



Date: 8 November 2018

Sydney, Australia

ASX: NOX

Noxopharm Limited

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NOX releases latest corporate presentation

- **Highlighting Veyonda® as a radio-enhancer**
- **R&D and commercial strategies**

Sydney, November 8, 2018. Noxopharm (ASX: NOX) is pleased to release its latest corporate presentation. The presentation is part of an engagement with New York-based public relations advisors, Life Science Advisors, relating to the Company's outreach to the U.S. investment and medical markets.

Graham Kelly, Noxopharm CEO, said, "The Company expects to be releasing clinical data from a number of clinical trials over the coming months. This updated presentation is a step towards keeping the market informed of the Company's growing activities."

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About Veyonda®

Veyonda® (previously known as NOX66) is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to preserve the anti-cancer activity of idronoxil in the body and to enhance its drug-like behaviour. Idronoxil is a kinase inhibitor that works by inhibiting a range of enzymes, pre-eminent among which is sphingosine kinase, a key regulator of cell pro-survival mechanisms, and which is over-expressed in many cancer cells. Idronoxil also is an immuno-oncology drug, increasing the activity of the body's innate immune system (NK cells).

About Noxopharm

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney, Hong Kong and New York. The Company has a primary focus on the development of drugs based on an isoflavonoid chemical structure. Veyonda® is the first pipeline product, with 3 other drug candidates for non-oncology indications under development in a subsidiary company.

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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

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NOXOPHARM

ASX: NOX



DISCOVER



DEVELOP



DELIVER

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Noxopharm At-a-Glance

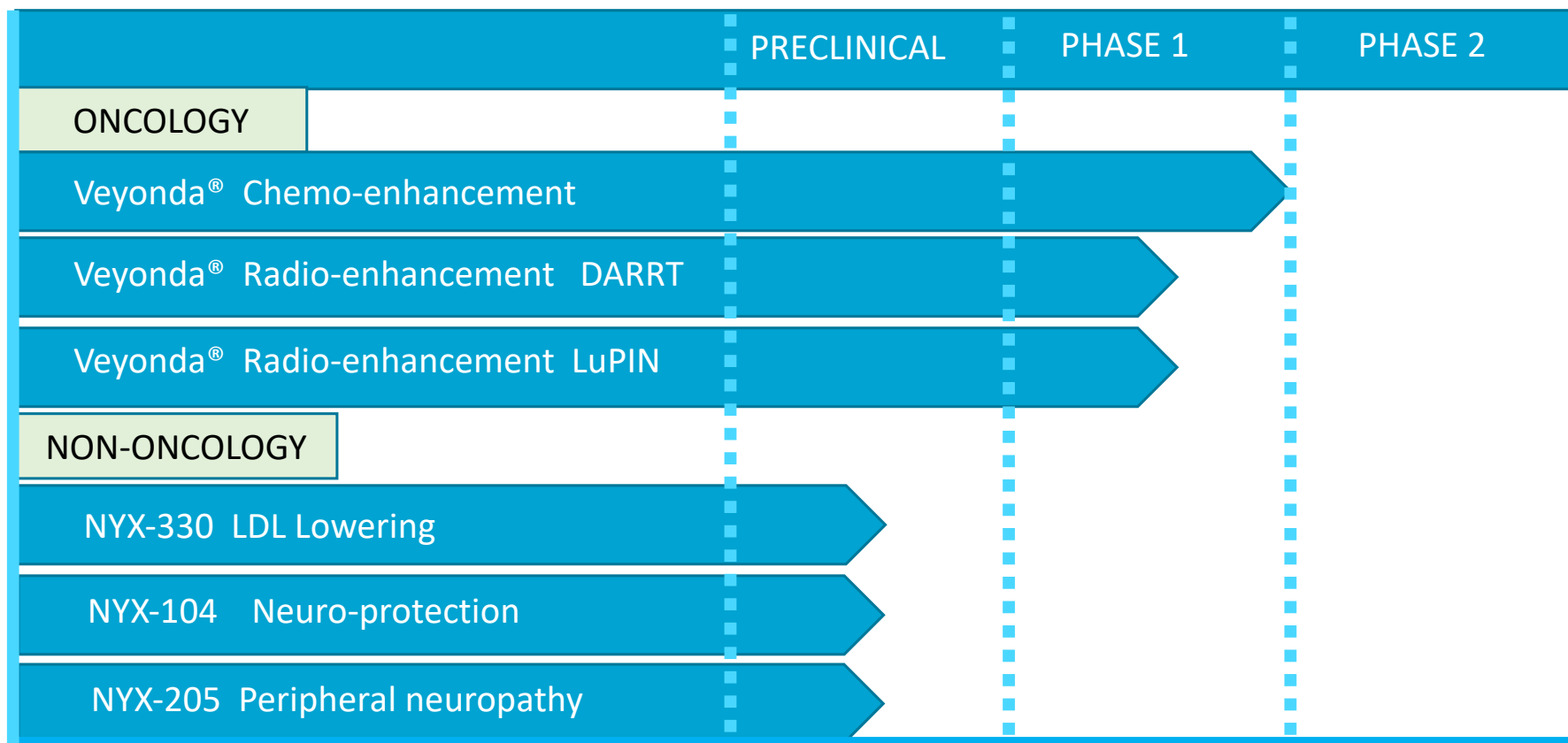
- Australian biotechnology company
- Offices Sydney, Hong Kong, New York
- Aim to bring Veyonda[®] to market in 2022 as first-in-class *dual-action radio-enhancing/immuno-oncology drug*
- Listed Aug 2016: ASX (NOX)
- Market cap: AUD\$53 million

PIPELINE OF 1 CLINICAL AND 3 PRECLINICAL DRUG PROGRAMS

Investment Highlights

- Leader in the development of isoflavonoid-based therapeutics, an emerging field of drug development
 - Novel family of G-protein inhibitors blocking key signaling pathways
 - Key proprietary know-how on maximizing drug-like activity
- Targeted applications across multiple therapeutic areas of high unmet need, including cancer, cardiovascular disease, neurodegenerative disease and autoimmune diseases
- Commencing with Veyonda[®], a sphingosine kinase inhibitor that boosts tumor response to chemotherapy and radiotherapy, major unmet needs
- Targeting 2022 for revenue generation through commercialization of Veyonda[®] in first instance as radio-enhancer
- Seasoned management and Board with deep public-company biotechnology experience
 - Founder and CEO, Graham Kelly, previously founded NASDAQ-listed companies - Novogen Ltd and Marshall Edwards Inc (MEI Pharma Inc).

