ASX Announcement |17 November 2020
Noxopharm Limited (ASX:NOX)

Noxopharm Releases AGM Corporate Presentation

Highlights:

- **Highly valued COLD to HOT anti-cancer function of Veyonda®**
- **Clinical strategy in developing sought-after anti-cancer action**
- **Commercial strategy to unlock shareholder value in shortest, most cost-effective way**
- **Joint participation of NOX and Bristol-Myers Squibb in important pilot clinical study**

Sydney 17 November 2020: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) is pleased to release its updated corporate presentation to be presented at today's AGM at 2.00 pm (AEDT).

The updated keynotes are:

- growing Company awareness (via its own clinical experience and independent laboratory validation) that its first-in-class immunotherapy drug, Veyonda, has the opportunity to transform cancer therapy across many forms of cancer and multiple forms of cancer therapy
- a clinical development strategy that seeks to exploit this opportunity
- a commercial strategy that seeks to realize shareholder value in the quickest, most cost-effective way
- co-involvement of NOX and Bristol-Myers Squibb (NYSE:BMY) (11th largest global pharmaceutical company at US$145 billion) in a pilot study that will provide guidance on the extent to which Veyonda will help in transforming the immuno-oncology market sector from its current US$30 billion p.a. value, to a projected US$150+ billion value
- the DARRT-2 Phase 2 multinational trial moving closer to patient recruitment
- the pending release of important survival data for the LuPIN study involving combination Veyonda + Novartis's experimental radiopharmaceutical drug
- the NOXCOVID study advances successfully.

Graham Kelly, CEO and Managing Director of Noxopharm, has approved the release of this document to the market on behalf of the Board of Directors.

-ENDS-

About Noxopharm
Noxopharm Limited (ASX:NOX) is an Australian clinical-stage drug development company focused on the treatment of cancer and septic shock.

Veyonda® is the Company's first pipe-line drug candidate currently in Phase 2 clinical trialling. Veyonda® has two main drug actions – inhibition of sphingosine kinase and inhibition of STING signalling. Activity against the former target contributes to its dual-acting oncotoxic and immunotherapy functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies, radiotherapy and immune checkpoint inhibitors. Activity against the latter target provides an anti-inflammatory effect, also contributing to an anti-cancer action, but also potentially blocking sepsis.
Noxopharm also is the major shareholder of US biotechnology company Nyrada Inc (ASX:NYR).

To learn more, please visit: noxopharm.com

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NOXOPHARM
Noxopharm Limited (ASX:NOX)
CORPORATE PRESENTATION
2020 AGM
Discover
Develop
Deliver

