**Date: 16 September 2019** **Sydney, Australia**

ASX Limited
20 Bridge Street
SYDNEY NSW 2000

# NOXOPHARM EGM CHAIRMAN'S ADDRESS AND PRESENTATION

- **Chairman's Address featuring short-term and medium-term funding strategies ahead of proposed U.S. listing**
- **Presentation detailing clinical strategy in developing Veyonda® as a potentially transformative treatment for prostate cancer**
- **Review of LuPIN data released by investigators**

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**Sydney, 16 September 2019:** Noxopharm Limited (ASX: NOX) ('**Noxopharm'** or the '**Company'**) today releases the Chairman's Address and Presentation for today's Extraordinary General Meeting.

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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, a spin-off company developing a pipeline of non-oncology drugs.

**About Veyonda®**
Veyonda® (previously known as NOX66) is a suppository dosage formulation of the experimental anti-cancer drug, idronoxil, that leads in the body to the formation of a proprietary pro-drug form. Idronoxil specifically inhibits the ability of cancer cells to respond to stress, such as that induced by radiation, leading to loss of pro-survival signaling via sphingosine-1-phosphate. Idronoxil is also a STING modulator, activating both the body's innate and adaptive immune systems.

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# Chairman's Address

This EGM has been called to seek shareholder approval to provide the company with further funding capacity with a facility with a potential total value of A$26 million.

I am going to focus in this address on 3 major topics. The first is the short- and medium-term funding strategies adopted by the Board. The second is about a change in Board remuneration. The third is about some clinical data involving Veyonda® that has been made public in recent days and which we need to provide some commentary on.

Let me start with the obvious question of why we need funding. Noxopharm has on its hands what it believes to be a potentially transformative anti-cancer drug in Veyonda® and it wants to add value to this drug candidate as quickly and as cost-effectively as possible. Drug development is expensive. The only way to not be expensive is to be unsuccessful.

We have achieved significant progress to date with remarkably little funding when you consider the cost of bringing a new drug through to the market. Taking Veyonda® to the next level of clinical testing means larger, more extensive and more expensive clinical studies. The cost of these programs, plus the general cost of running a growing business, we estimate will cost at least A$40-50 million over the next two years. If we have ongoing success, potentially propelling the drug candidate into a registration study, there may be more costs involved.

The Board has given considerable thought as to how to fund that growth. A key part of the strategy is to seek to dual list the Company on a U.S. securities exchange in the first half of 2020. The logistics of this are well advanced and we expect to be able to inform shareholders more about this process in the coming months.

A dual listing offers a number of positives. The first is that U.S. capital market participants are very familiar with the cost and timelines involved in drug development, backed up by strong market research capabilities. They are adept at placing a value on opportunities and they are good at recognising that a return on investment is a stepwise process over the 8-10 years it generally takes to bring a drug through the clinic to market. All of these feed into achieving what the Board believes is recognition of the true value of the Company's opportunity.

That's how we plan to address the medium-term funding situation. Today's meeting is about the **short-term** situation and how we intend to fund the Company up until a U.S. listing and IPO.

**And I refer everyone to the July 19, 2019 ASX announcement for the key details of this funding facility.**

I want to emphasise that if at any stage the Board believes it is in the best interests of the Company to vary this bridging financing arrangement, then it will do so.

We last raised capital 16 months ago. Since then, and prior to the current funding facility, the share price has undergone considerable movement. While we share some of the concern our shareholders may feel around these movements as we are also shareholders, the Board and management are not driven by movements in the share price to the extent that they are outside our control. Our focus is on bringing Veyonda® through its development program.

Some matters we can control, such as engaging the best medical advisors we can find in Australia and the U.S. to help steer our clinical program, ensuring we bring news of that program to the market as quickly as possible, and investing time and money in investor relations activities on the back of key developments.

My second topic is something we can do as a Board to demonstrate our confidence in the Company's future, and that is pegging Board remuneration to the Company's market capitalisation. Apart from preserving cash, this puts the Board on an equal footing with shareholders in terms of the fortunes of the Company. This change has been acted on immediately with a substantial cut in remuneration packages and I will have more to say about this ahead of our upcoming AGM.