Pipeline



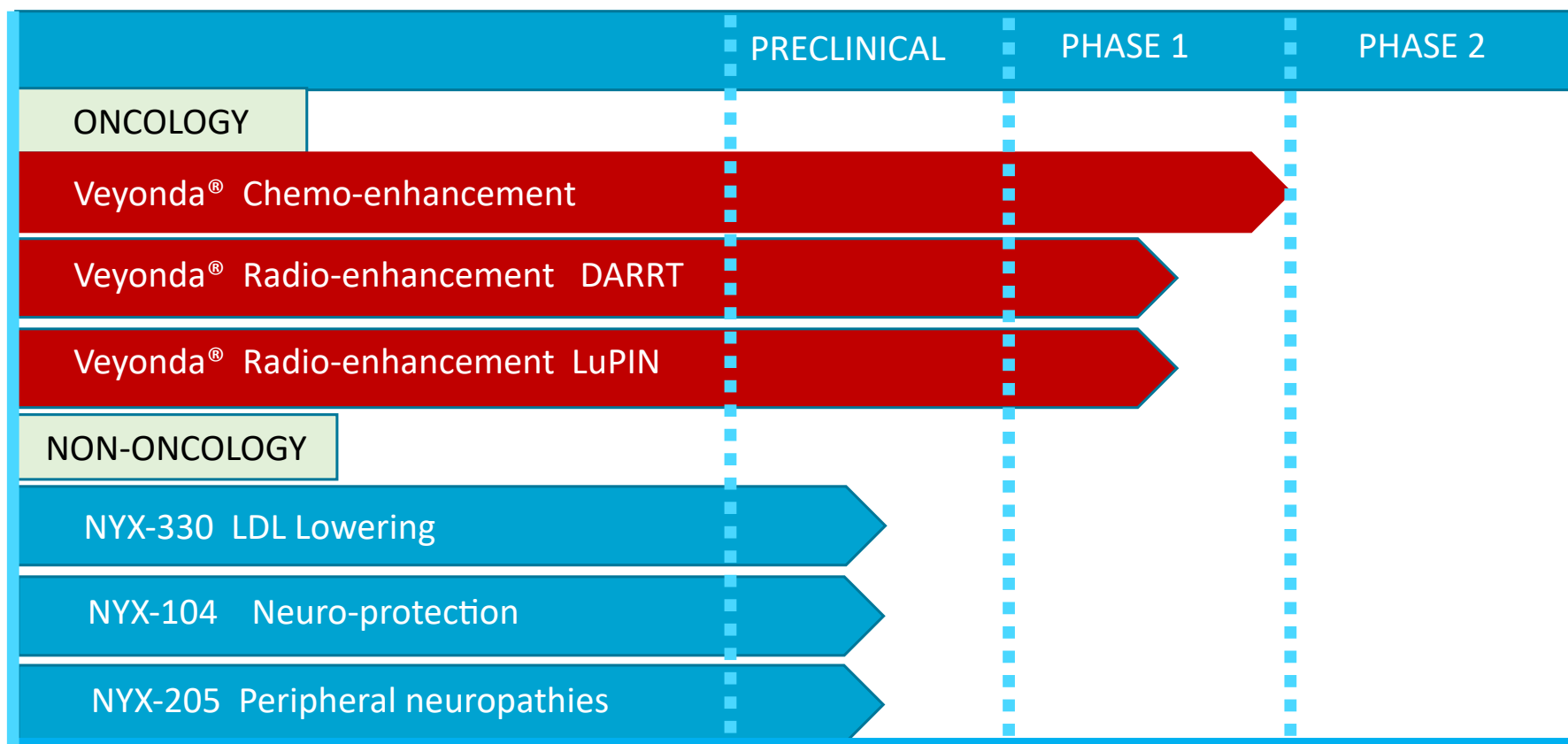
Overall Drug Development Strategy

- NOX to take Veyonda® through the registration process to marketing approval
- Final registration study to start H2 2019 as an enhancer of radiotherapy in late-stage prostate cancer (DARRT program). Objective = marketing approval by 2022
- In 2019 extend DARRT into lung cancer, sarcomas and brain cancer to expand market opportunities and establish Veyonda® as standard-of-care radio-enhancer
- Confirm use of Veyonda® as enhancer of Lu-PSMA (Endocyte Inc) therapy in prostate cancer ahead of anticipated marketing approval of Lu-PSMA in 2022
- Conduct Phase 2 study of Veyonda® as an enhancer of chemotherapy for patients where cytotoxic chemotherapy is considered inappropriate for safety reasons, further establishing the broader utility of this drug candidate
- Establish NOX as traditional biopharma company by extending the pipeline beyond oncology into a wide range of non-oncology indications

Overall Commercial Strategy

- NOX to remain an independent biopharma company based on proprietary IP enabling the development of a new class of drugs across a range of degenerative diseases
- Establish marketing collaborations with larger companies for larger markets
- NOX to retain some rest-of-world territories for itself
- Hong Kong office established ahead of clinical and commercial activities in China
- New York office established to raise profile of Company in the US investment and medical/patient sectors

Oncology Pipeline



Standard Radiotherapy – good but needs help

- **Pros:**

- Radiotherapy is an effective anti-cancer treatment that is potentially curative if used sufficiently early
- Short course, usually well tolerated, relatively inexpensive

- **Cons:**

- Radiation sickness caps amount and number of courses
- Lacks specificity → toxicity and damage to healthy tissue
- Restricted local use → ineffective against widespread metastases
- Relatively ineffective against larger tumors

= typically palliative use only in advanced cancers



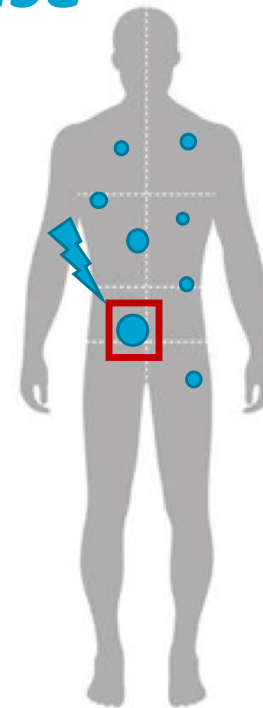
... that help now on offer in the form of a phenomenon known as an *Abscopal Response*