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Overview

Veyonda® emerging as major immunotherapy-oncology (I-O) drug

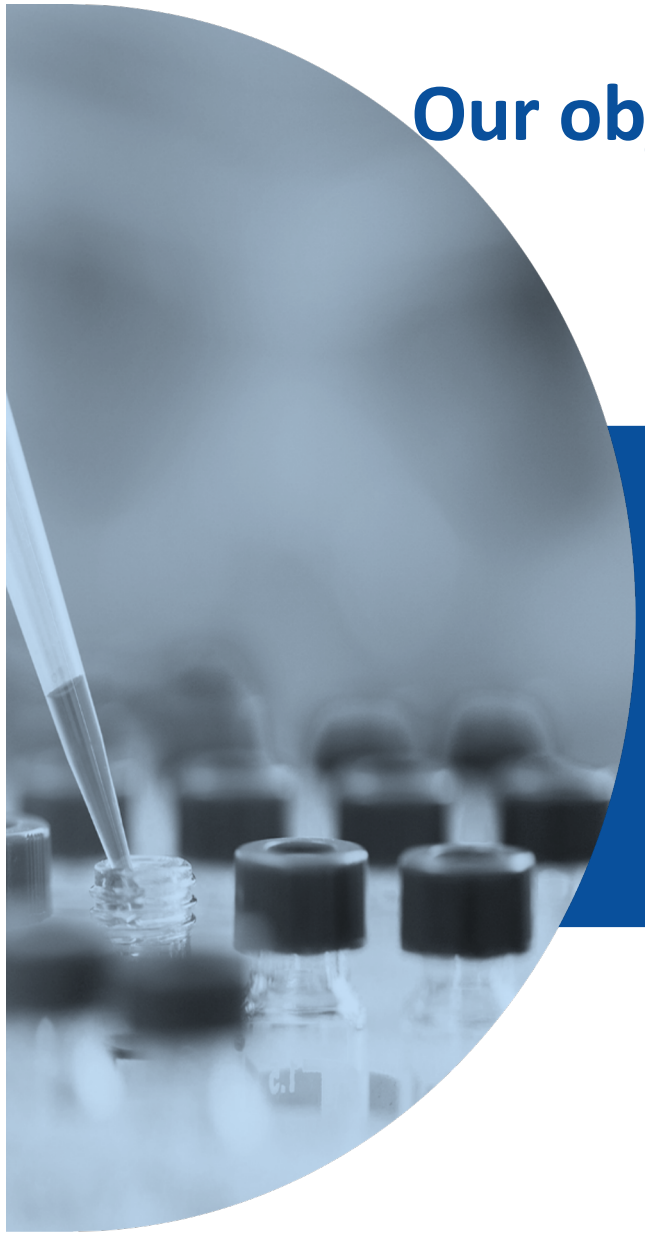
- Confirmed first-in-class anti-cancer actions recognized as major industry goals
- Clinical evidence of anti-cancer responses
- Potential use across most forms of solid cancer

Aim is to make it a key player in transformation of the I-O drug market from current US$30 billion into projected US$150+ billion p.a.

Some realities…….

Responses will vary from none to partial to complete. Objective is in most patients to extend life and to provide a better quality of life in a cost-effective, well-tolerated way

Gold standard proof will require a Phase 2 and at least one Phase 3 study, take 5-7 years and cost at least US$100M. Our goal is end of current round of trialling in 2.5 years.



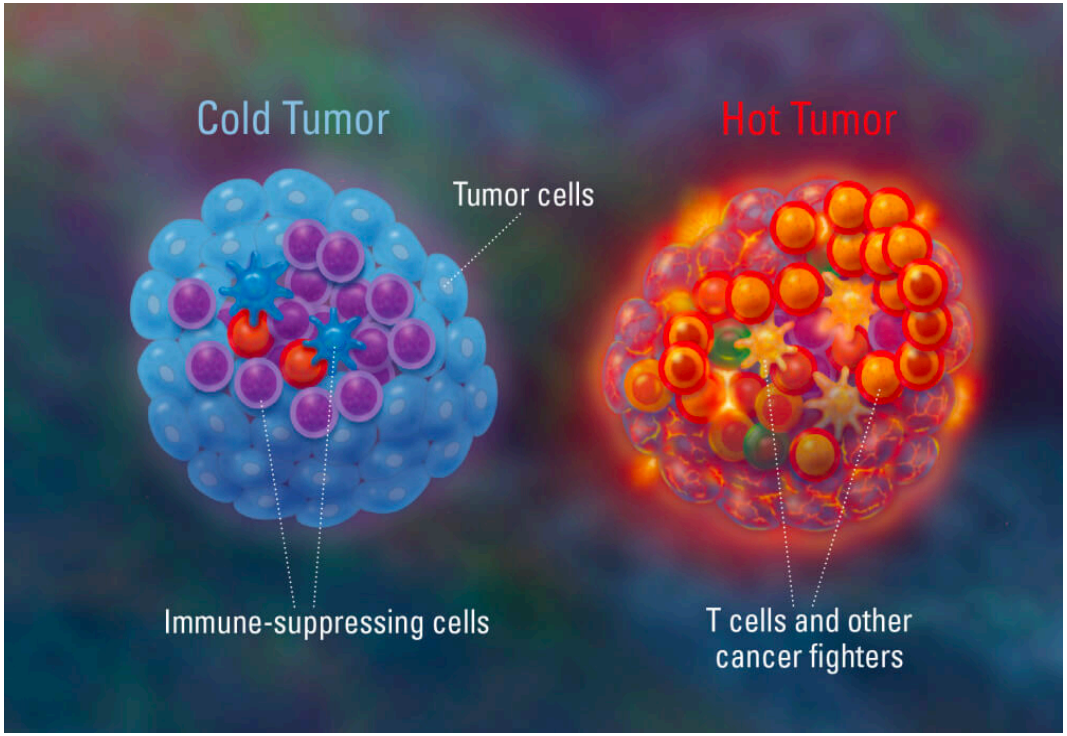
Our objective …….