Finally, to the third topic – the matter of clinical data. We originally scheduled two key clinical data reports for later this year. The first is the 6-month data from the second arm of DARRT-1. This data will reveal the depth and durability of the anti-cancer effect of a combination of Veyonda® and external beam radiotherapy in late-stage prostate cancer. The DARRT program is our leading clinical program, so that data will be important. That is due late-November.

The second data report concerns the LuPIN study. This is an important Investigator-Initiated Study being conducted at St Vincent's Hospital, Sydney. The Company's involvement is to provide Veyonda® along with some contributory funding. LuPIN involves treating 56 men with late-stage prostate cancer with a combination of Veyonda® plus the experimental radiopharmaceutical drug, $^{177}$lutetium-PSMA-617. The purpose of the Study is to see if Veyonda® can increase the clinical response rate to $^{177}$lutetium-PSMA-617, an emerging new treatment for late-stage prostate cancer. This study is expected to provide a final read-out in late-2020.

The Hospital previously has reported on the clinical outcome of their patients treated with $^{177}$lutetium-PSMA-617 alone or in combination with Veyonda®; these have been separate reports. The investigators recently combined the two sets of data to provide a comparison and this was accepted for presentation at a conference in mid-November 2019. There is nothing new

in these two sets of data; the novelty being in putting them together into the one report. We had been informed that this data would not be made public until early-November, but we have discovered in the last 24 hours that it has in fact been made public, which means we will need to issue a clarifying statement within the next 24 hours. In the meantime, and with the data now public, we can report what was apparent to anyone familiar with the two sets of data that the combination treatment has had a significantly better clinical response compared to $^{177}$lutetium-PSMA-617 alone.

This, and other ongoing work, is what underwrites the Board's excitement about the Company's future. We have a drug candidate that we believe continues to prove to have what it takes to be a major new immuno-oncology drug. We also believe we have the right team to bring it through its clinical program. In addition, we have a proposed dual Australia-U.S. listing to help raise the Company's profile, and we have secured the necessary short-term funding to see us to that point.

Something like only 1 in 9 drugs that enter the clinic in the U.S. go on to receive FDA approval. The further we go with Veyonda®, the more confident we are that Veyonda® is poised to join that elite club.

The fundamentals of the Company remain strong and we look forward to bringing you progress reports as we can, starting with what we regard as key clinical milestones in November this year.

I also want to point out that we are close to seeing our U.S.-registered subsidiary company, Nyrada Inc, being offered to the public. Noxopharm will be a majority shareholder in Nyrada. Which was the whole point in creating Nyrada in order to crystallise some meaningful value for Noxopharm and its shareholders in non-oncology IP.

Thank you for your time, and I commend today's resolutions to you.

Yours sincerely

Graham Kelly
Executive Chairman

September 2019
Extraordinary General Meeting

# Noxopharm Limited

Veyonda®

NOXOPHARM

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# The Opportunity

# The Opportunity for Veyonda®* in the management of prostate cancer is huge


According to Australian and U.S. Govt sources:

- **1 in 7** men will be diagnosed with PC by age **85**
- New cases annually
  - **19,000** (Aust)
  - **175,000** (U.S.)
- Deaths from prostate cancer annually
  - **3,300** (Aust)
  - **31,000** (U.S.)

* Veyonda® (NOX66/idronoxil) has yet to receive marketing approval

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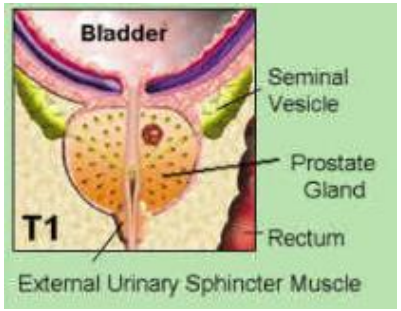
# Prostate Cancer – four main stages





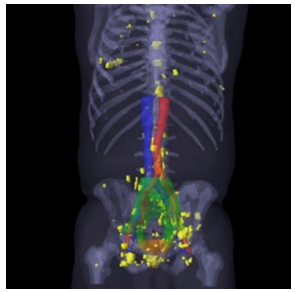
## Stage I

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.

