



**Date: 20 November 2019**

**Sydney, Australia**

ASX Limited  
20 Bridge Street  
SYDNEY NSW 2000

## **Noxopharm 2019 Annual General Meeting Corporate Presentations**

**Sydney, 20 November 2019:** Noxopharm (ASX: NOX) is pleased to provide shareholders and the market generally the corporate presentations for today's Annual General Meeting (AGM).

Following voting formalities, three presentations will be given;

- Executive Chairman and CEO, Dr Graham Kelly, will provide a general overview of the year ahead;
- Dr Gisela Mautner, the Chief Medical Officer, will provide an update on the clinical strategy and program; and
- Mr Alex Hunter, the Chief Commercial Officer, will give an update on the business, commercialisation and funding strategies.

The Noxopharm 2019 AGM will take place at 2pm today, Wednesday 20 November, at the following location:

Warrane Theatre, Museum of Sydney  
Corner Bridge and Phillip Streets  
SYDNEY. NSW

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**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](http://www.noxopharm.com)

**Investor & Corporate Enquiries:**

Prue Kelly  
M: 0459 022 445  
E: [info@noxopharm.com](mailto:info@noxopharm.com)

**Company Secretary:**

David Franks  
T: +61 2 9299 9690  
E: [David.Franks@automicgroup.com.au](mailto:David.Franks@automicgroup.com.au)



**Media Contact USA:**

Frank de Maria

Purposeful Communications

T: +1 347 647 0284

E: [frank.demaria@purposefulcommunications.com](mailto:frank.demaria@purposefulcommunications.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.

20 November 2019

# Noxopharm Limited

AGM Presentation



ASX: NOX



DISCOVER



DEVELOP



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## AGENDA

### 1. What we see as our future

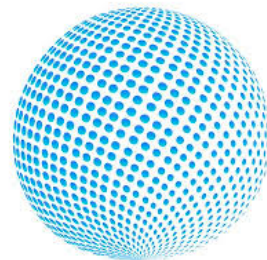
*Graham Kelly CEO/Exec Chairman*

### 2. Turning Veyonda<sup>®</sup> into a reality

*Gisela Mautner CMO*

### 3. How we intend to pay for the reality

*Alex Hunter CCO*



# Corporate Overview

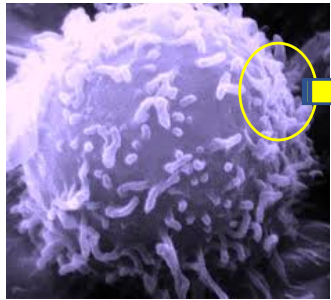
# *Veyonda*<sup>®</sup> (idronoxil)

## A sphingosine-1-phosphate inhibitor

- ❖ First in class
- ❖ Selective for cancer cells

... that we see having the potential to become a commonly-used anti-cancer drug within a few years

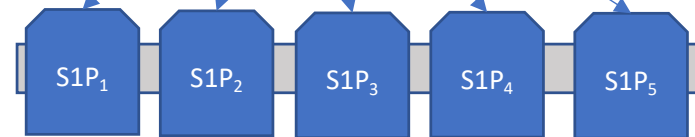
# sphingosine-1-phosphate (S1P) story



S1P is a vital **pro-survival** factor produced in the cell membrane of all cells



S1P exits cell in order to activate 5x S1P receptors on external cell surface



Promote:

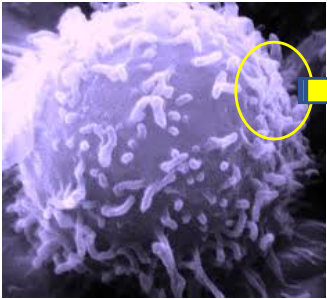
- cell survival
- cell growth
- cell migration
- cell differentiation



Normal tissue immune function

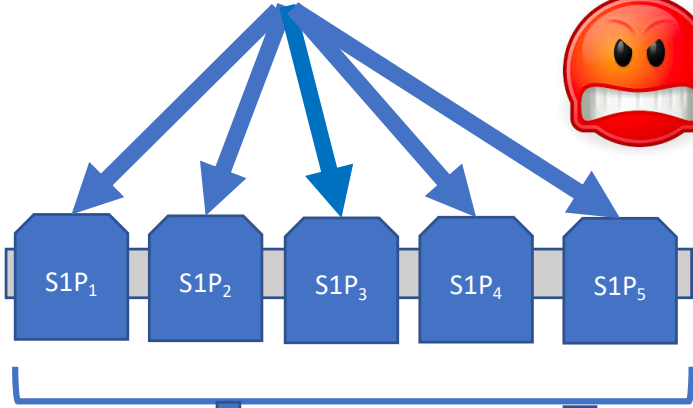


# S1P – major driver of cancer cell misbehaviour



S1P is over-expressed by most cancer cells

All five S1P receptors over-activated



**Cancer**

- Increased growth
- Increased migration

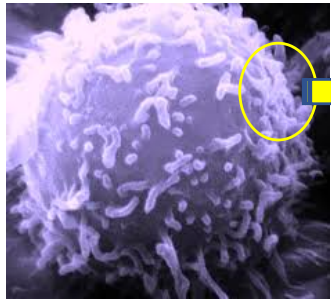
**Cancer**

- Resistance to chemotherapy
- Resistance to radiotherapy

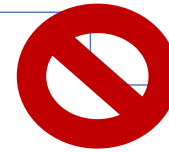
**Cancer**

- Reduced immune function within tumour

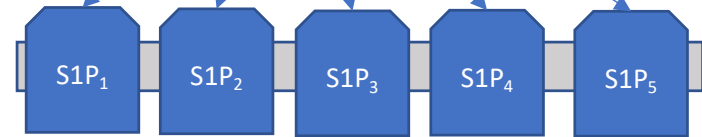
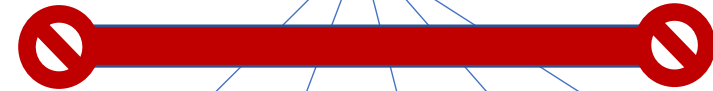
# Idronoxil blocks S1P production in cancer cells



S1P is over-expressed by most cancer cells



All five S1P receptors over-activated



**Cancer**

- less growth
- Less migration

**Cancer**

- Less resistant to chemotherapy
- Less resistant to radiotherapy

**Cancer**

- Increased immune function in tumour

# ***Veyonda*<sup>®</sup> first-in-class S1P inhibitor**

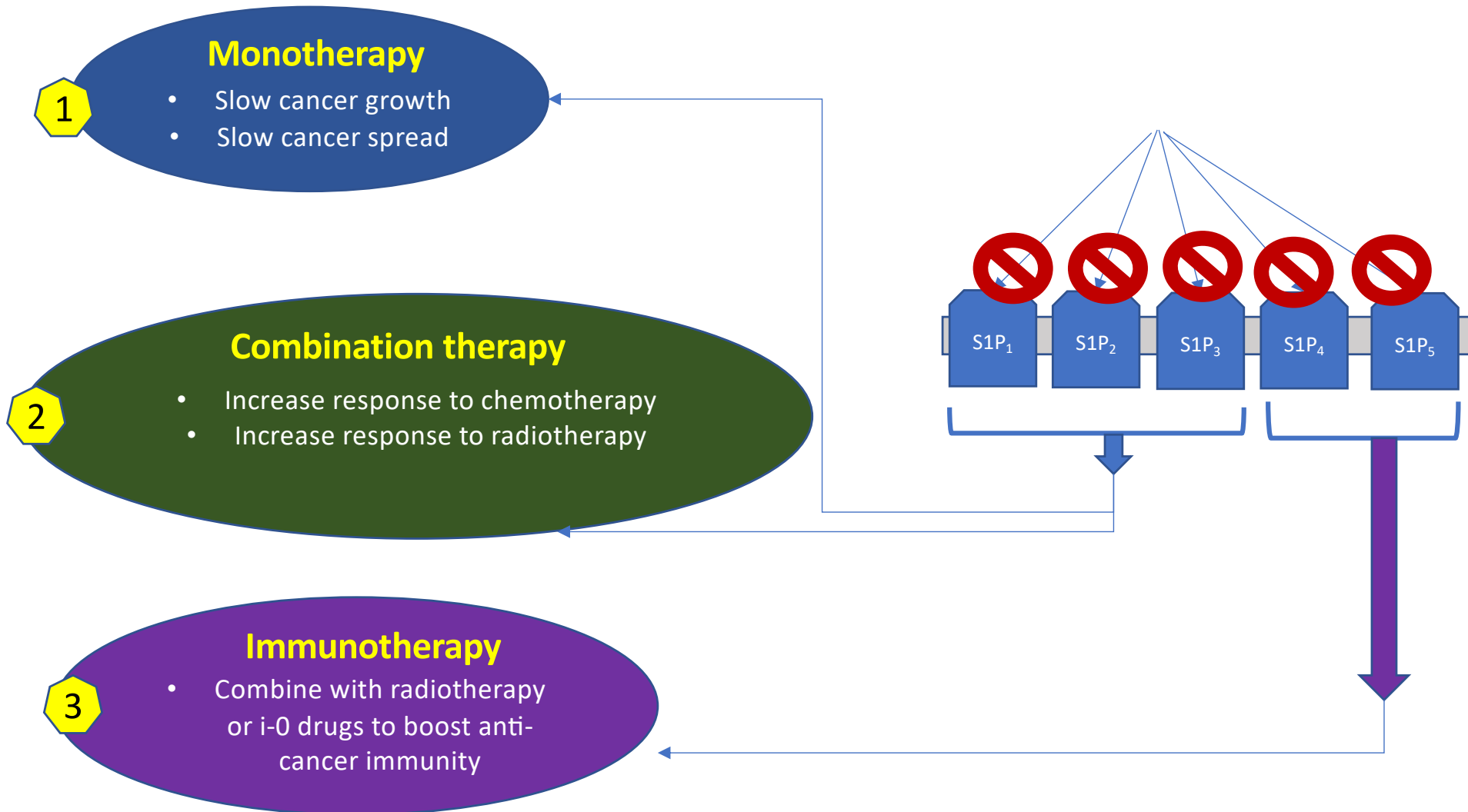
**Distinct from any other S1P inhibitor in that inhibitory effect is on an oncogene upstream of S1P**