- ▶ An **ABSCOPAL RESPONSE** is a response to radiation in tumors **outside the field of radiation**

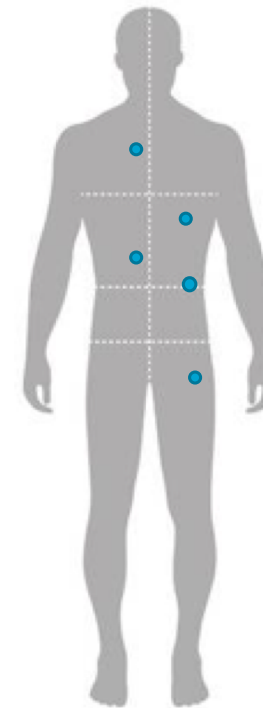
An abscopal response refers to an anti-cancer effect on non-irradiated lesions involving the following response spectrum:

- **stable disease** - <30% shrinkage; no new tumors
- **Partial abscopal response** - >30% shrinkage
- **Complete abscopal response** - no tumors evident
- **A mixture in the one patient of all of the above**

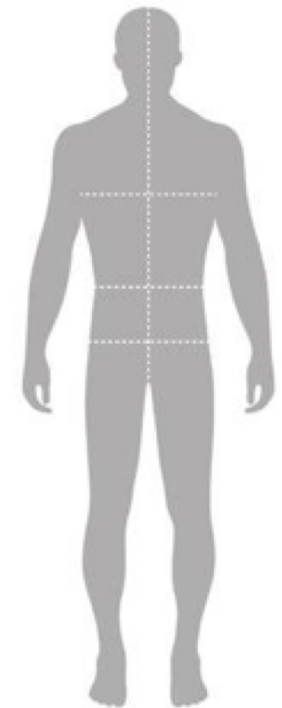
- ▶ The mechanism of the abscopal response remain unknown but is believed to involve both immunological and epigenetic (miRNA) components



Radiotherapy for single tumor



Partial abscopal response



Complete abscopal response

Abscopal Responses Now Can Be Deliberately Induced

Abscopal responses now recognized as a likely quantum leap forward in the treatment of cancer.

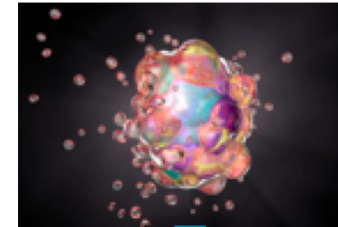
Up to 2005, very rare phenomenon

The introduction of immuno-oncology (i-o) drugs including PD-1 and PD-L1 inhibitors has increased the frequency of abscopal responses

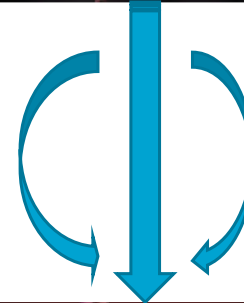
Exciting data shows combining i-o drugs with radiotherapy results in abscopal response rates of between 20-25% in certain cancers

Noxopharm believes that Veyonda[®] will surpass the abscopal response benefits seen with i-o drugs because:

- a) Veyonda[®] has multiple mechanisms of action, and
- b) Veyonda[®] is active across a broader spectrum of cancers.



Cancer cell damaged by radiation and dies



... releasing antigens and epigenetic signals ...

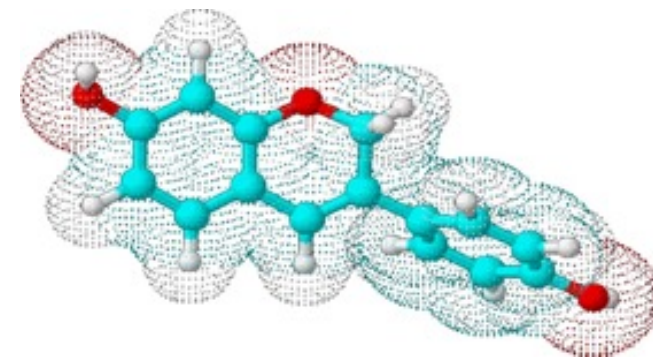


... that activate immune cells (NK cells/T cells) that then attack distant cancer cells.

IDRONOXIL: a multi-acting immuno-oncology drug

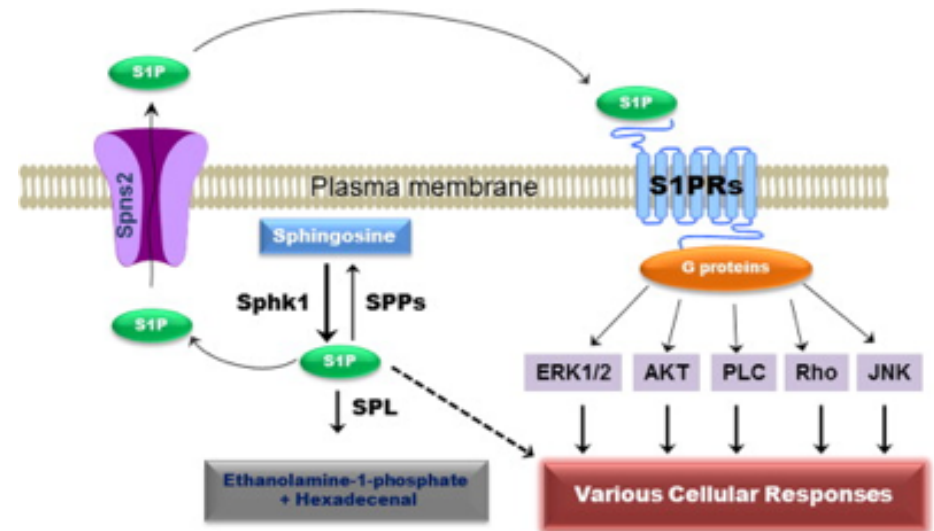
Idronoxil (Veyonda[®] active ingredient) works in 3 ways:

1. Idronoxil kills cancer cells on its own (*activates apoptotic pathways*)
2. Idronoxil enhances the cancer-killing effect of radiotherapy:
 - By increasing chromosomal damage from radiotherapy by holding cells at a stage of mitosis(G₂M) where they are most vulnerable to radiation
 - By blocking the cancer cell's ability to repair radiation-induced DNA damage by blocking DNA repair mechanisms
3. Idronoxil stimulates the body's innate immune system (NK cells)