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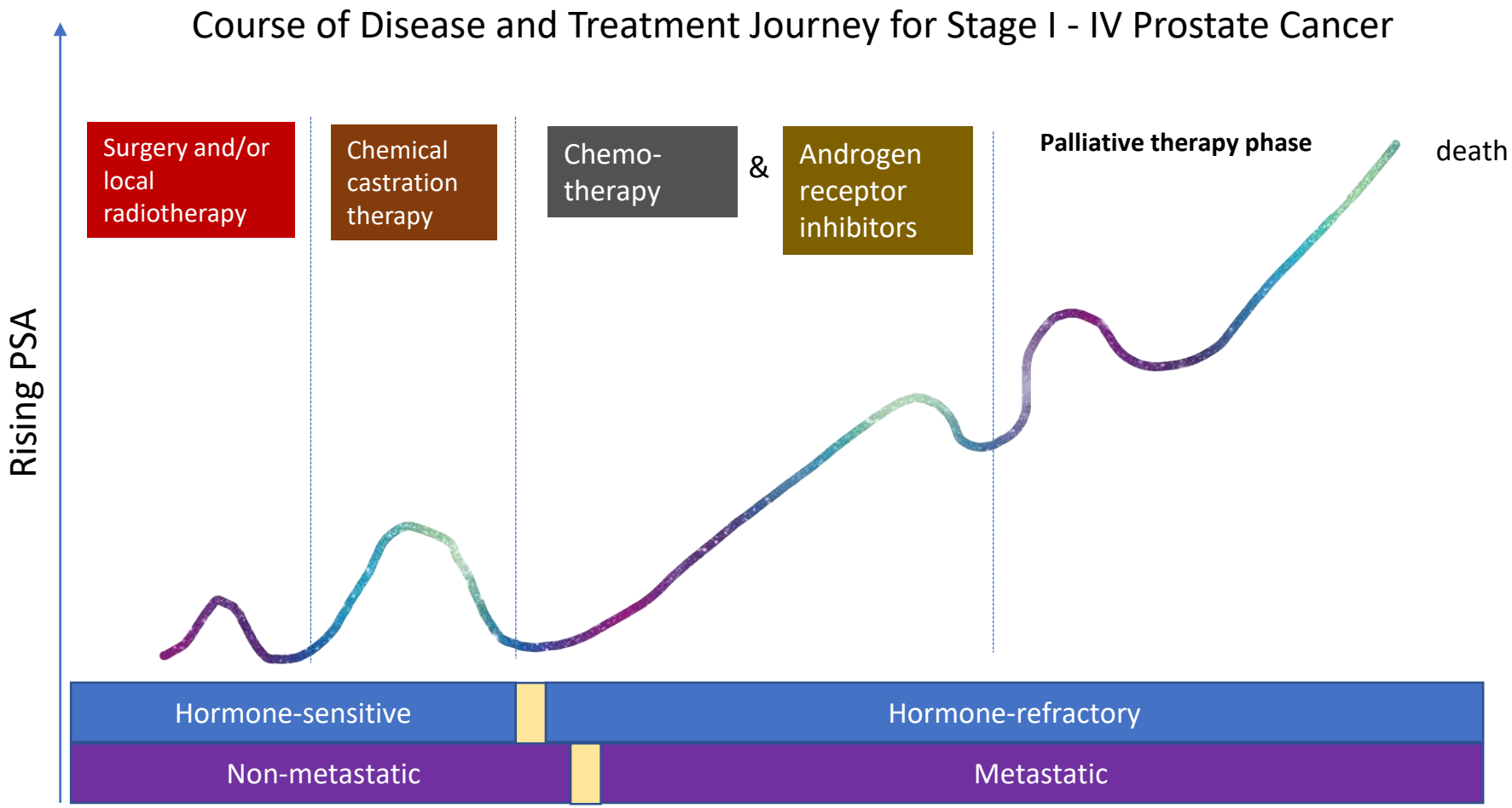
# Prostate Cancer Treatment Options