- ☛ is to prove that **Veyonda®**
- ☛ a first-in-class immunotherapy (based on S1P inhibition)
- ☛ is the answer to unlocking the power of the immune system to fight cancer

Immunotherapy-oncology (I-O) therapy …….

- ☛ aims to restore the body's immune system to fight cancer
- ☛ is the acknowledged future of cancer therapy
- ☛ but with only about 5% of patients responding, current 1st gen I-O therapies are in urgent need of assistance
- ☛ nevertheless has a current market value of ~ **US$30 billion**
- ☛ but with 95% of patients remaining unresponsive, has a projected potential of **US$150+ billion** p.a. if the response rate could be lifted

Converting US$30 B into US$150+ B



Source: Enhancing Immunotherapy: The Race to Make "Cold" Tumors "Hot". https://blog.dana-farber.org/insight/2018/06/enhancing-immunotherapy-race-make-cold-tumors-hot/)

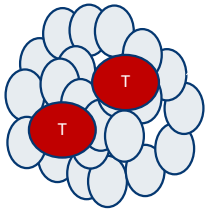
Cancers use a range of tricks to avoid immune attack. Expelling immune cells from the tumour seen as the key one. Referred to as **COLD tumours**

Any attempt by I-O therapy to re-enable the immune system is set to fail if there is no immune function present in the tumour to take advantage

Great majority of human tumours are **COLD,** believed to account for the very high I-O non-response rate

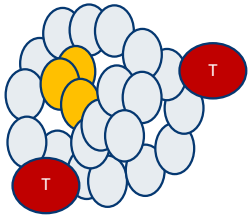
The race is on to find a way of restoring immune function to all tumours.
Known as converting **COLD** to **HOT**

COLD to HOT explained simply



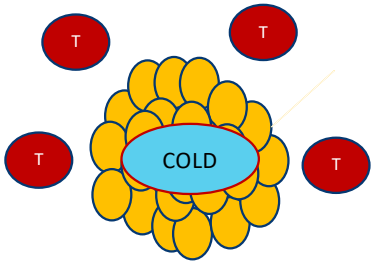
All healthy tissues contain immune cells (T cells) T

whose role is to detect and eliminate any abnormal cells



Emerging cancer cells

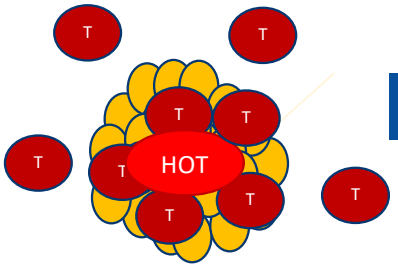
produce high levels of S1P (sphingosine-1-phosphate) that drive the immune cells out of the tissue



With tumour now fully established, ongoing high S1P levels keep immune cells excluded