**Only inhibits S1P in cancer cells and some high turn-over cells**

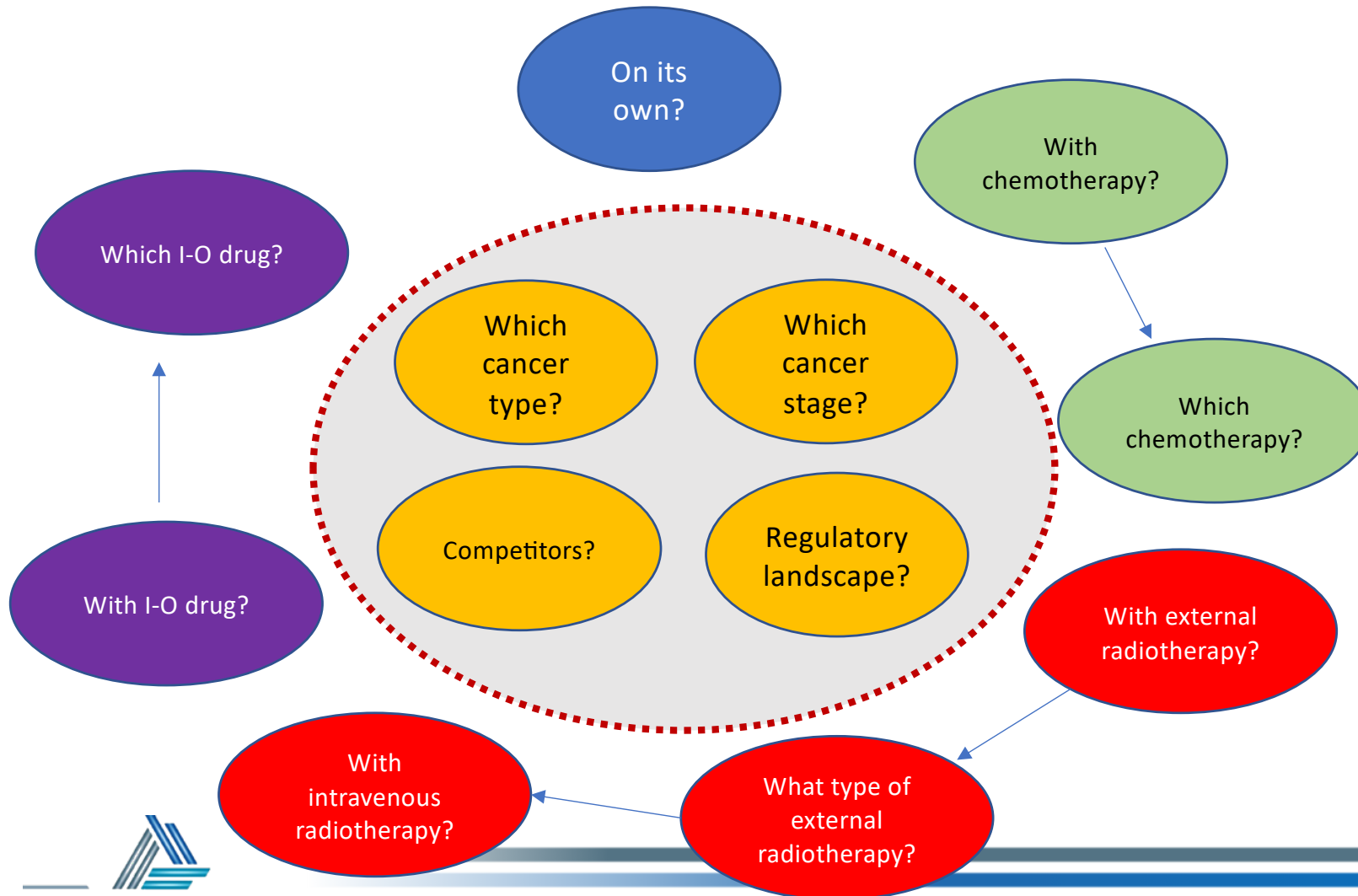


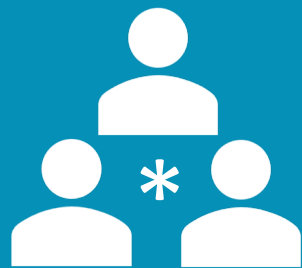
**Well-tolerated S1P inhibitor**

# Providing *Veyonda*<sup>®</sup> with 3 potential methods of use



# With multiple options for use, Years 1-3 have been about determining most assured path to market for *Veyonda*<sup>®</sup>



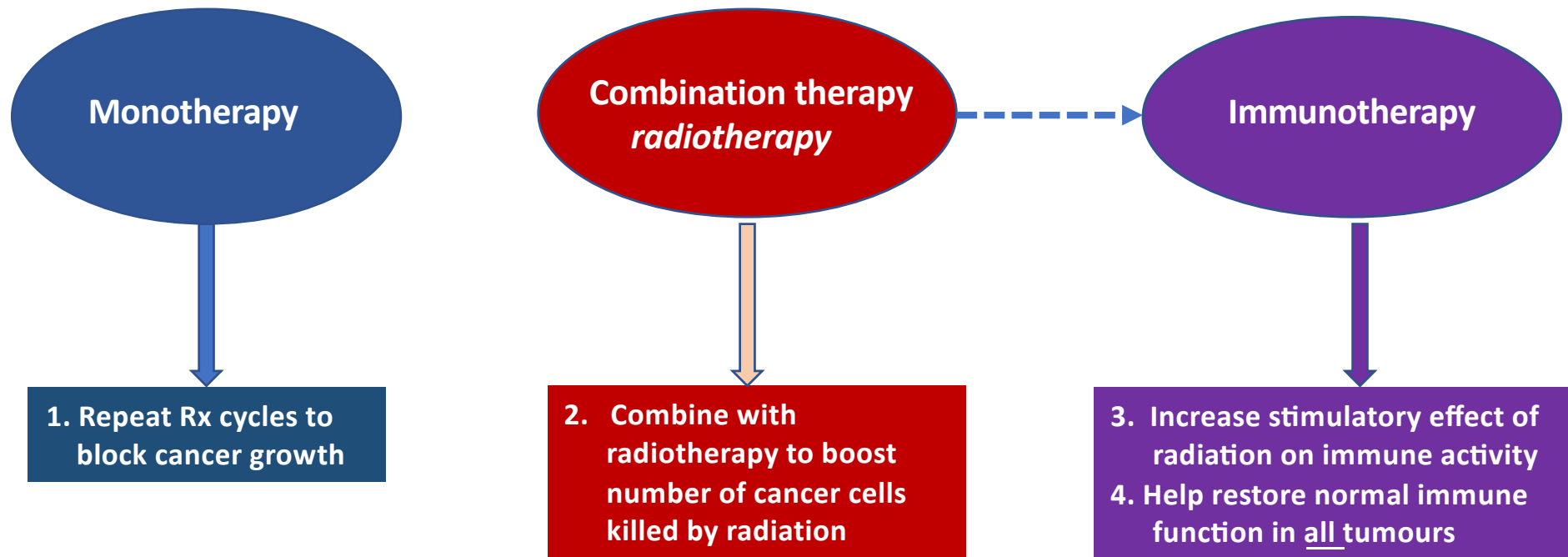


# Clinical Development Program

YEAR 4 .....