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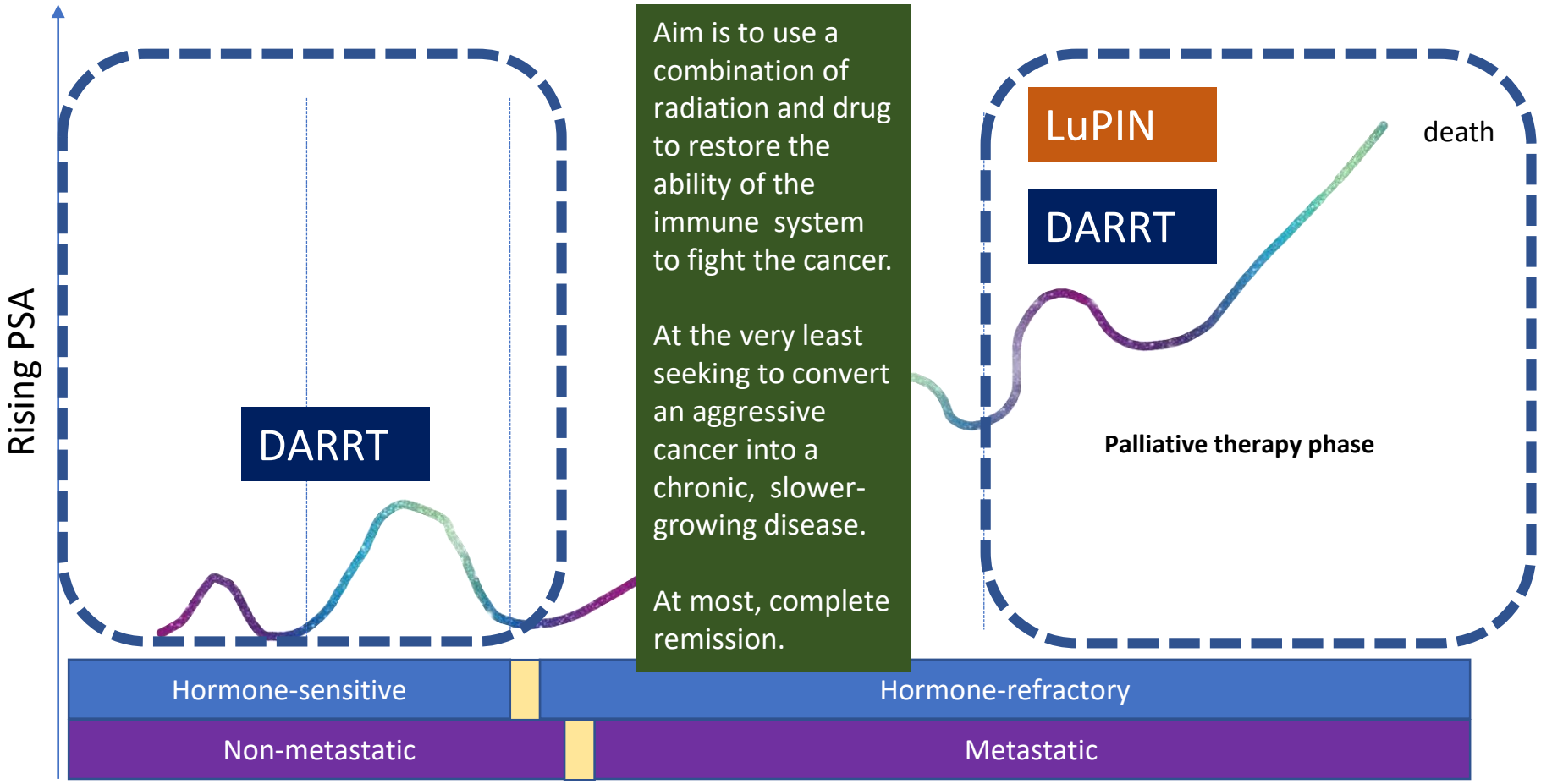
# Proposed Uses of Veyonda®*