IDRONOXIL: Cancer-specific Inhibitor of Sphingosine Kinase

- **Sphingosine kinase** is a primary regulator of pro-survival and growth signaling pathways
- Sphingosine kinase highly expressed in most cancers
- Idronoxil specifically **inhibits sphingosine kinase**, resulting in downstream inhibition of:
 - Cyclin dependent kinases (CDKs) = **mitotic arrest**
 - PARP-1, PARP-2, and topoisomerases 1 and 2 = block **DNA repair**
 - AKT, PI3K and mTOR pathways = inhibit multiple pro-survival pathways = **apoptosis**
- Idronoxil does **NOT** inhibit sphingosine kinase in **healthy cells**



Idronoxil: Additional Immuno-oncology Mechanism

In addition to its radio-enhancing activity, idronoxil also works through an additional immuno-oncology mechanism

Idronoxil activates the innate immune system (monocytes and natural killer cells)

Natural killer (NK) cells are the body's primary defence mechanism against cancer cells



Veyonda® - A Proprietary Formulation of Idronoxil

Veyonda® delivers a proprietary pro-drug form of idronoxil that...

Protects idronoxil from being inactivated by the body's detox enzymes

Increases the half-life of idronoxil from 45 minutes to >10 hours

Veyonda® is a convenient-to-use, self-administered dosage form that preserves idronoxil in a bio-available, active form at therapeutic blood levels over 24 hours.



Veyonda® - A First-in-Class Radio-Enhancer AND Immuno-Oncology Drug

Veyonda®:

Selectively enhancing radiation only in cancer cells, sparing healthy normal tissue

Increasing the cancer cell-killing effect of radiation 2-3 times

Working effectively across a broad spectrum of cancers

Well tolerated in combination with radiotherapy

Objective is to make Veyonda® a standard co-treatment with radiotherapy

Well tolerated:

Combination (Veyonda® + radiotherapy) tested to date in 38 patients with no dose-limiting toxicity

Short course of treatment for increased safety and reduced cost:

5 days of radiotherapy; maximum 21 days of Veyonda®

Use with palliative dosages of radiotherapy:

Allows radiotherapy to be used for tumors in sensitive tissues (e.g. spine, heart)

Potential use across the cancer spectrum:

Idronoxil active in the laboratory against all forms of cancer tested

Readily crosses blood-brain barrier:

Able to be tested for primary and secondary brain cancer

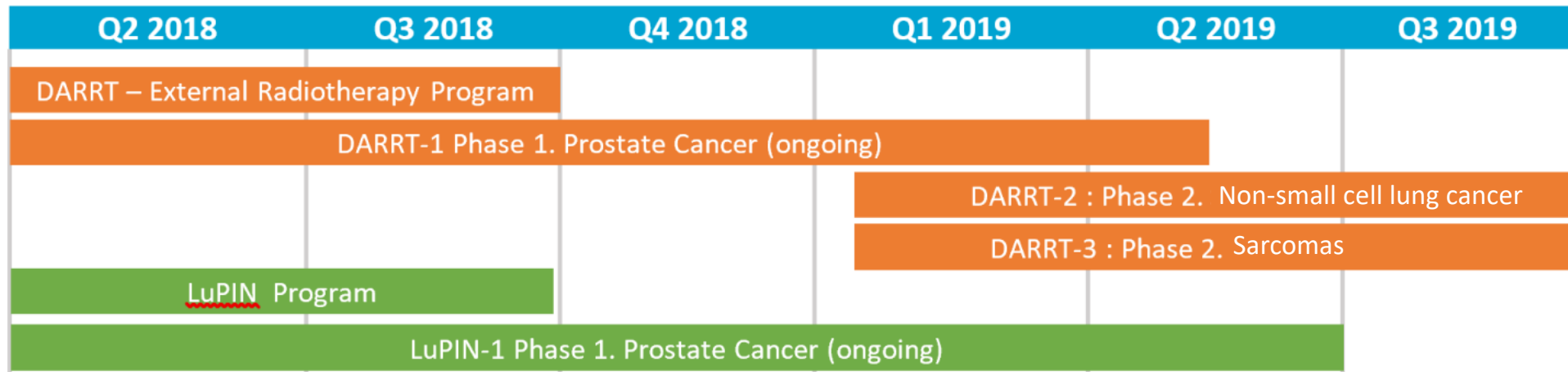
Veyonda[®] - Currently Being Evaluated as a Radio-enhancer in Two Clinical Programs

Veyonda[®]

DARRT - **D**irect and **A**bscopal **R**esponse to **R**adio**T**herapy

LuPIN - ¹⁷⁷**L**utetium-**P**SMA-617 **I**n Combination with Veyon**d**a

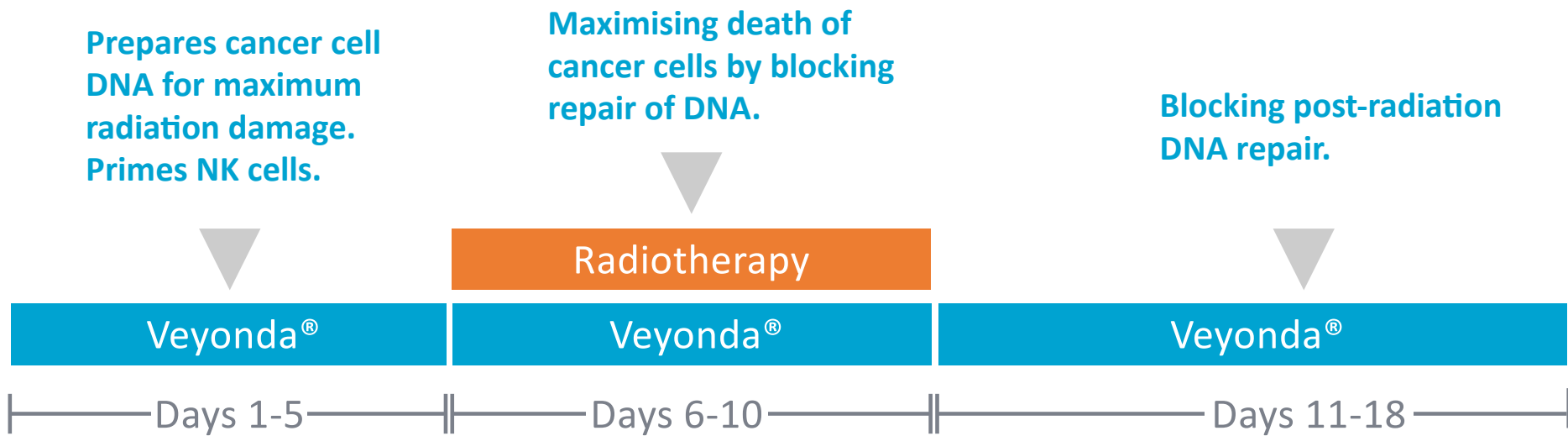
18-Month Development Plan



DARRT – A treatment regimen intended for patients with late-stage solid cancers who are eligible for palliative radiotherapy