**Veyonda<sup>®</sup> path to market now set**

## DARRT and mCRPC



Unique 4-way anti-cancer actions

## Selection of DARRT based on .....

- Positive clinical signals in DARRT-1
- Absence of disease progression at 6-months in >50% of men suggestive of ability to achieve OS outcome
- No safety issues observed
- Advice of Company's U.S. Prostate Cancer Med Advisory Board
- Large unmet need
- Opportunity to apply for FDA expedited review
- Opportunity for Phase 2 adaptive design
- Only 1 known competitive technology - *PSMA + radionuclide*



# Veyonda<sup>®</sup> - Clinical Program



## Clinical development priorities

<u>Priority</u>	<u>Indication</u>	<u>Objective</u>
1 <sup>o</sup> DARRT-2	Late-stage mCRPC	Path to NDA
2 <sup>o</sup> LuPIN	Late-stage mCRPC	Potential strategic alliance
3 <sup>o</sup> CEP-2	Soft tissue sarcomas + DOX	Orphan drug grant
4 <sup>o</sup> IONIC-1	NSCLC non-responding to i-o drugs	Potential strategic alliance

# Veyonda<sup>®</sup> - Clinical Program

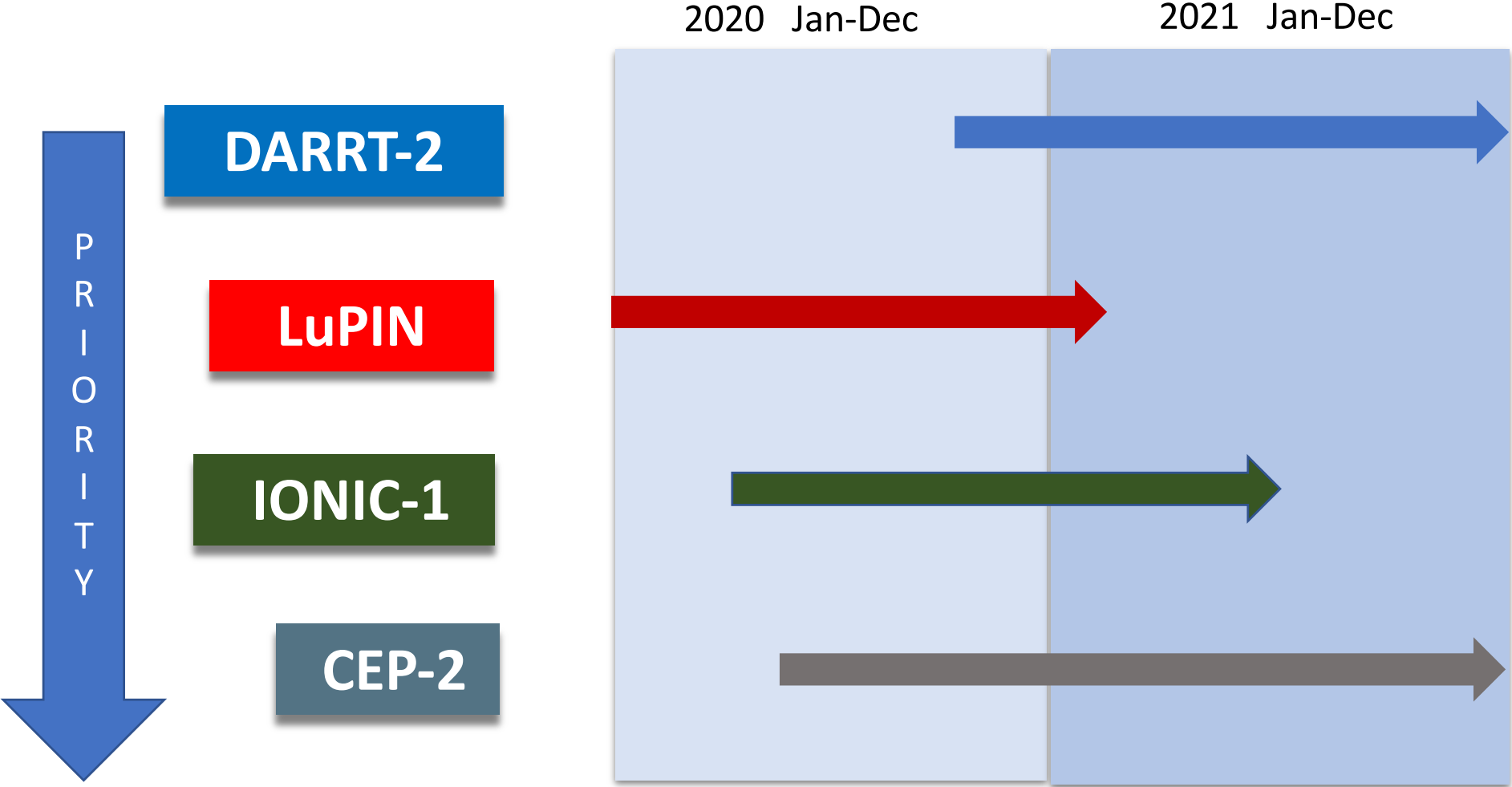


## 2<sup>o</sup> LuPIN

- 56-man Phase study  
*St Vincent's Hospital, Sydney - Garvan Inst of Med Res - Kinghorn Cancer Centre*
- NOX66 + <sup>177</sup>Lu-PSMA -617
- Full recruitment expected end-2019
- Final read-out Q1 2021
  
- Compassionate use scheme
- Providing valuable signals on response to NOX66 + <sup>177</sup>Lu-PSMA in men who fail to respond to <sup>177</sup>Lu-PSMA alone

# Clinical timetable

# 2020-2021





# Drug Pipeline Program



# Pipeline Program

Build Company value

## Indication

Glutamate receptor  
inhibitor

Glioblastoma multiforme

NOX66

Nasopharyngeal cancer

Cancer stem cell  
cytotoxic

Various cancers

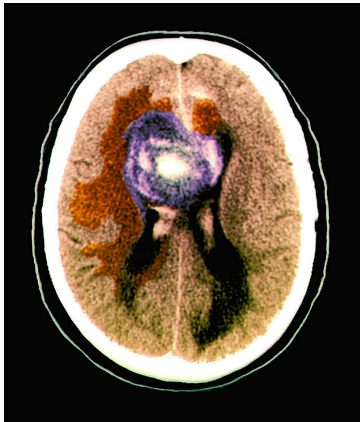
IRAK4 inhibitor

Various cancers

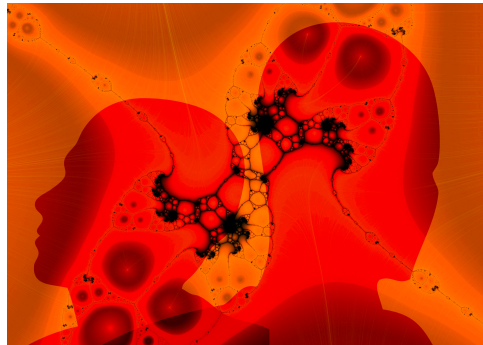
# Pipeline Program



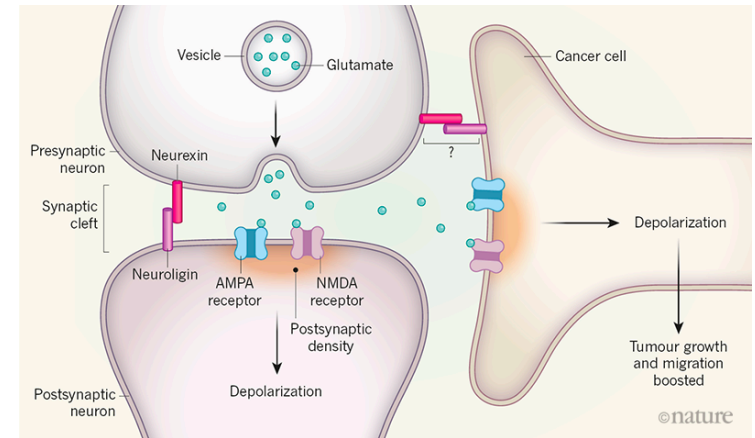
## Glutamate receptor inhibitor



GBM does not grow in the brain in isolation



GBM cancer cells form connections with neurons



Glutamate neurotransmitter drives growth of GBM cells

Aim is to be first glutamate-inhibitor in the clinic for GBM

In-licence existing glutamate receptor-inhibitor for oncology

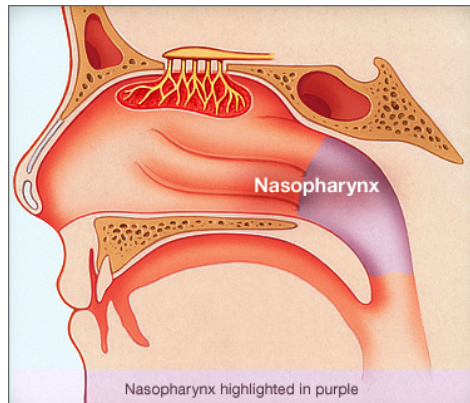
Developing world-first selective glutamate-inhibitor for stroke/TBI