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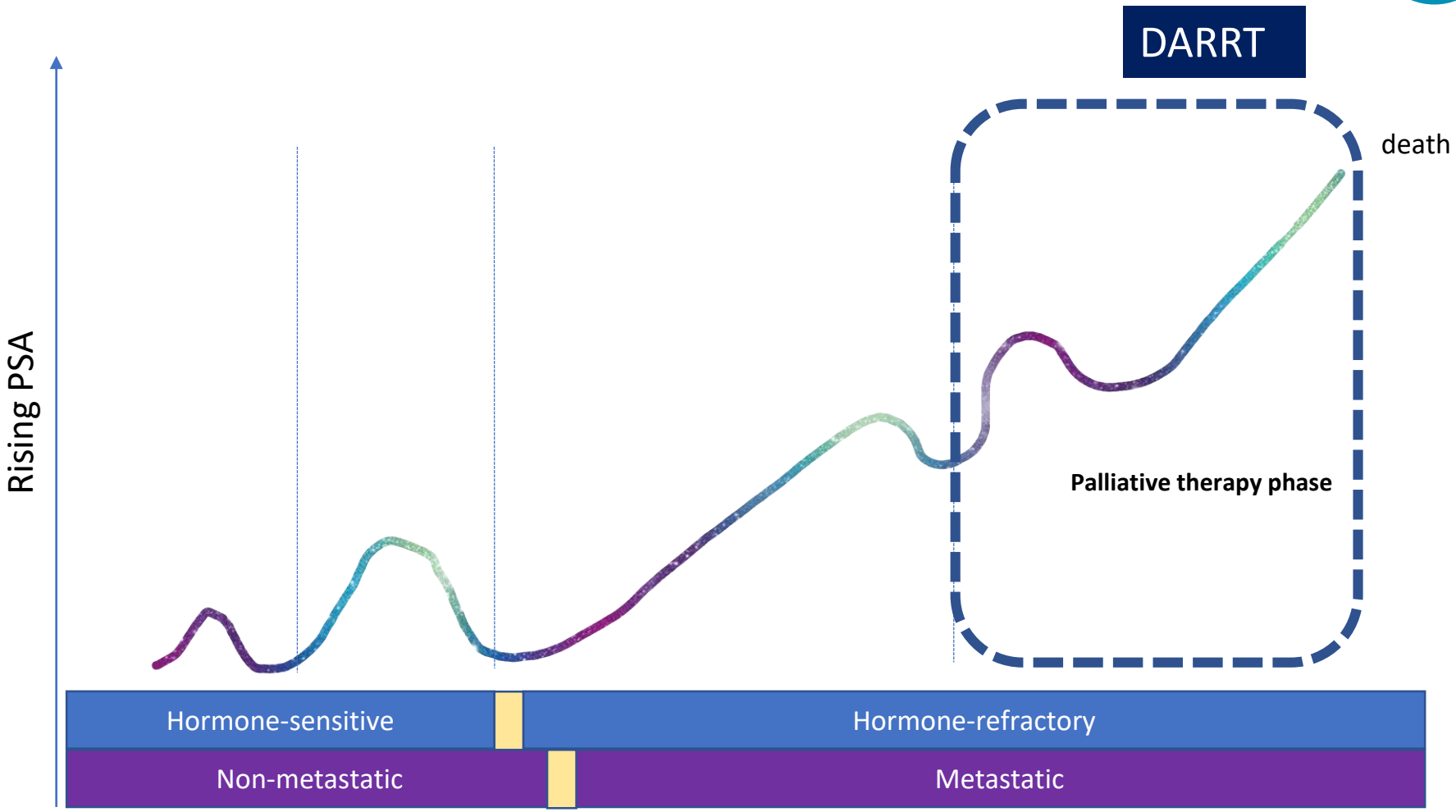
# Veyonda®

# DARRT

# Proposed Uses of Veyonda®*

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# DARRT – Late-stage cancer

**Characteristics of late-stage, metastatic, castrate-resistant prostate cancer (mCRPC)**

- Progressive disease
- Rising PSA levels
- Significant and increasing pain from bone secondaries
- Rising opioid use
- Poor quality of life
- Small (5-9%) PSA response (>50% decline) with palliative RT alone
- 30% 5-year survival rate
- Expected survival < 12 months

**What would the Company, patients, doctors and regulators be likely to regard as a worthwhile treatment in late-stage mCRPC?**

Delivering in a significant number of men:

- PSA response (> 50% decline)
- No disease progression over 6 months
- Reduction in pain (> 30% decline)
- Improved quality of life
- Increased overall tumour response

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# DARRT-1 Clinical data to date highly encouraging

Part A
(Dose-finding: 400/800/1200 mg)
14 patients
6 months FINAL

- 5/14 (36%) with PSA response at any time
- 8/14 (57%) no tumour progression at 6 months
- 6/14 (43%) with pain reduction (>30%) and 2/14 pain-free at 6 months