Cancer cells now free to grow in the absence of immune cells

= COLD tumour



Veyonda is first-in-class inhibitor S1P production by cancer cells

With S1P levels down, immune cells now enter and repopulate tumour

Restored immune function kills cancer cells

= HOT tumour

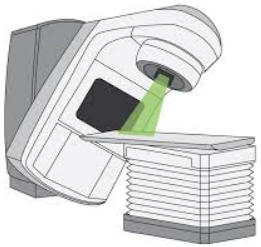
Veyonda® I-O strategy

To use the **COLD** ➡ **HOT** effect of **Veyonda**
to boost the efficacy of two 1st generation I-O therapies in **solid cancers**

Checkpoint inhibitor

→ **IONIC Program**

Radiation



→ **DARRT Program**

Veyonda® IONIC Program

IONIC-1

Veyonda® + checkpoint inhibitor

Bristol-Myers Squibb	**(NYSE:BMY)**
Market cap	**US$145 billion**
Pharma ranking	**11th**
2019 sales	**US$26 billion**
2019 Opdivo sales	**US$8 billion**
2019 Celgene acquisition	**US$74 billion**

Immuno-Oncology With Veyonda® In Combination

Veyonda® + nivolumab (Opdivo®)
(Bristol Myers Squibb)

A study involving both NOX and Bristol-Myers Squibb

Veyonda® IONIC Program

IONIC-1

Veyonda® + checkpoint inhibitor

Clinical objectives:

1. Improve the modest (10-30%) response rates in responsive cancers (eg. lung, melanoma, bladder, kidney)
2. Achieve responses in remaining cancers where Opdivo® not currently used due to very poor response rates (eg. prostate, ovarian, pancreatic, sarcoma etc)

Commercial objectives:

1. To make Veyonda® + Opdivo® combo a standard of care for many cancer types
2. To make Opdivo® the most favored and most valuable checkpoint inhibitor
3. To lift sales of Opdivo® well above current **US$8 billion**
4. **Thereby making Veyonda® a highly prized asset**

A study involving both NOX and Bristol-Myers Squibb

Veyonda® IONIC Program

IONIC-1

Veyonda® + checkpoint inhibitor

Phase I/II study
Investigator-initiated
30 patients
3 Australian hospitals
Early-Q1 2021 start

Two Cohorts:

Cohort 1. Patients recently treated with Opdivo® with mild disease progression

Cohort 2. Opdivo® naive patients

Three End-points:

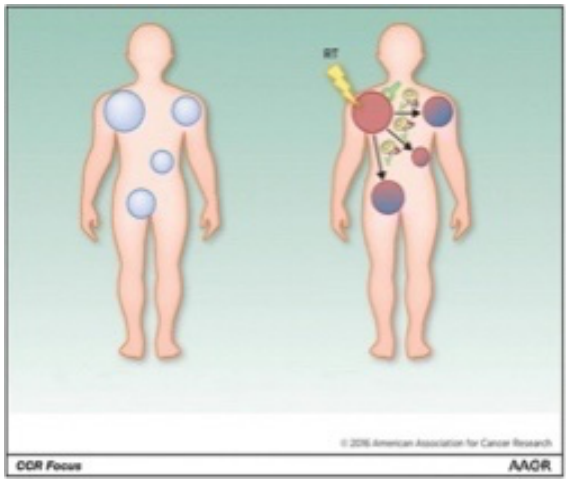
- Safety of Veyonda® + Opdivo® combo
- Clinical response
- Biomarker response

