Q 2020	•	<b>♦</b>								
DARRT-2											
Protocol Development/CRO appoin't  •Medical advisory board consultation •Appoint CRO	now- Sep Q 2020										
Commence trial (indicative)	Early 2021						<b>•</b>				
DARRT-2 trial under way (indicative)	2021 onwards										
LuPIN											
Trials complete	Dec Q 2020					•					
Commercial partnerships	2020 & 2021										



# Mr Alex Hunter MBA, BE, GradDipCorpSecFinLaw, GradDipAppFin Corporate Overview

**Executive Summary** 

**Company Details** 

**Market Opportunity** 

Nyrada Inc.

**Investment Highlights** 





### **Executive Summary**



- Australian biotech company listed on Australian Securities Exchange (ASX:NOX)
- Oncology focus
- Proprietary drug Veyonda® well advanced in clinical development phase
- First-in-class inhibitor of sphingosine-1-phosphate
- Intended as adjunct to radiotherapy
- 2 active clinical trials studying improved efficacy of radiotherapy in late-stage mCRPC:
  - (Phase 1b) DARRT, Veyonda® + external beam radiotherapy
  - (Phase 2a) LuPIN, Veyonda® + <sup>177</sup>Lu-PSMA-617
  - Strong clinical signals achieved in both trials
- Preparing for Phase 2 DARRT clinical trial
- Unique dual market opportunity for Veyonda® in late-stage prostate cancer space
- ~30% equity in Nyrada Inc., a promising listed subsidiary focused on novel small molecule drugs (ASX:NYR)
- Experienced board and management team, strong technical & commercial experience

Noxopharm believes that its DARRT and LuPIN treatments will become standard of care for late-stage prostate cancer, offering patients and doctors two new treatment options

## **Company Details**



#### Noxopharm Limited (Jan 2020)

Listed on Australian Securities Exchange (ASX:NOX) Aug 2016

Shares on issue 132m

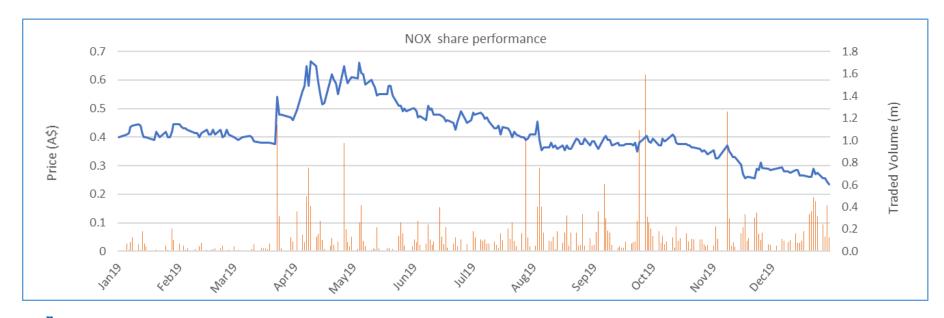
Share Price A\$0.23.5-A\$0.29

Market Cap A\$31-38m

Cash A\$1.7m

Convertible notes A\$4.7m

Board and Key Management	
Dr Graham Kelly. <i>PhD</i>	Chairman & CEO
lan Dixon. <i>PhD, MBA</i>	Non-Executive Director
Peter Marks. MBA, BEc, LLB	Non-Executive Director
Dr Gisela Mautner. MD-PHD, MPH, MBA	Chief Medical Officer
Alex Hunter. MBA, BE	Chief Commercial Officer
Greg Ambra. <i>MS</i>	SVP North American Ops
Dr John Wilkinson. <i>PhD</i>	Chief Scientific Officer
Shawn Van Boheemen. BBus MCom	Chief Financial Officer





### **Market Opportunity**



Noxopharm believes Veyonda® has potential use in most forms of solid cancer

Noxopharm believes the fastest, lowest risk path to market for Veyonda® is as a treatment for **mCRPC** 

mCRPC currently is treated palliatively. Noxopharm is intended to go beyond palliation and provide a meaningful, durable and well tolerated anti-cancer effect

2019 Prostate Cancer	Australia	USA
New cases of Prostate Cancer diagnosed	19,500	175,000
Deaths from Prostate Cancer	3,300	31,600

#### **Market Opportunity**

- Noxopharm believes Veyonda® has potential applications in most forms of solid cancer as both a radio-enhancer and chemo-enhancer
- Noxopharm has selected radio-enhancement (DARRT regimen) in metastatic prostate cancer (mCRPC) as the path to first market approval:
  - o DARRT-1 has shown that Veyonda® provides a meaningful anti-cancer effect including cessation of tumour growth in about half of mCRPC patients, and considerable (average 80%) pain relief
  - o Management of mCRPC is a major unmet need, with palliative treatment the current standard of care
  - o The need is predicted to grow with increasing longevity and a growing global middle class
  - Ease of enrolment due to high disease incidence and 12-months end-points (limited life expectancy of typically 6-9 months) suggests relatively short trial duration
  - o Potential high demand and low drug costs could result in blockbuster revenue
- A number of recent multi-billion dollar deals in the mCRPC space (see table below)