Part B
(Dose-expansion: 1200 mg)
11 patients
3 months INTERIM

- 6/11 (55%) PSA response rate*

* 6-month data expected late-Nov 2019

NB. Combination of Veyonda®* + low-dose EBRT well-tolerated

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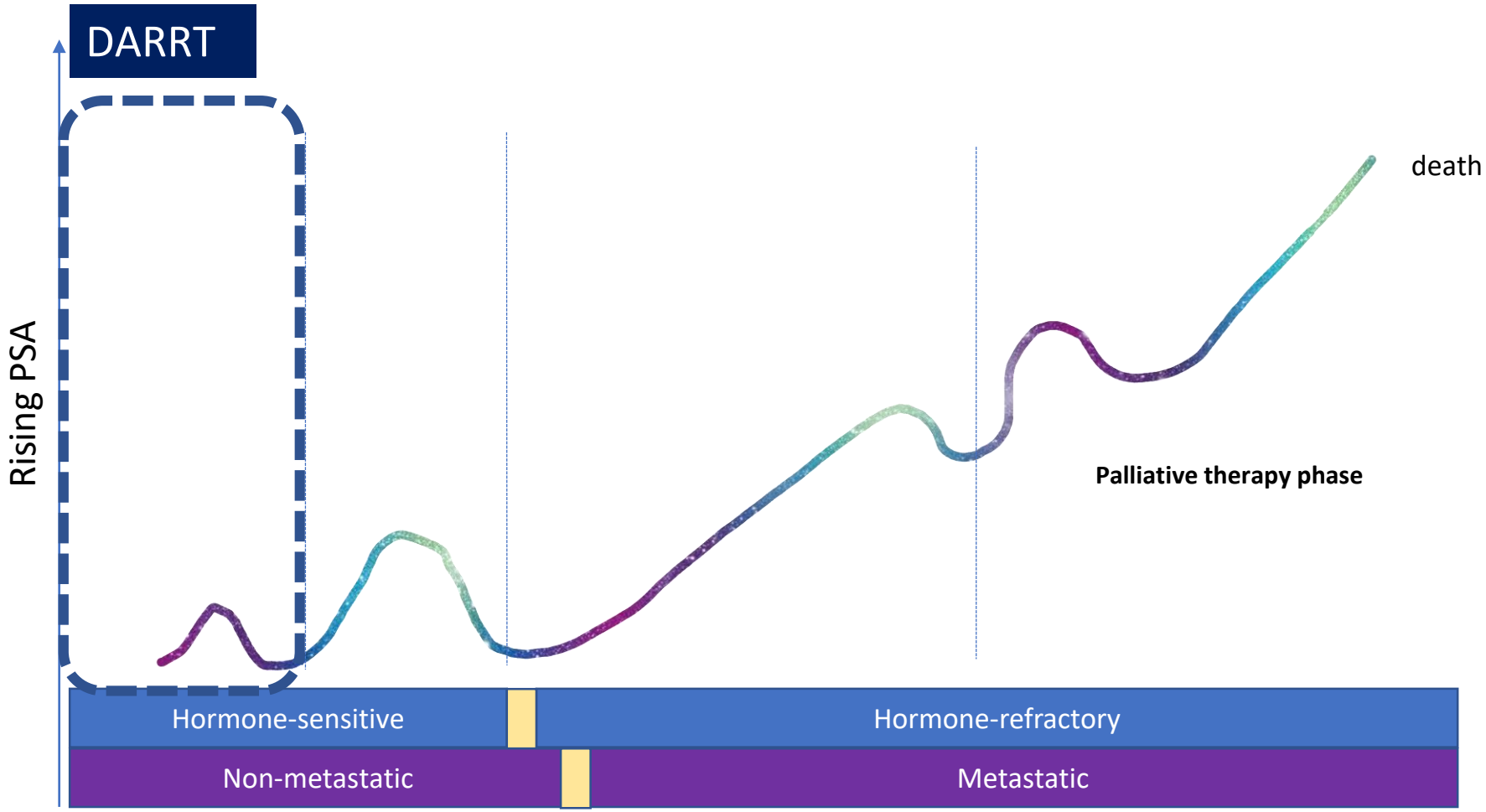
# Proposed Uses of Veyonda®*

