



**A clinical-stage oncology drug company  
developing a disruptive technology for the  
treatment of solid cancers by  
radiotherapy and chemotherapy**

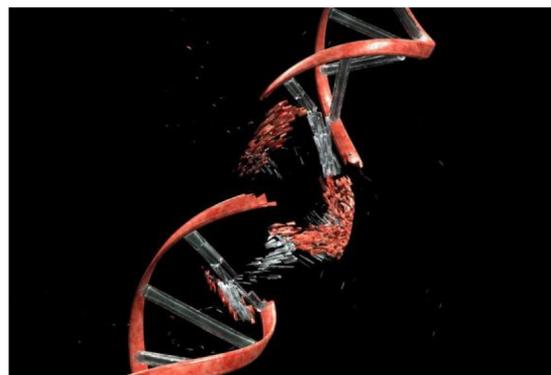
**Open Briefing June 2018**

Unique dual-acting anti-cancer drug

**NOX66** Idronoxil (lipophilic form)

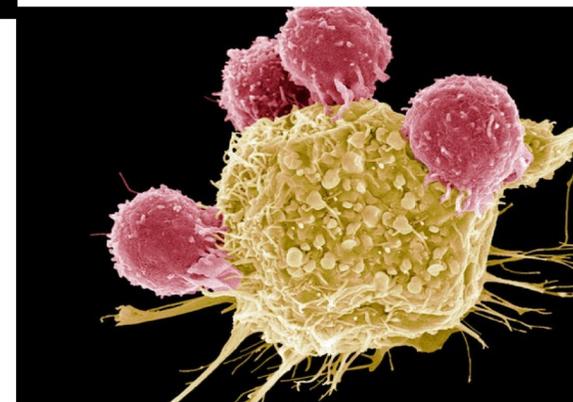
**inhibits DNA repair**

*inhibits PARP-1, topoisomerases 1 and 2*



**promotes anti-tumour immunity**

*Increases NK (natural killer) cell activity*



## 3-horse race



DARRT

- Risk mitigation
- Identify optimal route to market
- Expand post-registration markets

CEP

DARRT

LuPIN

# Chemotherapy Enhancement Program

## Objective:

- ❖ To enable salvage chemotherapy in patients with late-stage, resistant cancers
- ❖ NOX66 in combination with low-dose cytotoxic chemotherapy
- ❖ Aim to deliver a meaningful anti-cancer effect  
in at least 50% patients  
in a well tolerated way

## CEP-1 Phase 1 Sighting study

### Details:

- ❖ 19 patients; late-stage, metastatic cancer; no remaining standard Rx options
- ❖ Breast, lung, ovarian, prostate
- ❖ 14-day NOX66 run-in
- ❖ 6 cycles; each cycle = NOX66 (7 days) + carboplatin (1 day) each month
- ❖ 3 patients withdrew voluntarily; 1 carboplatin sensitivity; 1 sudden death; 4 death from progressive disease; 2 non-evaluable

# CEP

## CEP-1



### Outcomes

#### Safety:

- 5 Grade 3 toxicities, all resolved. All other toxicities mild.
- No toxicity associated with NOX66

#### Efficacy:

	<u>Partial response</u>	<u>Stable disease</u>	<u>Disease progression</u>	<u>Total</u>
3 cycles	0	12	2	14
6 cycles	1	5	4	10*

\* 12 started: 1 withdrew: 1 sudden death

- ❖ Phase 2
- ❖ NOX66 Dosage: 800 mg
- ❖ Platinum based therapy. Which drug?
  - Carboplatin
  - Cisplatin
  - Oxaliplatin
- ❖ Which cancer type(s)? What end-points?
- ❖ Protocol design
  - Q3 Meet with Advisory Board
  - Q4 Final protocol
  - Early-2019 Study opens