A study involving both NOX and Bristol-Myers Squibb

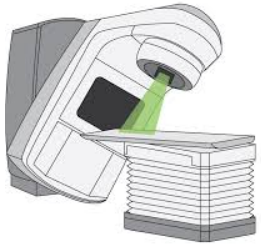
Veyonda® DARRT Program

DARRT Program

Radiotherapy



Direct and Abscopal Response to Radiotherapy



Veyonda® + external beam radiotherapy

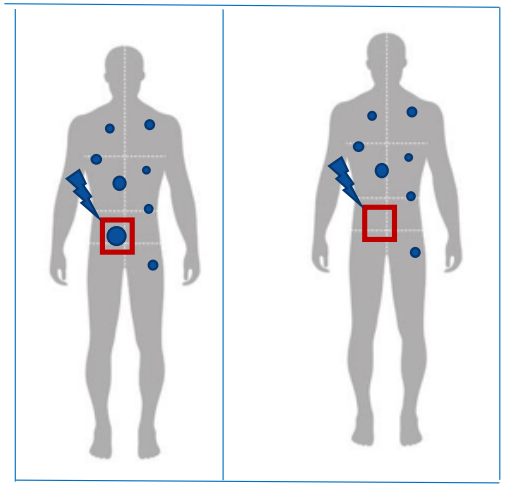
Transforming a local anti-cancer effect of radiation into a whole-of-body anti-cancer effect (**abscopal response**)

Veyonda® DARRT Program

DARRT Program

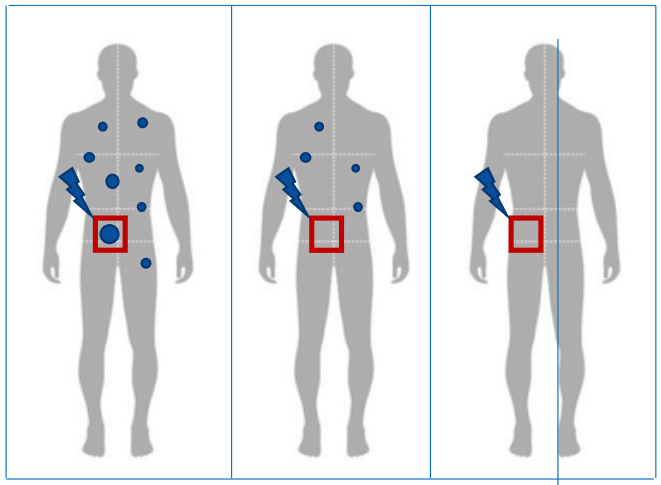
Radiotherapy

4-step DARRT process:
Step 1. Radiation applied to single tumour
Step 2. Radiation activates immune cells
Step 3. Veyonda augments that local immune response
Step 4. Veyonda then spreads that immune response to all other tumours throughout the body



Resolution of Irradiated tumour

Standard response



Partial abscopal response

Complete abscopal response

Abscopal response

Veyonda® DARRT Program

DARRT Program

Radiotherapy

Clinical objectives:

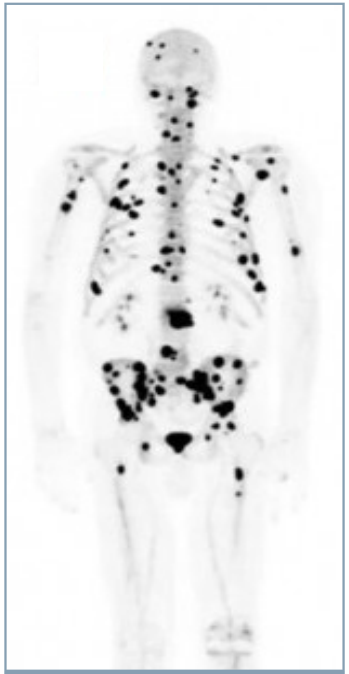
1. To convert the **abscopal response** from a very rare phenomenon (< 1 in 100,000) to a more commonplace event (~50% of cancer patients)
2. To produce long-term remission in metastatic cancers where survival prospects currently are poor

Features of DARRT therapy:

- Very well tolerated treatment
- Highly accessible (external beam RT widely available globally)
- Potential for all solid cancer types
- Expected to be most cost-effective I-O therapy (vs $230K - $1M costs)