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# DARRT – Early-stage cancer

Potential benefits for early-stage prostate cancer:

- Lower dosage of radiation less damaging to bowel and bladder (lower rates of infection and treatment-generated cancers)
- Delay or abrogate need for hormone therapy (feminization of men, loss of libido)

- Short courses of Veyonda®*
- Veyonda® self-administered
- Short course of radiotherapy
- Well-tolerated combination treatment
- No in-patient hospitalization required

* Veyonda® (NOX66/idronoxil) has yet to receive marketing approval

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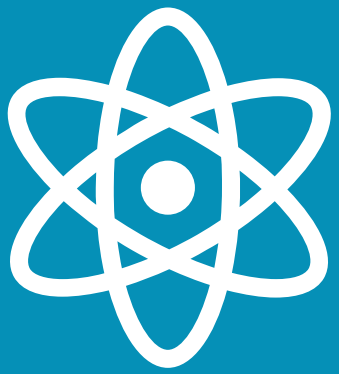
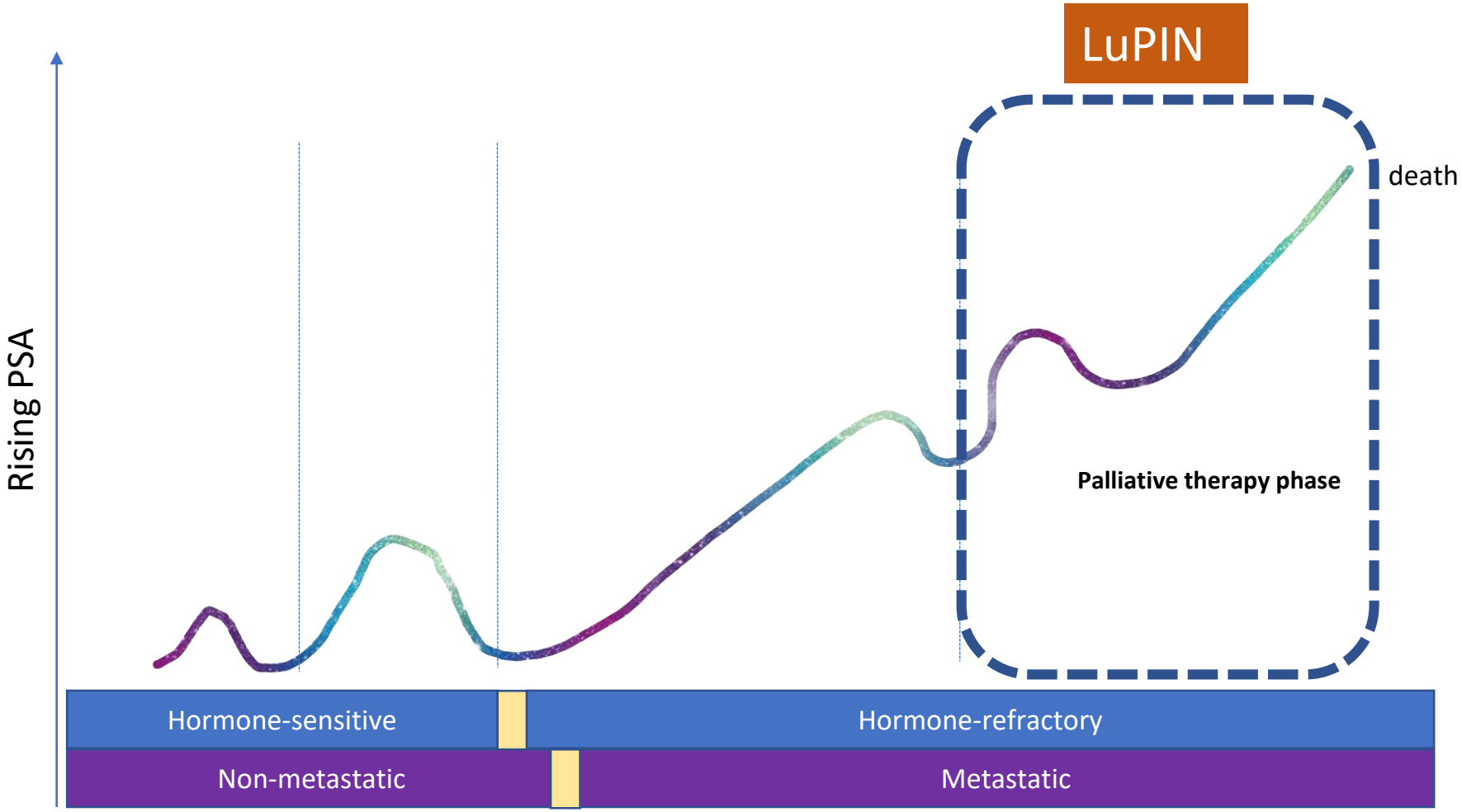