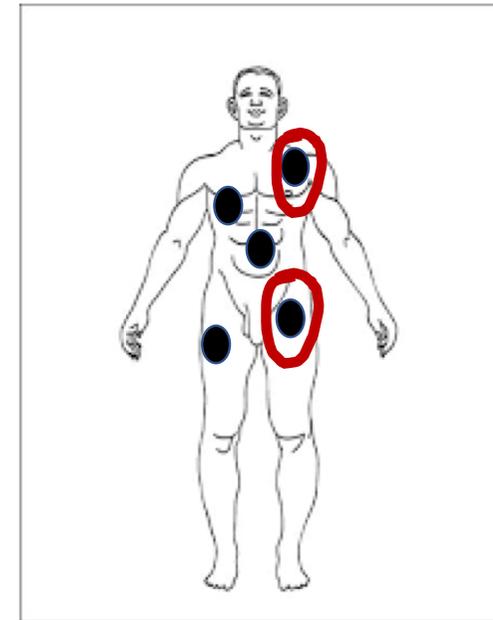
# DARRT

## Direct and Abscopal Response to Radio-Therapy



External Beam RT  
or  
Stereotactic Body RT

- Patients with multiple (>3) tumours
- Irradiate 1-2 tumours (5 days)
- NOX66 14 days
- Scan + 6 weeks and 12 weeks

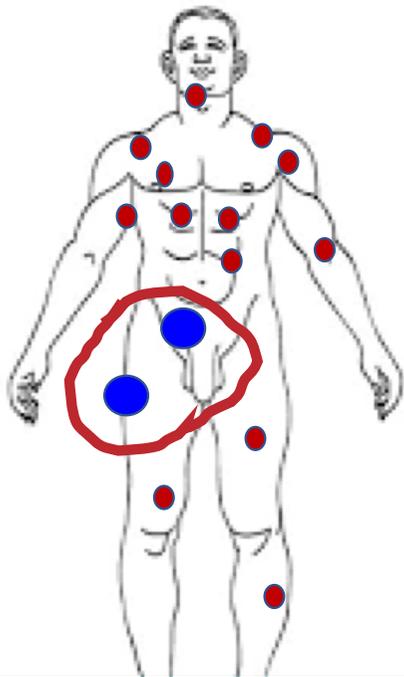


# DARRT

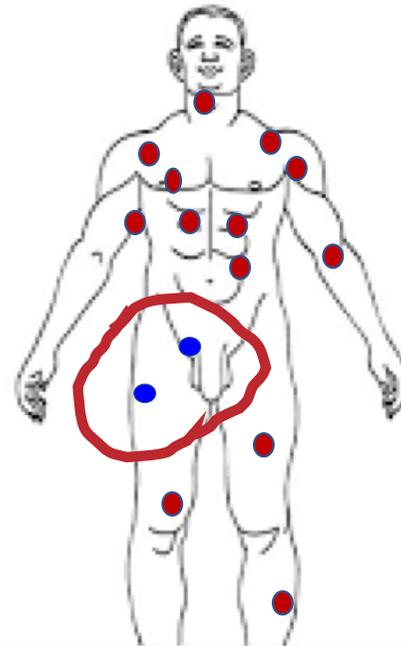
## Direct and Abscopal Response to Radio-Therapy