Nyrada inc

# Pipeline Program



## NOX66 for nasopharyngeal cancer



Cancer upper throat/back of nasal cavity



High incidence in ethnic Chinese in southern China and SE Asia

- Incidence 25x rest of world
- Responsible for 18% of cancers in Southern China
- Associated with EBV infection



## NOX66 for nasopharyngeal cancer

- Collaboration with Hong Kong University (NPC KOL)
- Recently awarded \$50,000 bridging grant from Australian Academy of Technology and Science
- Idronoxil highly active against NPC cells *in vitro*. New study to determine role of NOX66 in restoring immune function within NPC tumours
- Strategy: collaboration to support future clinical study/strategic partnership in China





## Commercial and Financial Perspective

Alex Hunter, Chief Commercial Officer

# Commercial & financial perspective



My key focus as Chief Commercial Officer is to work with Noxopharm's highly experienced scientific and management team to:

*Finesse commercial structure and business systems*

- ensure Noxopharm has the necessary commercial structure and business systems in place to support our growth;

*Secure funding*

- secure necessary funding;

*Build critical US relationships*

- build suitable banking and commercial relationships;

*Drive implementation*

- drive implementation of our clinical development plan; and
- pursue and implement other commercialization pathways

I will draw on my extensive corporate finance, business management and US business experience in fulfilling this role.

# Next nine months



## Next nine months critical focus:

*Business readiness  
for clinical plan  
implementation*

- Work with NOX management team to prepare business for optimal implementation of clinical development plan

*Profile raising  
Australia & US*

- Undertake investor roadshows in Australia & USA to raise profile of Noxopharm and DARRT 2

*Build US  
relationships*

- Build banking relationships ahead of intended US IPO
- Build US clinical & commercial relationships

*Research coverage*

- Secure research coverage of Noxopharm

*Secure DARRT 2  
funding*

- Secure funding for DARRT 2 potentially via US IPO

# Beyond nine months



## **Beyond nine months** critical focus:

*Finalise DARRT 2  
clinical plan*

- Finalise DARRT 2 clinical plan in preparation for submission of applications

*Enter commercial  
agreements &  
contacts*

- Enter multitude of commercial agreements required to implement DARRT 2

*Submit DARRT 2  
applications*

- DARRT 2 application submission (IND/FDA and/or other jurisdictions)

*Commence DARRT  
2 clinical trials*

- Commence DARRT 2 clinical trials

*Pursue other  
commercialisation  
& pre-clinical  
opportunities*

- Provide ongoing business and financial support for Noxopharm's broad pipeline of commercialisation, clinical and pre-clinical opportunities

20 November 2019

# Noxopharm Limited

AGM Presentation



ASX: NOX



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# Noxopharm AGM, 20 November 2019 in Sydney

[www.noxopharm.com](http://www.noxopharm.com)

**Veyonda<sup>®</sup>**



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Did you know?



**EACH DAY**

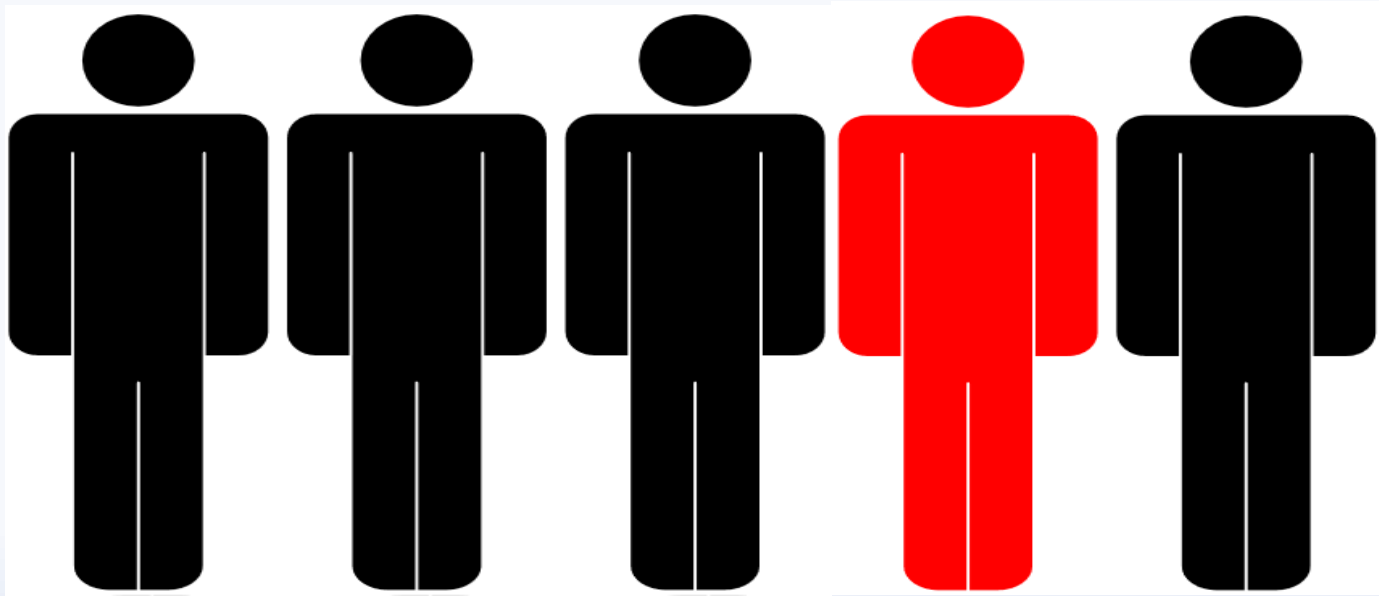
in Australia

**50 MEN**

are diagnosed with

**PROSTATE CANCER**

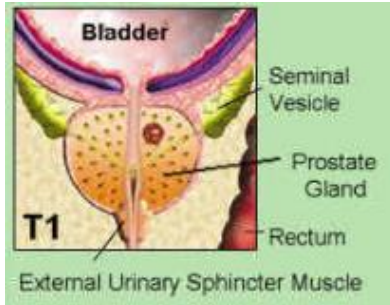




**1 in 5 men**

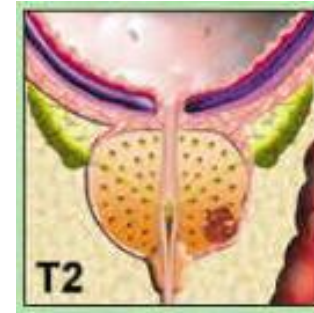
**develop prostate cancer  
before they turn 85**

# Prostate Cancer – four main stages



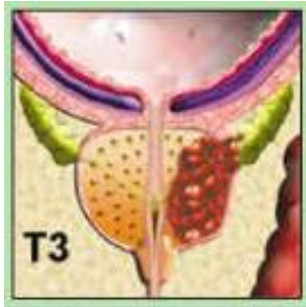
## Stage I

The cancer is small and confined to the prostate.



## Stage II

The cancer is still confined to the prostate but is large enough to be detected by physical examination.



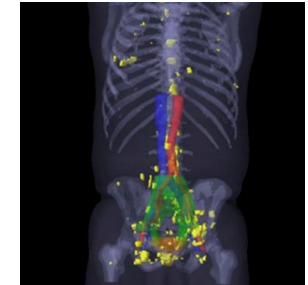
## Stage III

The cancer has spread beyond the prostate into the pelvis (bladder, rectum, lymph nodes).