Veyonda® DARRT-1 *Completed*

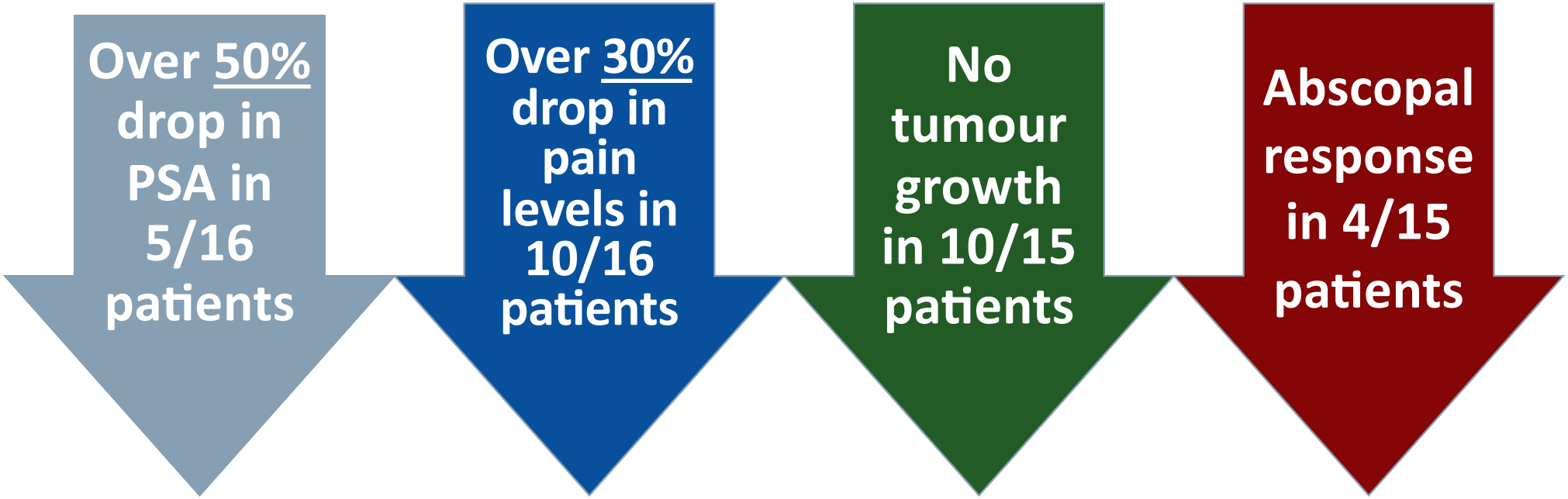
- DARRT-1 **Completed** 25 men late-stage progressive **prostate cancer**
- Metastatic castration-resistant prostate cancer (mCRPC)
- No remaining standard treatment options
- Low-dose (palliative) radiotherapy (RT) to single soft tissue tumour
- Treatment with low-dose RT (5 days) and Veyonda® (14 days)



Bone scan with metastatic disease

Veyonda® DARRT-1 *Completed*

In patients evaluable after 6 months* …..



* 15 patients eligible for RECIST; 16 for PSA and pain

Veyonda® DARRT-2 *Starting 2021*

- Phase 2 study 150 - 200 patients multi-national Parexel CRO
- Late-stage cancer. No remaining standard treatment options
- **Final planning current. Enrolment to start H1 2021**
- Main focus on prostate cancer; exploratory cohort of breast and lung cancer
- Boosted therapy compared to DARRT-1 (up to 2400 mg vs 1200 mg; multiple cycles of Veyonda vs 1 cycle

Secondary questions …….

NOXOPHARM

1. Will **Veyonda®** boost the anti-cancer effect of **^{177}Lu-PSMA-617** in late-stage prostate cancer?

2. Could one of the anti-cancer functions of **Veyonda®** (STING antagonism) be used to prevent **septic shock** in **COVID-19 patients**?