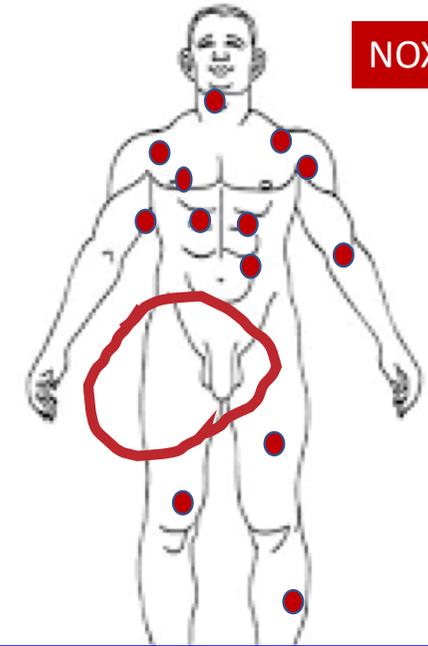
### Direct Response



Radiotherapy applied to large tumours for pain relief



Shrinkage of irradiated tumours



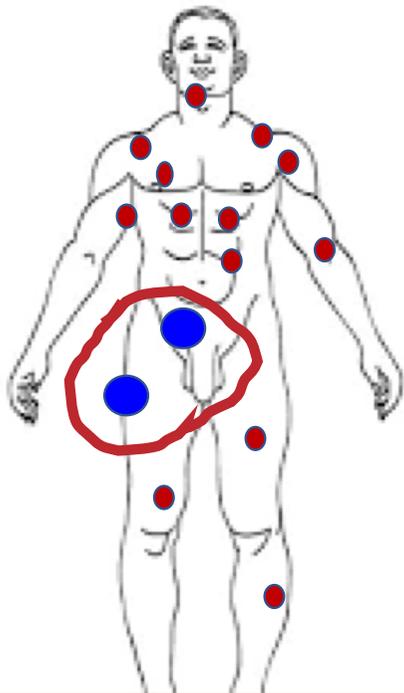
Seeking **complete remission** of irradiated tumours

# DARRT

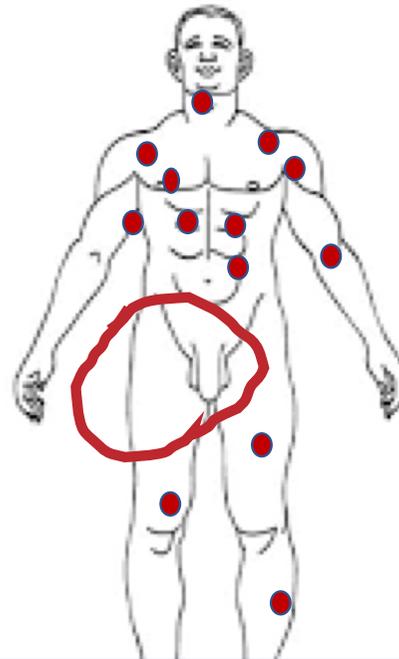
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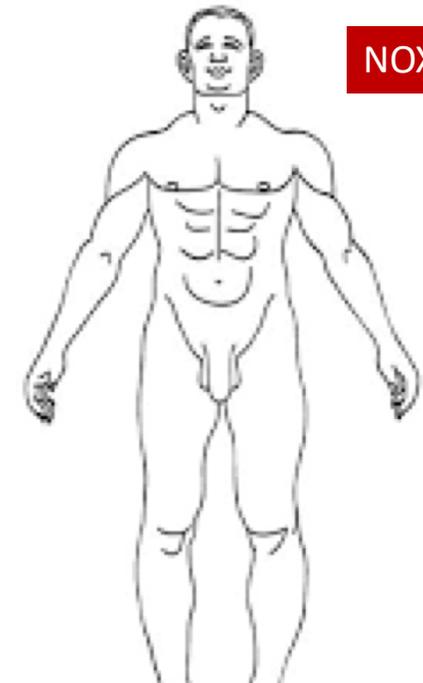
### Abscopal Response



Low-dose radiotherapy



Seeking **complete remission** of irradiated tumours



NOX66

Abscopal response

# DARRT

## DARRT-1

### Details:

- ❖ Phase 1b multi-national study
- ❖ 24 patients; metastatic castrate-resistant prostate cancer
- ❖ NOX66 + External beam RT
- ❖ RT (5-10 days) ▲ NOX66 (duration of RT + 7 days)
- ❖ 4 Cohorts:
  - 400 mg NOX66 (4 patients) *completed*
  - 800 mg NOX66 (4 patients) *completed*
  - 1200 mg NOX66 (4 patients) *enrolled*
  - Best NOX66 dose (12 patients)