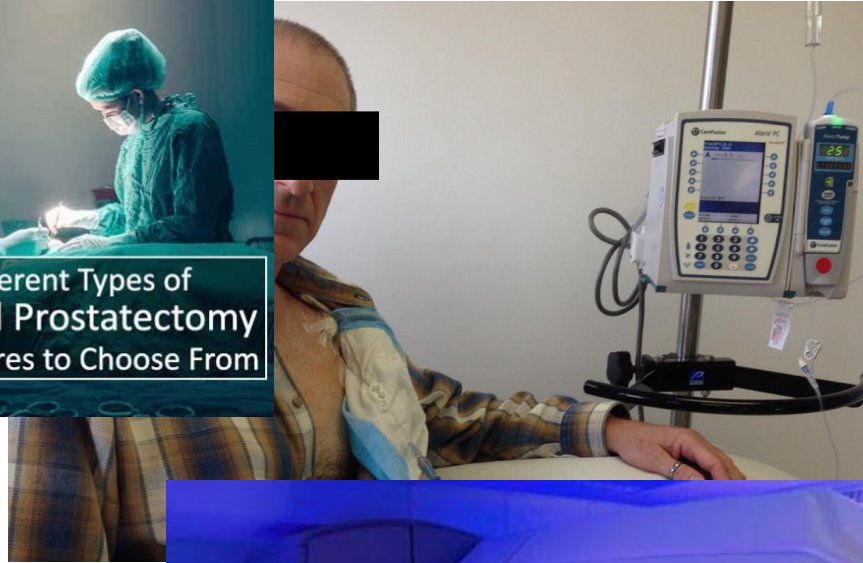
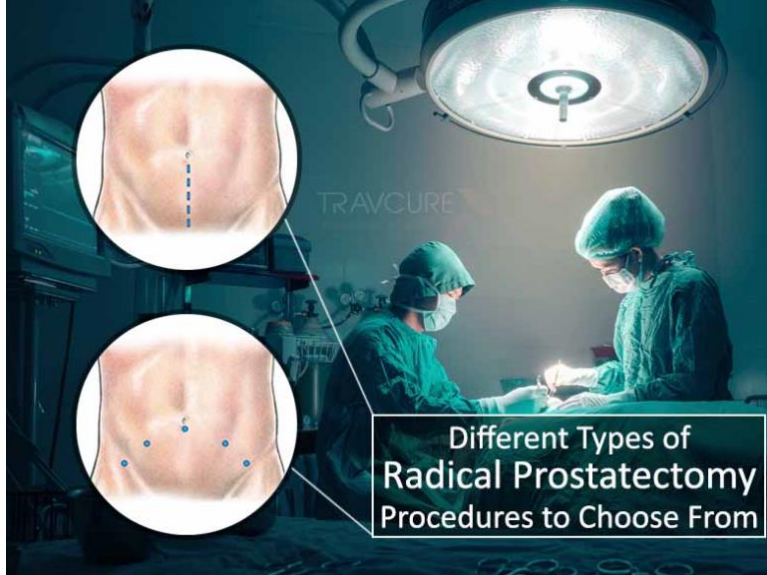


## Stage IV

The cancer has spread locally and to distant organs and bones.