Recent acquisitions	Buyer	Seller	Price range
XTANDI® mCRPC (2016)	Pfizer	MEDIVATION	US\$14 billion
<sup>177</sup> Lu-PSMA-617 mCRPC (2018)	U NOVARTIS	ENDOCYTE	US\$2.1 billion
<sup>177</sup> Lu-PSMA-617 & others mCRPC (2018)	U NOVARTIS	A d v a n c e d Accelerator Applications	US\$3.9 billion



## Nyrada Inc. (ASX:NYR)





Noxopharm's
shareholding in
Nyrada has a market
value of \$10-14m
based on Nyrada's
recent trading range

#### **NYRADA**

- Nyrada is a pre-clinical stage, drug company specialising in the development of novel small molecule drugs pertaining to the underlying pathological processes involved in cardiovascular, neurodegenerative and chronic inflammatory diseases
- Nyrada listed on the ASX on 16<sup>th</sup> January 2020
- The Company's vision is to become a high growth pharmaceutical company specialising in drug discovery where few if any, effective or well-tolerated therapies exist
- The Company has four current drug development programs:
  - Cardiovascular: A PCSK9 inhibitor for the treatment of high blood LDL-cholesterol levels in patients poorly responsive to, or unable to take statin drugs
  - Neuroprotection: A neuroprotectant drug to improve patient outcomes and prevent long-term disability in patients with ischaemic stroke and traumatic brain injury
  - o Inflammation/pain: A drug to treat pain associated with peripheral nerve damage (such as sciatica), and
  - o Inflammation/autoimmunity: A drug to treat autoimmune diseases such as psoriasis

Nyrada Share price trading range	Noxohparm shareholding*	Implied market value NOX shareholding		
\$0.215	AE 272 0AE	\$9.8m		
\$0.305	45,373,845	\$13.8m		
* Includes 33.4m CDI's and 12m performance shares				

Board and Key Management					
John Moore	Non-executive Chairman				
Dr Graham Kelly PhD	Founder, Non-exec Director				
Peter Marks	Non-executive Director				
Marcus Frampton	Non-executive Director				
Rudiger Weseloh PhD	Non-executive Director				
Christopher Cox	Non-executive Director				
James Bonnar	Chief Executive Officer				
Benny Evison PhD	Chief Scientific Officer				



### **Investment Highlights**



#### Noxopharm Investment Highlights

- Significant clinical milestones over next 12 months from DARRT and LuPIN trials
- Potential standard of care: Noxopharm believes that its DARRT and LuPIN treatments have the potential to become standard of
  care for late-stage prostate cancer where treatment currently is palliative
- Potential dominant position: Company in unique position of having two potential treatments for late-stage mCRPC, providing a likely dominant position in a critical sector
- **DARRT marketing approval**: With planning now in progress for DARRT-2 pivotal trial, Company within reach of Veyonda® generating significant revenue
- **LuPIN treatment**: Current LuPIN clinical trial suggesting that Veyonda® is at least doubling the anti-cancer activity of <sup>177</sup>Lu-PSMA-617, a drug candidate the subject of a US\$6 billion series of acquisitions in 2018
- **Broader market opportunity**: Approval of Veyonda® for mCRPC cancers (DARRT & LuPIN), including early-stage prostate cancer, likely to substantially increase the commercial value of the Company
- Equity in Nyrada provides additional corporate value \$10-15m

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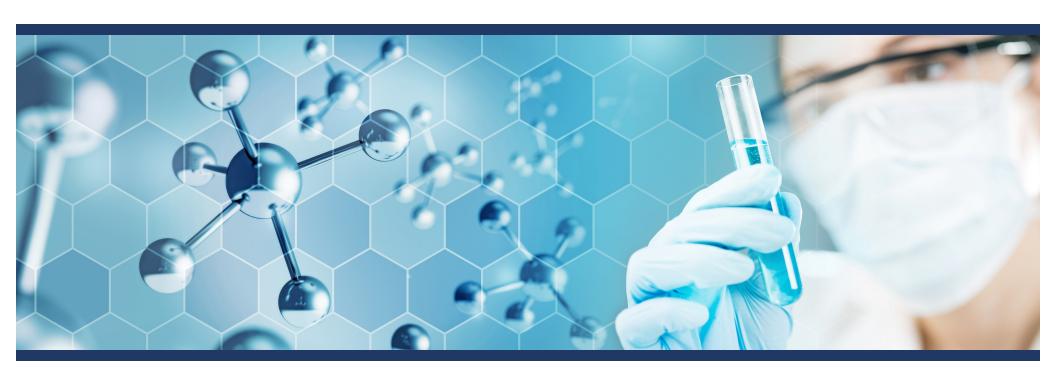
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For further information please visit www.noxopharm.com

**Veyonda**<sup>®</sup>