### SCHEDULE

- ❖ Late-July 2018. Complete treatment and 6-week scans on first 3 cohorts.
  - Independent review of data
  - Select NOX66 dosage
  
- ❖ Late-Aug 2018. Commence recruitment of Cohort 4.
  - Target complete recruitment of all 24 patients in Q3 2018
  - 12 week review for all patients Q4
  - Study complete Q1 2019

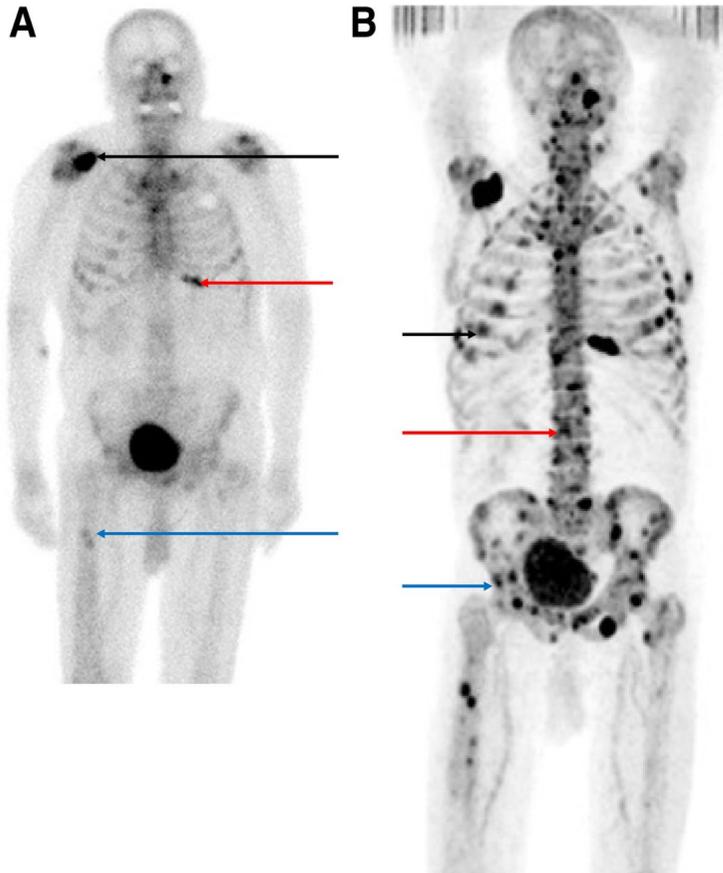
### DATA RELEASE

- ❖ Early-July 2018. Presentation at ANZUP
  - Study outline, safety of initial treatment
  
- ❖ Aug 2018. Release of 6-week data.

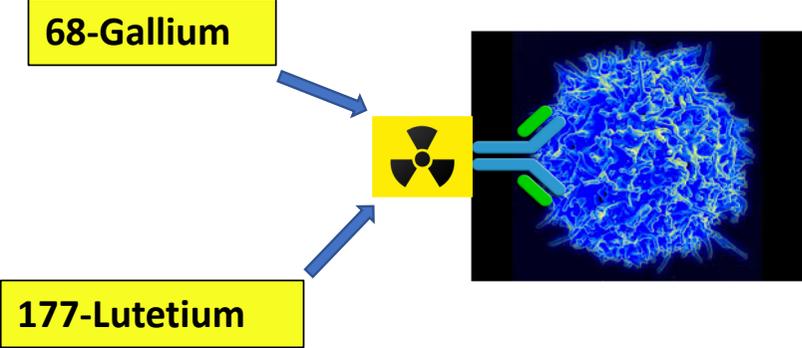
- ❖ DARRT-2: Solid tumours
  - Phase 1b; expanding DARRT-1 research beyond prostate cancer
  - Provide guidance on criteria which may suggest better response to NOX66
  - Decision point – DARRT-1: 12 patient, 6 weeks scan → drive protocol development
  - Commence study Q4 2018
- ❖ DARRT-3: Phase 2/3 registrational planning
  - Key study for first registration of NOX66
  - Feasibility, country and site identification (global) commence Q3 2018
  - Decision point – DARRT-1: 24 patients, 12 week → submission processes begin
  - Commence mid 2019
- ❖ Supportive research
  - Further small investigator led research studies
    - Specific patient populations; treatment regimen (e.g. stereotactic RT)