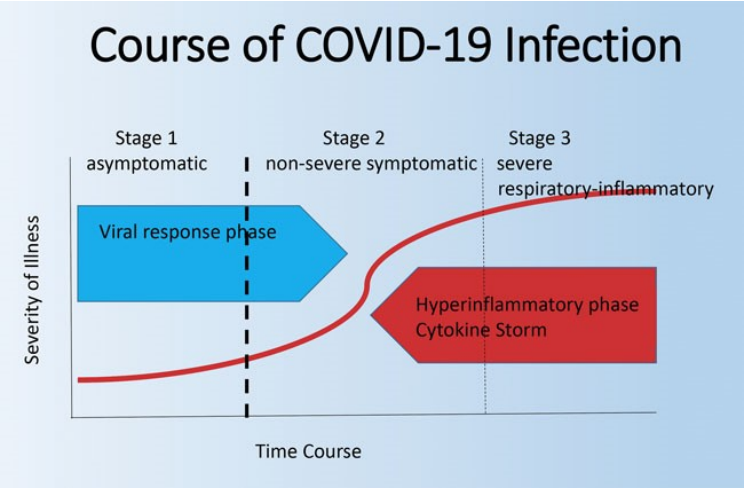
Veyonda® LuPIN program

- **LuPIN program** = **Veyonda** + **^{177}lutetium-PSMA-617** for late-stage prostate cancer
- **^{177}lutetium-PSMA-617** acquired by **Novartis** in 2018 in **US$6 billion** transaction
- **St Vincent's Hospital Sydney** testing ability of LuPIN therapy to boost modest survival effect of Novartis drug alone
- **LuPIN-1 =** Phase 2 study in 56 men with late-stage cancer that has progressed on all forms of therapy
- First report of median overall survival from first **32 men** (**400/800 mg** Veyonda) highly encouraging at **17.1 months**
- Median overall survival from all **56 men** (**400/800/1200 mg** Veyonda) to be reported **Feb 2021**

Veyonda® Septic shock

NOXCOVID-1 Study.
Phase 1 study:

- ~40 patients; moderate lung damage; supplementary oxygen
- Veyonda® treatment for up to 28 days
- Measuring safety, clinical response, cytokine levels



The aim is to use Veyonda® to prevent progression of patients with early-stage lung damage requiring supplementary oxygen, into ICU care requiring mechanical ventilation

pharmorage

NOXOPHARM

Wholly-owned NOX subsidiary focused on novel targets in the STING signalling pathway. Emerging as important new drug target in inflammation and autoimmunity

Collaboration with Hudson Institute of Medical Research and John Curtin School of Medical Research, ANU

Initial focus on a safe, effective treatment for septic shock that is responsible for est. 11 million deaths p.a.

Objectives

Over the next 2.5 years, with a modest investment of shareholder funds, to show that ….

IONIC	**Veyonda increases the response rate to nivolumab (Opdivo) (BMS), establishing its potential to boost checkpoint inhibitor drug sales well above current US$30 billion p.a.**
DARRT	**Veyonda + radiotherapy and the abscopal response is a valid, cost-effective alternative form of I-O treatment for a range of solid cancers**
LUPIN	**Veyonda boosts the response rate in advanced prostate cancer to ^{177}Lu-PSMA-617 (Novartis)**
PHARMORAGE	**The Company's technology platform holds the potential to develop a family of new drugs for the treatment of septic shock, inflammatory diseases and autoimmune diseases**

So building a highly valuable and compelling acquisition/partnering target

Key Metrics

Number of Shares	**213.24 M**
Outstanding options	**76.38 M ($0.30-$1.19) (expiry 27/11/20 – 16/12/23)**
Board shareholding	**19.8%**
Share price	**A$0.64** (16 Nov 2020)
Market cap	**A$135 M** (16 Nov 2020)
Cash position	**AU$3.9 M** (30 Sept 2020) [*R&D Rebate >$4M due Q4*]

Discover  Develop  Deliver 

NOXOPHARM

A second generation I-O therapy to transform the management of cancer

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