# Prostate Cancer Therapy



# Prostate Cancer Therapy – Side Effects



Erectile dysfunction



Diarrhea



Depression



Nausea and vomiting

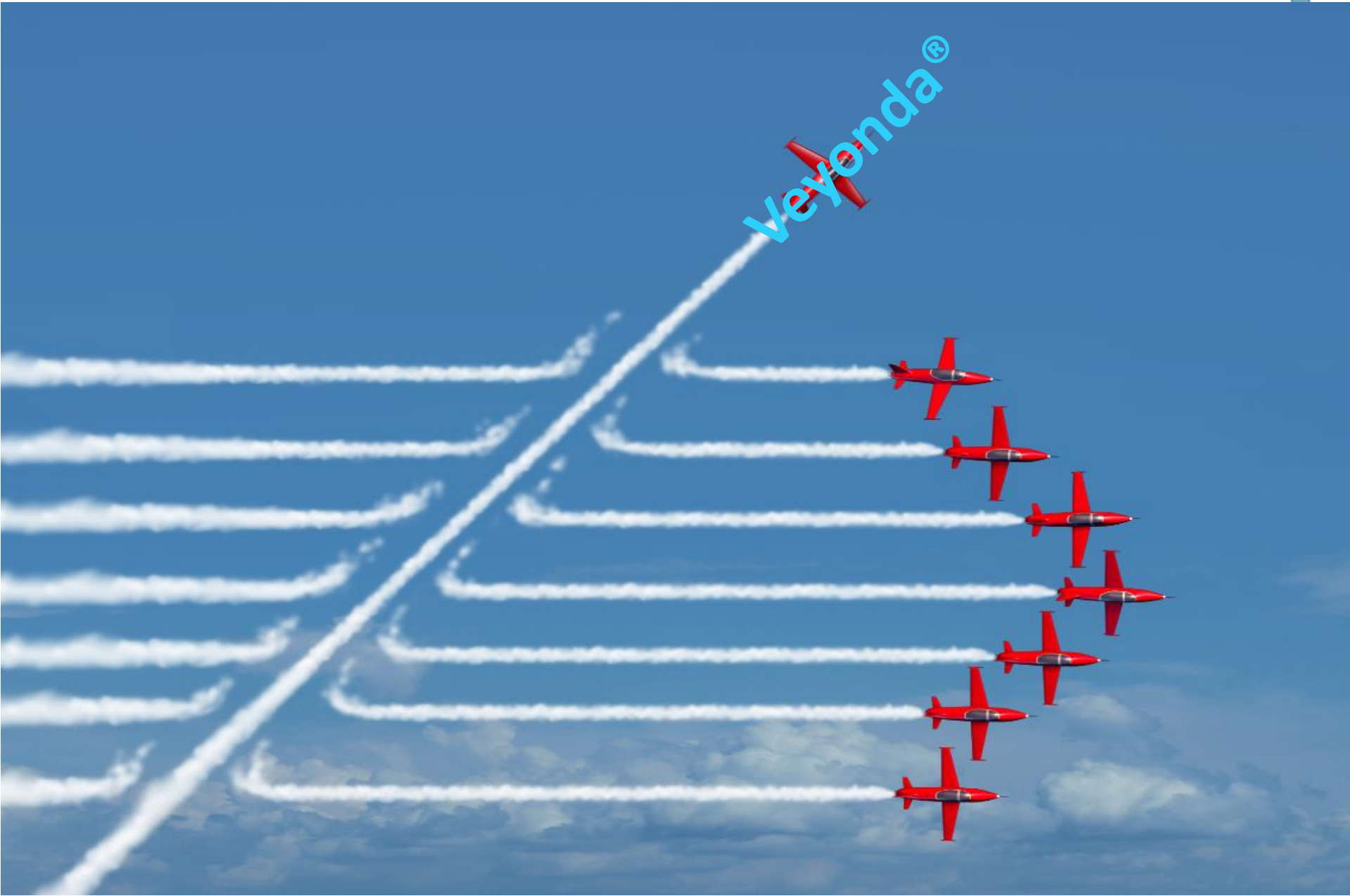


Hair loss

# Our Goal is to Revolutionise Cancer Therapy



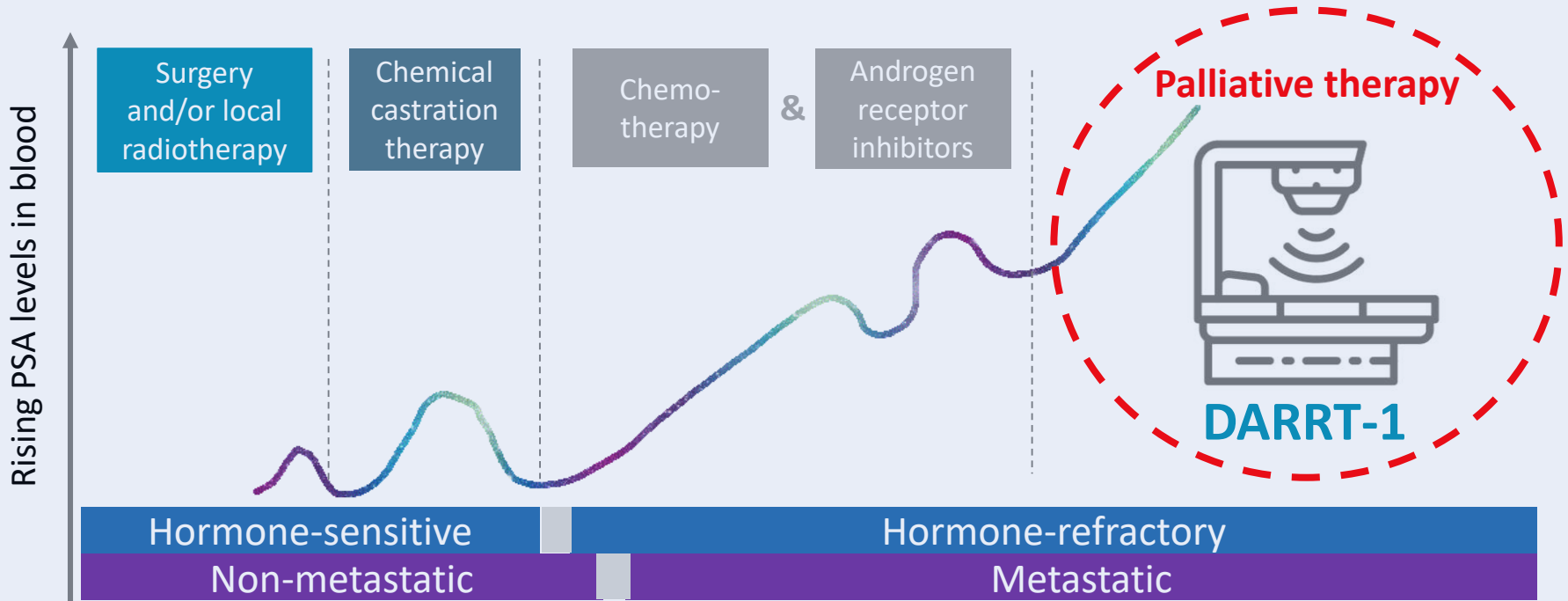
Veyonda®



# Prostate Cancer and Treatment Options

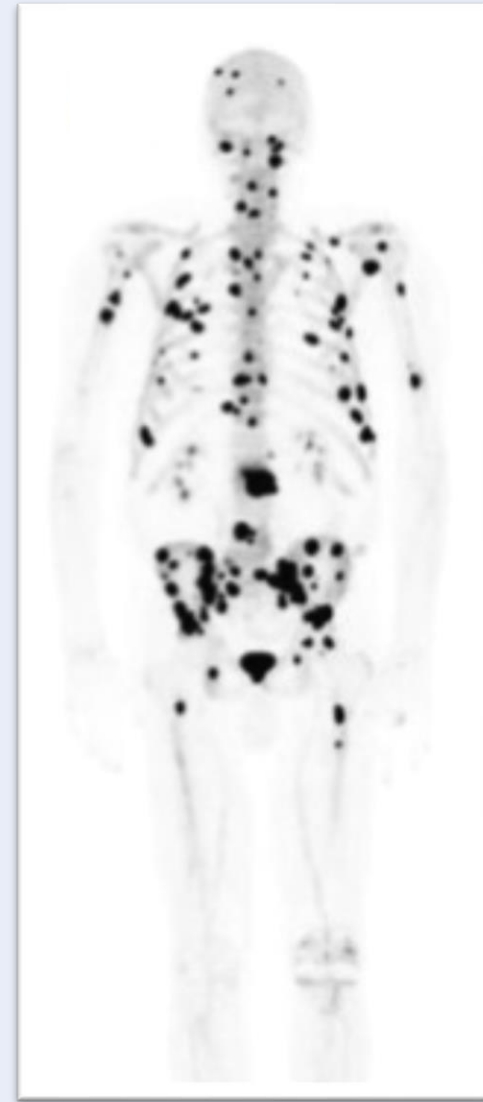


## Course of Disease and Treatment Journey for Stage I - IV Prostate Cancer





- 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)



Bone scan with metastatic disease

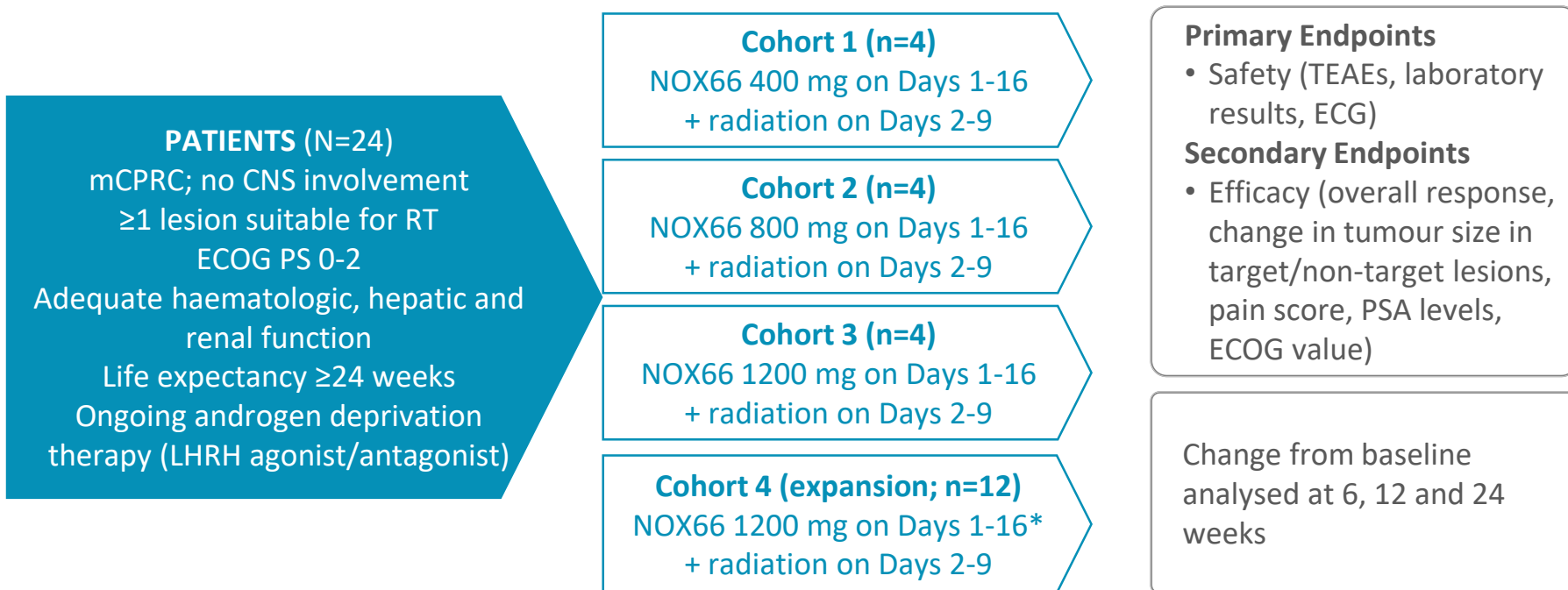
DARRT = Direct and Abscopal Response to Radiation Therapy; RT = Radiation Therapy



# DARRT-1: Study Design<sup>1</sup>



- Phase 1b, open label, non-randomised study of NOX66 in combination with palliative radiotherapy in patients with mCRPC



\* The 1200mg dose for Cohort 4 was selected by the Study Steering Committee based on the interim safety and tumour response data from Cohorts 1,2 and 3

CNS = central nervous system; ECG = electrocardiogram; ECOG PS = Eastern Cooperative Oncology Group Performance Status; LHRH = luteinizing hormone-releasing hormone; mCRPC = metastatic castrate resistant prostate cancer; PSA = prostate-specific antigen; RT = radiation therapy; TEAEs = treatment-emergent adverse events

1. Available at: <https://clinicaltrials.gov/ct2/show/NCT03307629>. Accessed March 2019.



# DARRT-1: Interim Data



- Veyonda<sup>®</sup> in combination with radiation therapy appeared to be **well-tolerated**<sup>1</sup>
- In the 22\* patients who were evaluable at 3 months<sup>1</sup>

\* 4 patients lost to follow-up

DARRT = Direct and Abscopal Response to RadioTherapy; PSA = prostate specific antigen

1. Noxopharm. Data on file.

# DARRT-1: Interim Data



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  - **The PSA levels fell in 7 patients**  
(7/22 patients achieved  $\geq 50\%$  reduction in PSA at 3 months)

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  - **The Pain levels fell in 12 patients**  
(12/22 patients achieved  $\geq 30\%$  reduction in pain at 3 months)