# Veyonda®

## LuPIN

# Proposed Uses of Veyonda®*

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# LuPIN - $^{177}$Lutetium-PSMA-617 + Veyonda®*

Seeking to show that combination versus $^{177}$Lutetium-PSMA-617 alone leads to a significant increase in …..

- PSA responses (> 50% decline)
- Progression-free survival
- ability to complete at least 4 treatment cycles
- pain responses and quality of life
- overall survival

Interim data *(July 2019)*
Dose-finding: 400/800mg
16 patients

- 10/16 (69%) PSA rate overall
- 9/16 (56%) completed 6 cycles
- 13/16 (93%) overall survival at 6 months
- 10/16 (81%) overall survival at 12 months

* Veyonda® (NOX66/idronoxil) has yet to receive marketing approval

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# Outlook and Next Steps

# Upcoming Results

## Upcoming clinical data reports

**DARRT-1**

6-month, cohort 4: 1200 mg Veyonda®*
(**11 patients**)

- PSA response rate
- Pain response rate
- Progression-free survival
- Overall tumour response (RECIST)

Data expected late-November 2019

* Veyonda® (NOX66/idronoxil) has yet to receive marketing approval

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# Upcoming Results

## Upcoming clinical data reports

**LuPIN**

$^{177}$Lu-PSMA-617 alone
vs $^{177}$Lu-PSMA-617 + **Veyonda®**

Comparison of two previously published sets of data:
$^{177}$Lu-PSMA-617 alone
https://www.ncbi.nlm.nih.gov/pubmed/30425003
$^{177}$Lu-PSMA-617 + Veyonda
https://www.noxopharm.com/site/PDF/2007_4/ConferenceHearsofPositiveInterimDatafromLuPINTrial

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# LuPIN - $^{177}$Lutetium-PSMA-617 + Veyonda®*

| | $^{177}$lut-PSMA alone | $^{177}$lut-PSMA + Veyonda® |
|---|---|---|
| No. patients | 14 | 16 |
| Median PSA (ng/ml) | 88 | 147 |
| PSA response (>50% fall) | 36% | 69% |
| PFS (months) | 2.0 | 8.4 |
| Complete 4 cycles | 21% | 69% |

No significant adverse treatment-related events reported

Accepted for presentation at the 46th Annual Scientific Meeting of the Clinical Oncology Society of Australia 12-14 November 2019

Ardolino L et al. **177Lu-PSMA-617 as monotherapy or in combination with NOX66 for the treatment of men with late-stage metastatic castrate resistant prostate cancer (mCRPC): An exploratory analysis.** (66985)

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# The Veyonda® Radiotherapy Program

| | | |
|---|---|---|
| DARRT | **Late-stage metastatic, castration-resistant prostate cancer** | Multi-centre, multi-national, randomised controlled study<br>*Veyonda®* + palliative EBRT versus palliative RT alone* |
| DARRT | **Early-stage, hormone-sensitive prostate cancer** | Phase 1 study<br>*First-line therapy Veyonda ®* + RT* |
| LuPIN | **Late-stage metastatic, castration-resistant prostate cancer** | Completion of current Phase 2 study |

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# Managing the Opportunity

# Managing the Opportunity

Putting an experienced team in place, both at executive and Board level

Having experienced advisors, both CRO and Medical Advisory Boards (both Australian and U.S.)

Proposed dual U.S. listing H1 2020 + IPO to raise funding for extensive clinical trial program

Major PR/IR effort planned for U.S. Q4 2019 and Q1 2020 around Nov 2019 clinical data

Flexible funding facility (bridging finance arrangement) in place until U.S. IPO, with ability to change

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