Veyonda®

DARRT



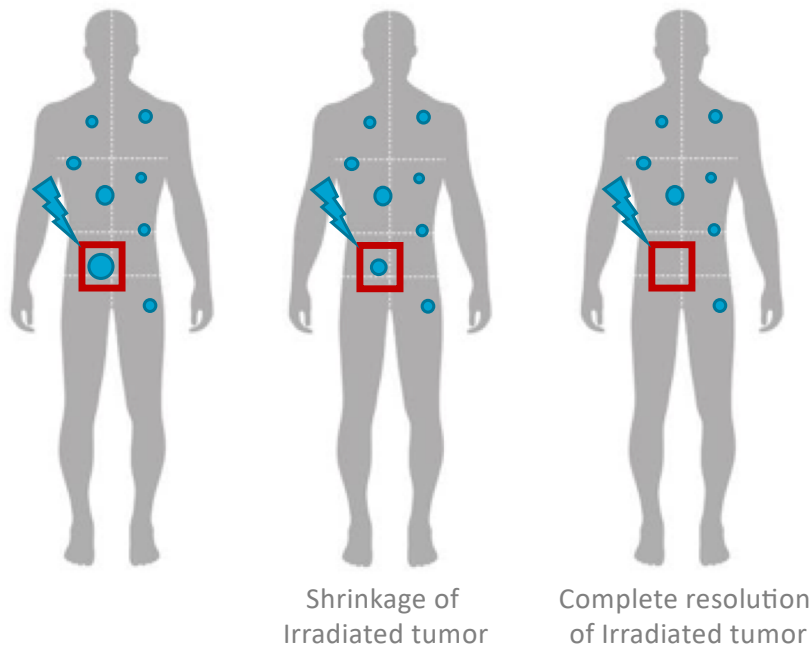
DAART – Anticipated Clinical Benefits

Veyonda®

DARRT

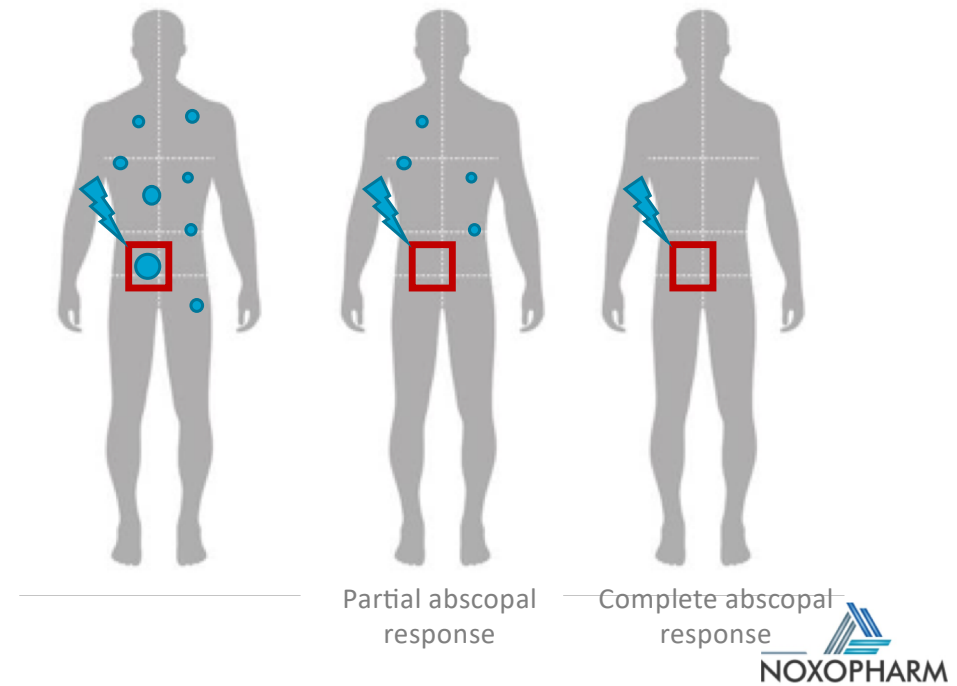
DIRECT RESPONSE

At a minimum, Veyonda® is expected to lead to better DIRECT responses to radiotherapy by functioning as a **radio-enhancer**



ABSCOPAL RESPONSE

The best expected outcome would be an improved DIRECT response, plus and ABSCOPAL response driven by its i-o drug properties



Veyonda[®] projected to provide meaningful survival benefits

Veyonda[®]

DARRT

		+ Veyonda [®]	+ Veyonda [®]
	Palliative radiotherapy only	Effect limited to irradiated tumors	Effect on irradiated + non-irradiated tumors
CLINICAL BENEFIT	Symptoms (pain)	+	+++
	Quality of Life	+	+++
	Time to disease progression	+	+++
	Overall survival	+	++++

NOTE: Palliative radiotherapy alone intended to relieve symptoms such as pain; it is not expected to deliver anything more than a temporary and minor effect on disease progression

DARRT-1: Phase 1b clinical trial evaluating the safety and efficacy of Veyonda® in men with late-stage prostate cancer eligible for palliative radiation for pain and symptom management

Veyonda®

DARRT

► Combining Veyonda® with palliative radiotherapy to determine:

- Safety across three dose cohorts (400, 800, 1200 mg)
- Determine dosage for Phase 2/3 registration study
- Signals of efficacy to support expansion of trial to additional solid tumor indications (lung, sarcoma)
- Secondary endpoints include:
 - *Longer progression-free survival (through stable disease or abscopal response)*
 - *Change in tumor size in target irradiated or non-irradiated lesions measured by RECIST*
 - *PSA response*