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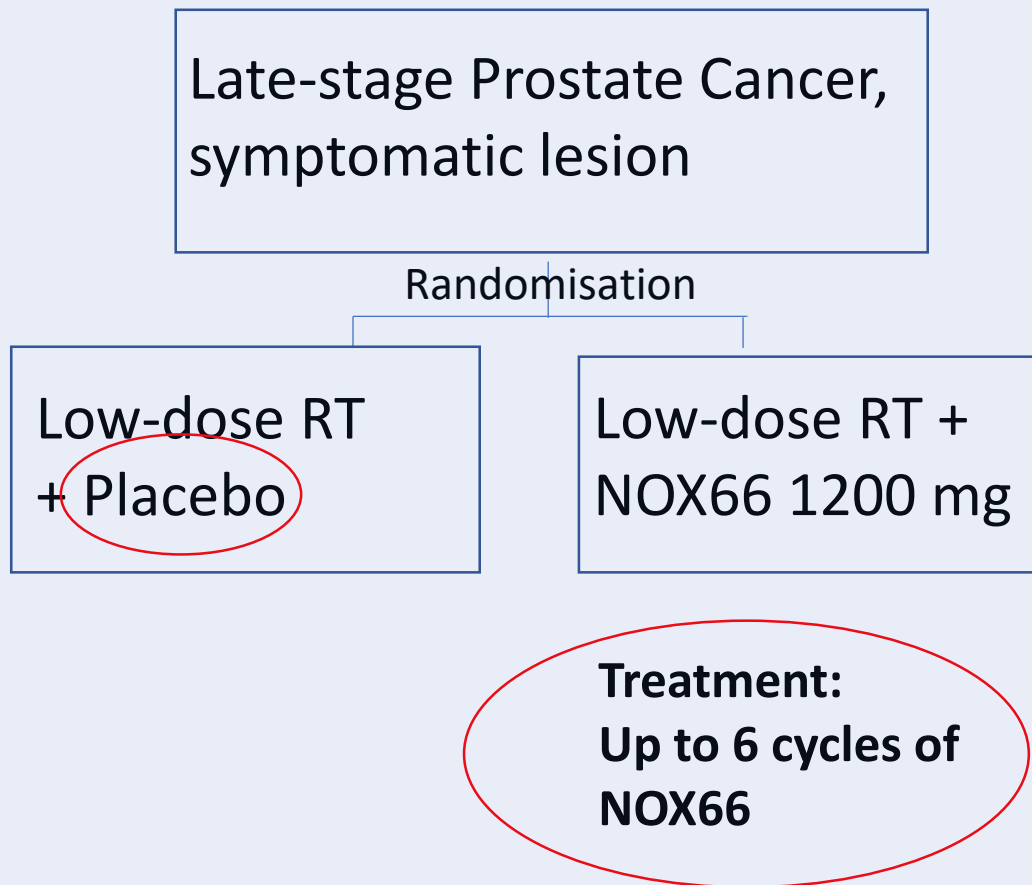
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(7/22 patients achieved  $\geq 50\%$  reduction in PSA at 3 months)
  - **The Pain levels fell in 12 patients**  
(12/22 patients achieved  $\geq 30\%$  reduction in pain at 3 months)
  - **The Tumours stopped growing or reduced in size in 16 patients**  
(3 patients achieved a partial response and 13 achieved stable disease at 3 months)

\* 4 patients lost to follow-up

DARRT = Direct and Abscopal Response to RadioTherapy; PSA = prostate specific antigen

1. Noxopharm. Data on file.

# DARRT-2 – In Planning



*There are more than 100 Types of Cancer*



**All Cancers**

Lavender

**Bladder Cancer**

Yellow

**Brain Cancer**

Grey

**Breast Cancer**

Pink

**Cervical Cancer**

Teal/White

**Childhood Cancer**

Gold

**Colon Cancer**

Dark Blue

**Esophageal Cancer**

Periwinkle

**Head & Neck Cancer**

Burgundy/Ivory

**Kidney Cancer**

Orange

**Leiomyosarcoma**

Purple

**Leukemia**

Orange

**Liver Cancer**

Emerald

**Lung Cancers**

White

**Lymphoma**

Lime

**Melanoma**

Black

**Multiple Myeloma**

Burgundy

**Ovarian Cancer**

Teal

**Pancreatic Cancer**

Purple

**Prostate Cancer**

Light Blue

**Sarcoma/Bone Cancer**

Yellow

**Stomach Cancer**

Periwinkle

**Testicular Cancer**

Orchid

**Thyroid Cancer**

Teal/Pink/Blue

**Uterine Cancer**

Peach

**Honors Caregivers**

Plum

# Sarcoma – Two main Types



## Bone tumors

Osteosarcoma



## Soft tissue tumors

50-100 sub-types



# Current Classification of Sarcomas

## Vascular STS

- Angiosarcoma
- Hemangiosarcoma
- Lymphangiosarcoma
- Hemangioendothelioma
- Hemangiopericytoma
- Kaposi sarcoma

## Neural STS

- Malignant peripheral nerve sheath tumor
- Malignant paraganglioma
- Neuroblastoma, neuroepithelioma
- Granular cell tumor

## Adipose STS

- Atypical lipomatous tumor
- Myxoid/round cell liposarcoma
- Dedifferentiated liposarcoma

## Pleomorphic STS

- Liposarcoma, malignant fibrous histiocytoma

## Neuromuscular STS

- GIST

## Unclassified

## Smooth Muscle STS

- Gastrointestinal, genitourinary, cutaneous, vascular

## Skeletal Muscle STS

- ARMS, ERMS, pleomorphic RMS

## Fibrous STS

- Fibrosarcoma
- Fibromyxoid sarcomas
- Desmoid tumor
- Dermatofibrosarcoma
- Inflammatory myofibroblastic tumor

## Unknown Tissue

- Synovial sarcoma
- Alveolar soft part sarcoma
- Epithelioid sarcoma

## Bone Sarcomas

- Osteosarcoma (+ variants)
- Chondrosarcoma (+ variants)
- Giant cell tumor of bone
- Ewing sarcoma family of tumors

## Extraskeletal Bone Sarcomas

- Osteosarcoma
- Ewing sarcoma family
- Chondrosarcoma

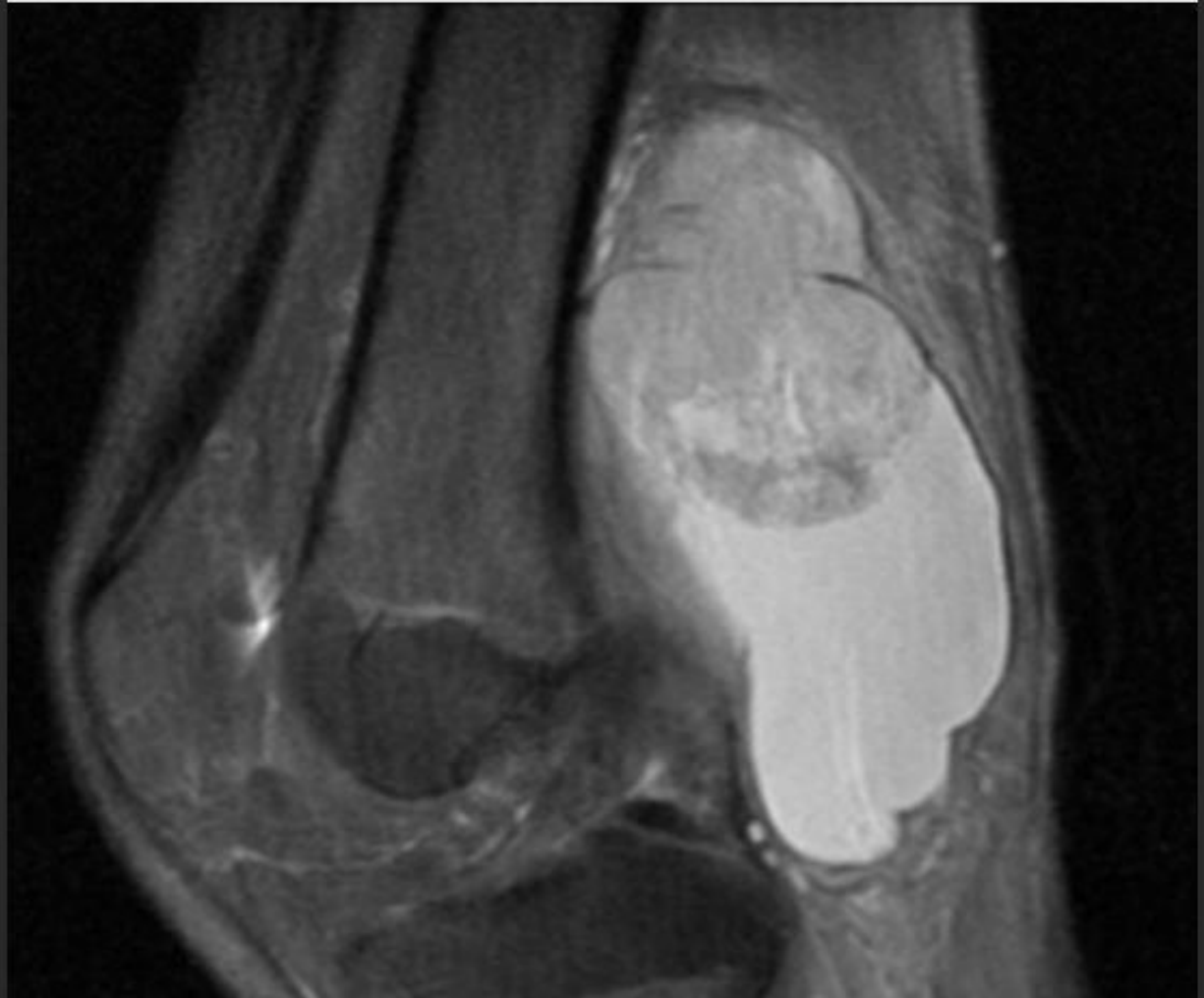
ARMS = *alveolar rhabdomyosarcoma*;

ERMS = *embryonal rhabdomyosarcoma*; RMS = *rhabdomyosarcoma*; STS = *soft tissue sarcoma*