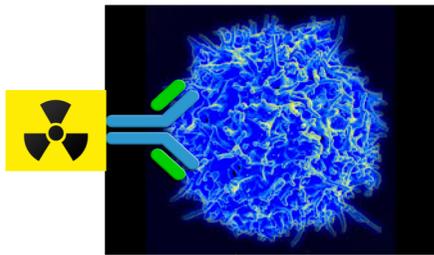
# LuPIN

## Lutetium-PSMA In Combination With NOX66



### THERANOSTICS





THERANOSTICS

- Phase 1b study; investigator-initiated; St Vincent's Hospital Sydney
- Late-stage prostate cancer (metastatic castrate-resistant disease)
- <sup>177</sup> Lutetium-PSMA-617
- 6 x monthly intravenous injections of LuPSMA + 10 days NOX66
- 6 patients 400 mg NOX66; 10 patients 800 mg NOX66

### ❖ LuPIN-1

- Recruitment ongoing – presentation of trial outline at ASCO 2018
- First 4 patients in 5<sup>th</sup> cycle of therapy; first key data expected late-2018

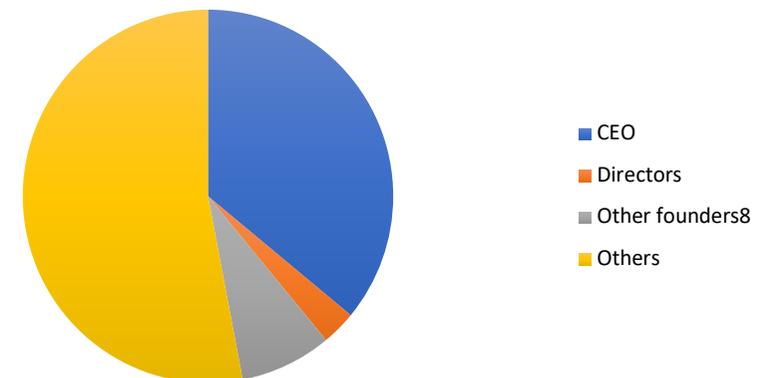
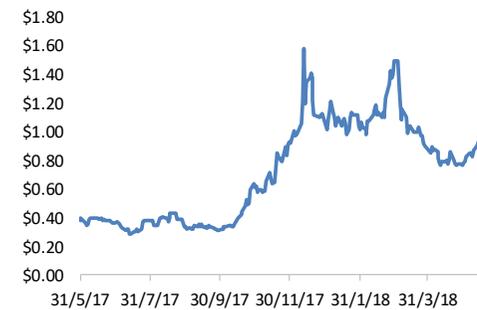
### ❖ Next Steps

- Development of expanded LuPIN study
  - Phase 2 multi-centre, sponsored study
  - Planned commencement early-2019
- Other targeted radionuclides
  - Partnership planning for other targeted therapies
  - Phase 1 studies early-2019

# Key metrics .....



Number of Shares	<b>121.9M</b> : Free float 66.8%
Market Cap (6.6.2018)	\$90M
IPO price	20 cents
12 month high/low	\$1.58/0.29
Average daily turnover	\$0.54M
Cash position	AU\$ 11.8 (31 March 2018)



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# NOXOPHARM