Aim of the DARRT regimen is to slow or stop cancer progression to deliver a meaningful survival benefit

DARRT-1 Prostate Cancer: Early clinical Evidence of Halt to Disease Progression

Veyonda[®]

DARRT

Cohort 1: 400 mg Veyonda[®]

- 4 patients

12 weeks:

- 3 patients with stable disease
- 1 patient disease progression

Cohort 2: 800 mg Veyonda[®]

- 2 patients
- (+ 2 replacement patients treated but yet to be reviewed)

12 weeks:

- 1 patient disease progression
- 1 patient **partial abscopal response**

Cohort 3: 1200 mg Veyonda[®]

- 1 patient
- (+ 3 patients treated but yet to be reviewed)

12 weeks:

- 1 patient **partial abscopal response**

NOTE: All patients entered study with progressive disease. End-point of DARRT is to increase the time to disease progression which is measured by PSA levels and where even an abscopal response in the form of stable disease is a highly significant outcome for this patient population

Case Study: Example of a Complete Abscopal Response

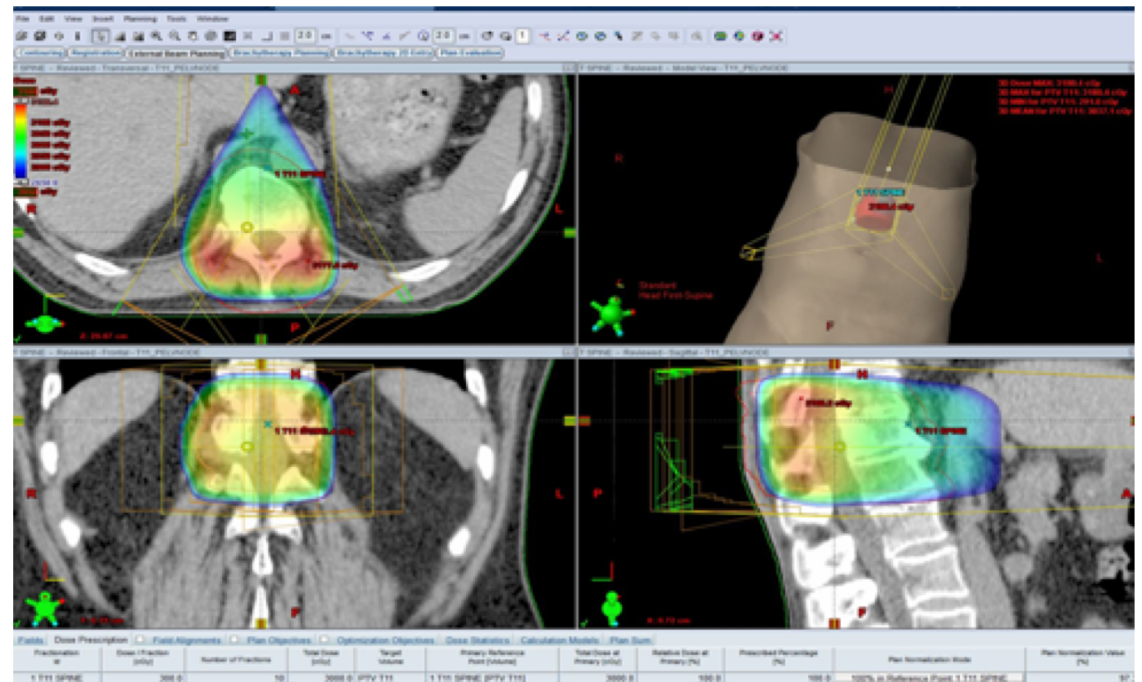
Veyonda®

DARRT

Patient with **metastatic castrate-resistant prostate cancer**. Being treated with palliative radiotherapy for spinal lesions.

Combined with Veyonda® produced a complete abscopal response within 2 months.

After 4 years remains lesion-free and with undetectable PSA levels

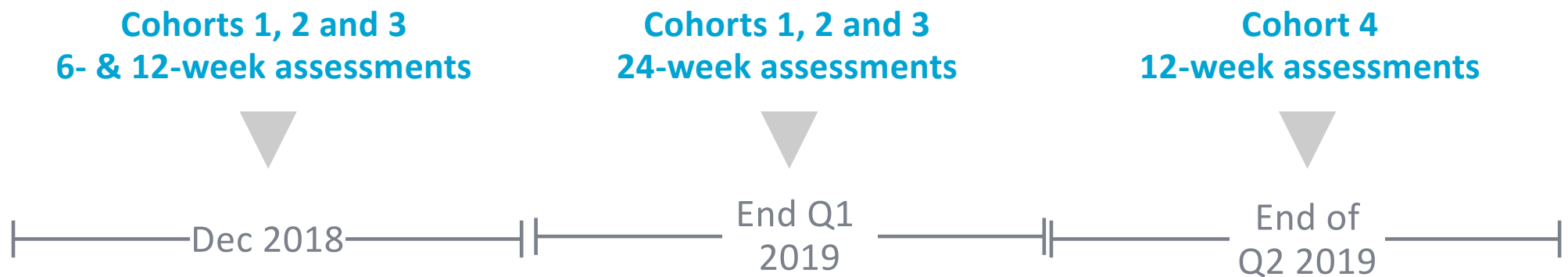


	7/7/14	29/9/14	28/11/14	2/3/15	30/4/15
Total PSA	140	170	13	0.18	0.07

DARRT-1 Prostate Cancer: Data Read-outs

Veyonda®

DARRT



Company planning to report 6-week and interim 12- and 24-weeks data from Cohorts 1-3 by year-end 2018