# Synovial Sarcoma



# Sarcomas



- A heterogeneous group of malignant tumours in connective tissue such as bone, cartilage, muscle, fat, blood vessel and lymphoid tissue
- Divided into two major groups: Osteosarcomas (bone sarcomas) and Soft Tissue Sarcomas – each have multiple subtypes
- Two thirds of Soft Tissue Sarcomas occur in extremities
- Constitute ~1% of cancers in adults, but ~15% in children
- The overall 5-year survival rate for sarcomas is ~65-67%



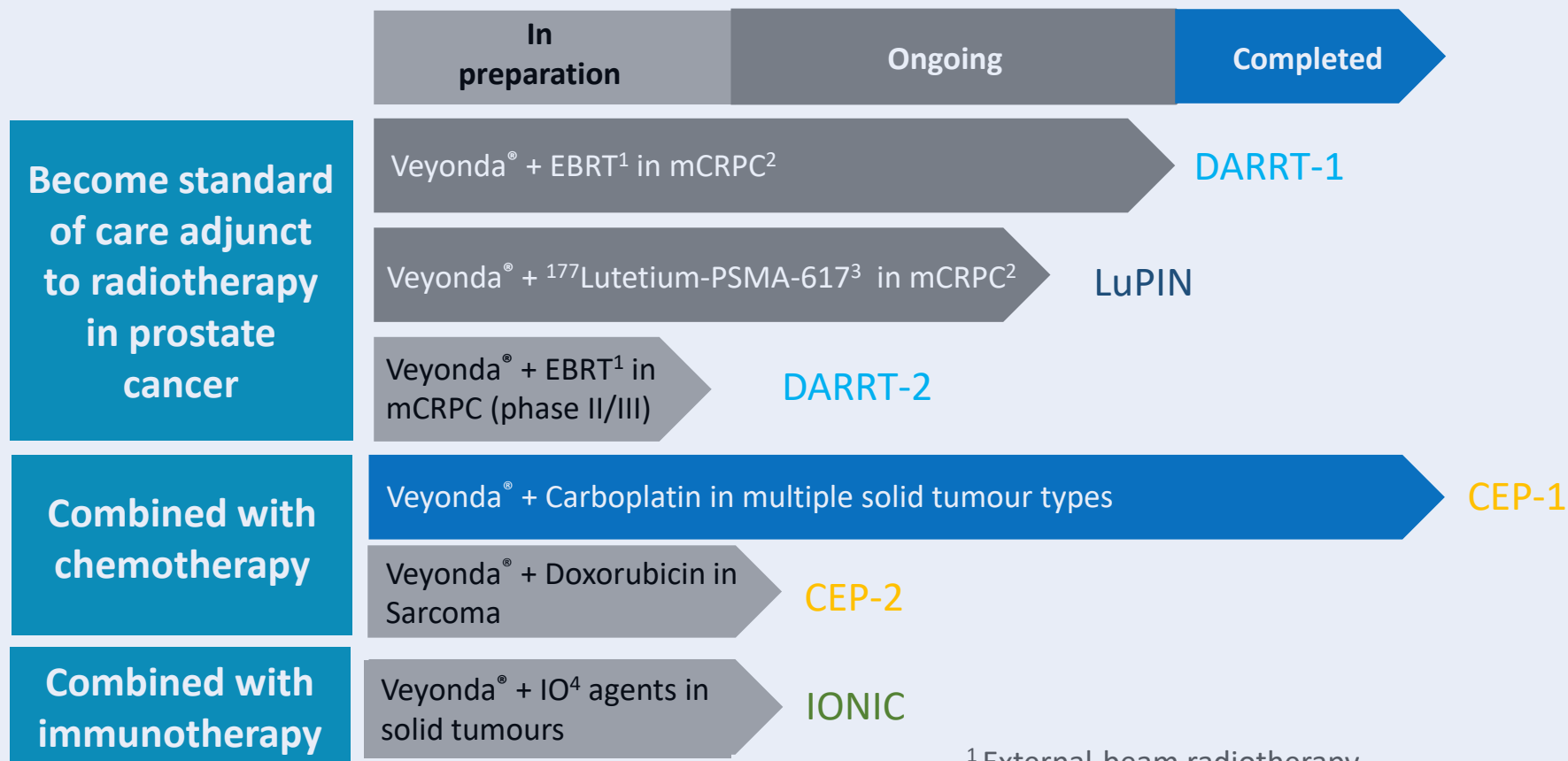
# FDA – Orphan Drug Designation



- Seven-year exclusivity
- Protocol assistance by FDA
- Tax credits of 50% of the clinical drug testing cost
- Research grants awarded by FDA
- Waiver of NDA application fee

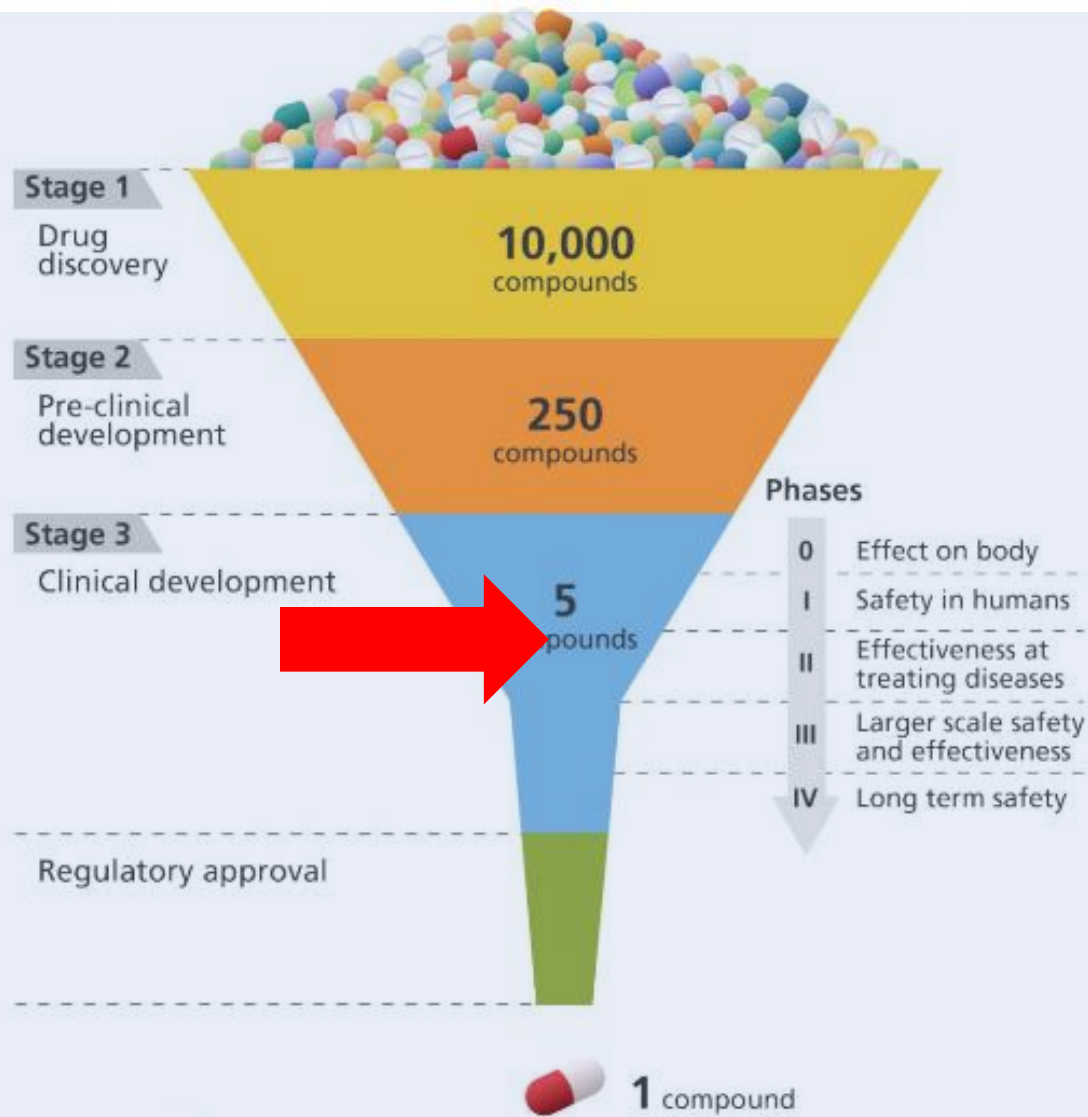


# Veyonda® - Clinical Program



<sup>1</sup> External-beam radiotherapy  
<sup>2</sup> Metastatic castration-resistant prostate cancer  
<sup>3</sup> Targeted intravenous radionuclide therapy  
<sup>4</sup> Immuno-oncology

# Drug Development Process





**For further information please visit  
[www.noxopharm.com](http://www.noxopharm.com)**

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DISCOVER



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