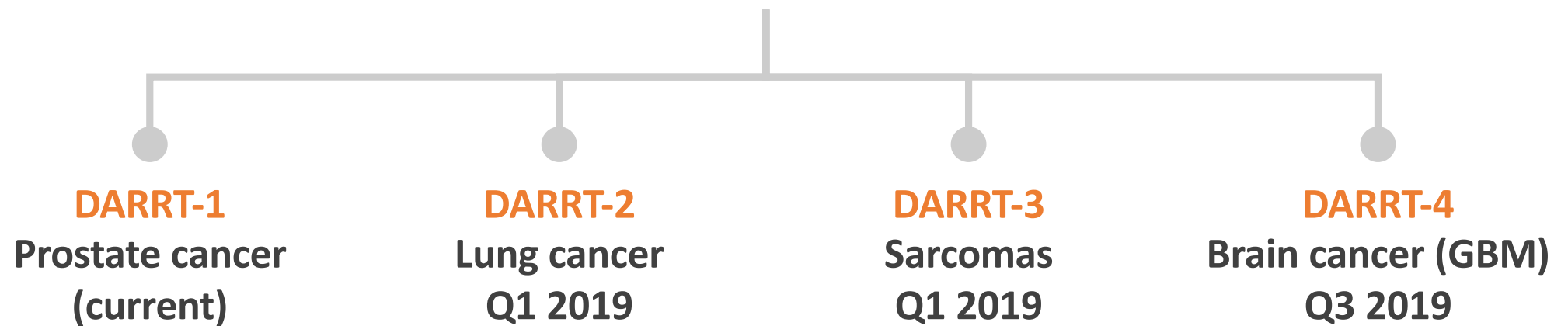
DARRT: Broad Potential Utility In Solid Tumors

Veyonda®

DARRT

PROGRAM STRATEGY 2018/2019

DARRT



Endocyte's Lutetium-PSMA-617 Targeted Brachytherapy for Prostate Cancer

Veyonda®

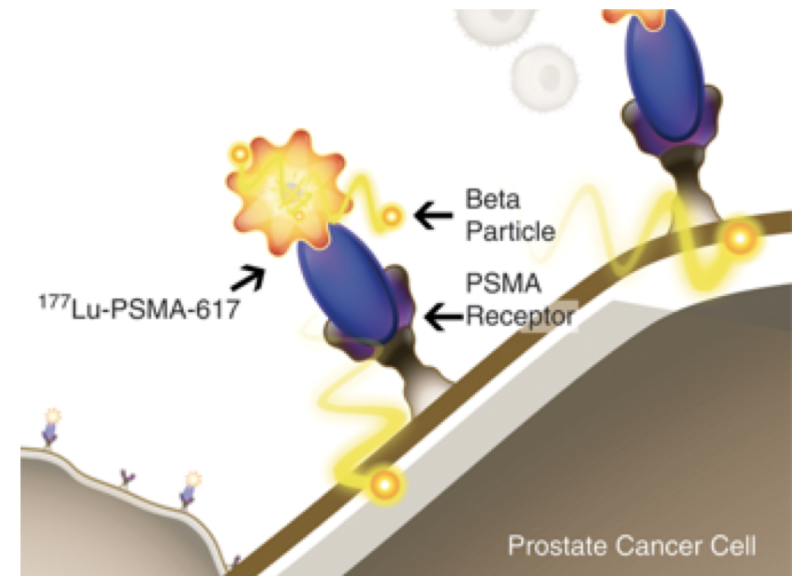
LuPIN

PSMA-617 is a peptide that recognizes and targets prostate specific membrane antigen (PSMA). 85-90% cases of prostate cancer are PSMA +ve

Lu-PSMA-617 links radioactive lutetium isotope to PSMA-617, delivering radioactivity directly to prostate cells and sparing healthy tissue

While a very promising approach, efficacy has been limited:

- Only 1/3 of patients show durable responses
- 2/3 of patients fail to complete 36-week course of treatment due to not responding or relapsing during treatment
- Radiation from ¹⁷⁷Lutetium only penetrates to a maximum of 2mm, limiting efficacy to micro-metastases and being much less effective against larger lesions



NVS-ECYT Deal Shows Growing Interest in Targeted Radiotherapy and Lu-PSMA

Novartis pending acquisition of EndoCyte for \$2.1 billion

Provides Novartis access to **177 Lu-PSMA-617 (Lu-PSMA)** currently being evaluated by Endocyte in a Phase 3 registrational study for metastatic castration-resistant prostate cancer

Australian hospital currently running a **Phase 1b trial** (LuPIN-1) using Veyonda® as a sensitizing agent in combination with ¹⁷⁷ Lu-PSMA-617 provided by EndoCyte



Significant positive potential implications for Noxopharm if Veyonda® is shown to boost Lu-PSMA efficacy

LuPIN: Phase 1b investigator-initiated dose finding study evaluating the safety and efficacy of Veyonda[®] in combination with Lu-PSMA-617 in men with advanced, metastatic prostate cancer

Veyonda[®]

LuPIN

Rationale: That combining Veyonda[®] with Lu-PSMA-617 will:

- **Boost the cancer cell-killing effect of Lu-PSMA-617 including larger tumors**
- **Potentially provide an abscopal response**
- **Improve the response rates to Lu-PSMA-617**
- **Ensure that the majority of men complete their full 36-week treatment course (compared to current 33% level)**
- **Deliver a more durable response that will deliver meaningful increase in survival**

LuPIN-1 Study Design

Veyonda®

LuPIN

Enrollment: Late-stage prostate cancer -metastatic castrate-resistant disease

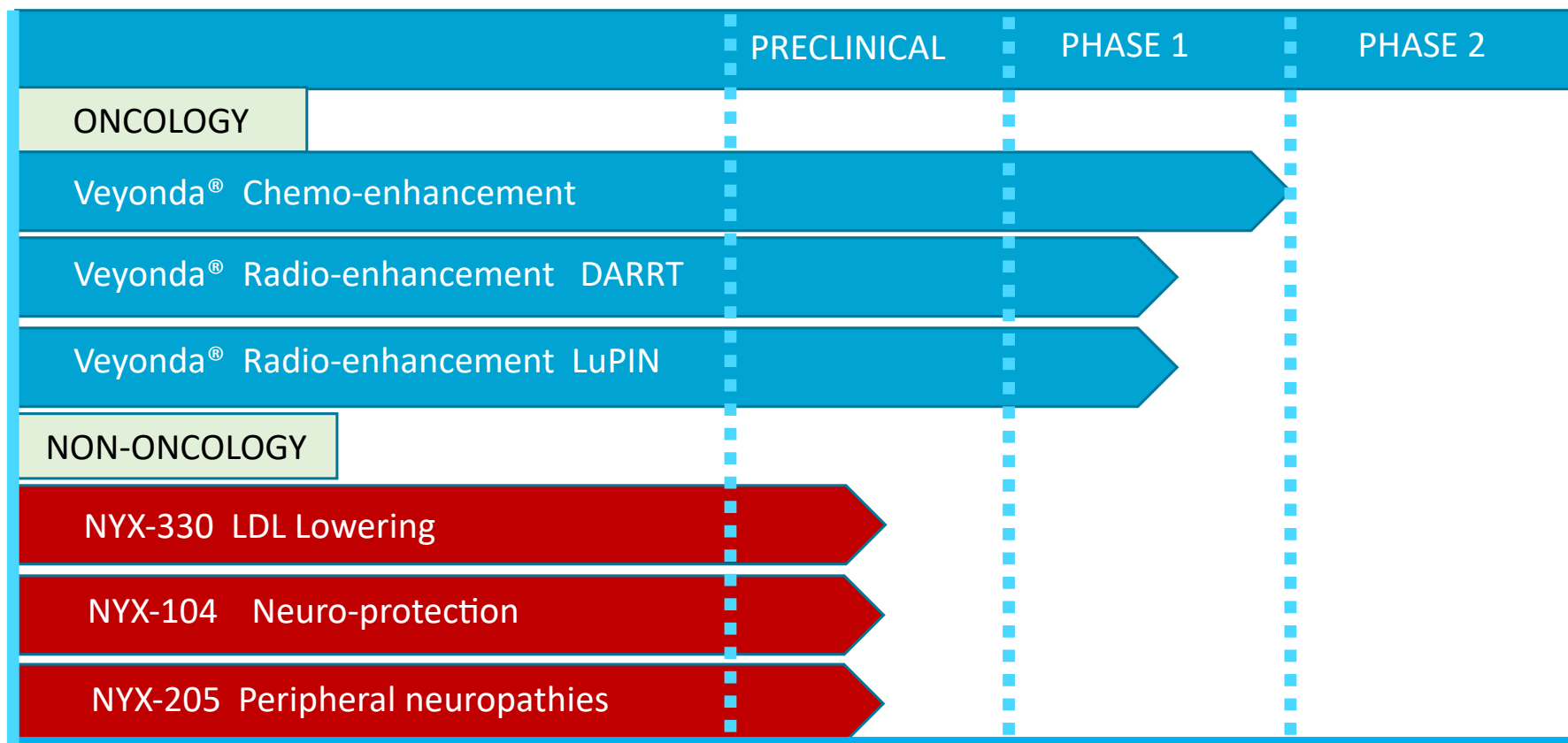
Trial Design: 6 x 6-weekly IV injections of ¹⁷⁷Lutetium-PSMA-617 + 10 days Veyonda® with each injection

Two dosing cohorts: 8 patients 400 mg Veyonda®; 24 patients 800 mg Veyonda®

Two primary endpoints:

- Safety
- Clinical response measured by PSA levels, scans and clinical evaluations at 3, 6 and 12 months

Non-Oncology Pipeline



Three first-in-class drug candidates aiming to meet significant unmet medical needs

NYX-104

STATUS: Lead optimization

First-in-class neuro-protectant

To protect brain from secondary nerve damage caused by excitotoxicity associated with concussion, TBI, stroke and severe epilepsy

Blocks glutamate-induced calcium overload from intra-cellular and extra-cellular sources

Preclinical data demonstrates 56% reduction in excitotoxicity in mouse model of ischemic stroke

NYX-205

Lead confirmed

▶ First-in-class anti-inflammatory for peripheral neuropathy

- ▶ Inhibits all major inflammatory cytokines and thromboxane; spares prostaglandins
- ▶ Readily crosses animal blood-nerve barrier and enters peripheral nerves
- ▶ 200 different causes of peripheral neuropathy
- ▶ Clinical indications(s) currently being evaluated in animal models

NYX-330

Lead optimization

First-in-class small molecule PCSK9 inhibitor

To inhibit binding between PCSK9 and LDL receptor

Potential once a day oral treatment to be used in combination with statins to achieve better control of LDL cholesterol levels

Potential to allow lower statin dosage to avoid negative side effects associated with statin use such as muscle damage and risk of diabetes

Expected Upcoming Milestones

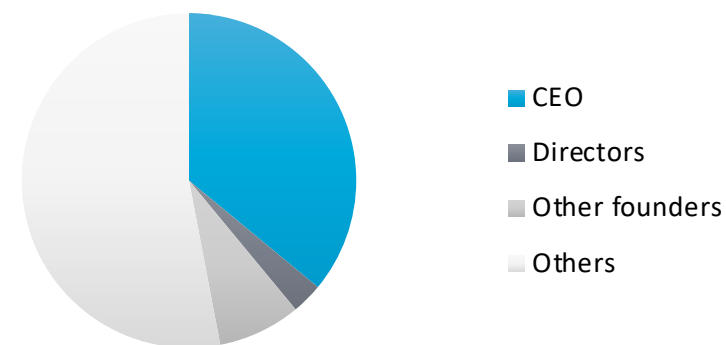
Dec 2018	DARRT 12-week assessments (Cohorts 1,2,3)
1Q 2019	DARRT 24-week assessments (Cohorts 1,2,3)
1Q 2019	Initiation of DARRT-2 (lung cancer)
1Q 2019	DARRT 12-week assessment (Cohort 4)
1Q 2019	Completion of LuPIN-1 enrollment
1Q 2019	Commence planning of DARRT-3 (sarcomas)
2Q 2019	Interim Phase 1 LuPIN-1 results
3Q 2019	Initiation of DARRT-4 (brain cancer)
3Q 2019	Initiation of Phase 2/Phase 3 DARRT-5 (prostate cancer)

Experienced Leadership Team

	Executive	Title	Prior Experience
	Graham Kelly, PhD	Founder and CEO	Novogen, Marshall Edwards Inc (MEIP)
	Greg van Wyk, MD	Chief Medical Officer	Eli Lilly
	John Wilkinson PhD	Chief Scientific Officer (Oncology)	Biotron
	James Bonnar	Chief Scientific Officer (Non-Oncology)	Neuren

Key metrics

Number of Shares	121.9M : Free float 66.8%
Market Cap (1 Nov 2018)	AU\$73M
IPO price	20 cents
12 month high/low	\$1.80/0.48
Average daily turnover	\$0.54M
Cash position	AU\$ 9.6 (30 Sept 2018)





Dr. Graham Kelly

Chief Executive Officer

graham.kelly@noxopharm.com



ASX: NOX



DISCOVER



DEVELOP



DELIVER