Date: 20 May 2019 **Sydney, Australia**

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LuPIN Trial Demonstrates High Rates of Response

- **Data published today describes positive interim results from the LuPIN trial Veyonda® (NOX66) dose-finding study**
- **69% combined PSA response rate is higher than that observed in studies of ^{177}Lu-PSMA-617 alone**
- **75% of men treated with Veyonda® 800 mg and ^{177}Lu-PSMA-617 achieved a PSA response.**

SYDNEY, 20 May, 2019: Noxopharm (ASX: NOX) **('Noxopharm'** or the **'Company'**) is pleased to announce that A/Professor Louise Emmett will deliver an oral presentation of interim results from the LuPIN trial at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2019 Annual Meeting. LuPIN is investigating ^{177}Lu-PSMA-617 in combination with Veyonda® in men with late stage metastatic castration-resistant prostate cancer (mCRPC)

An abstract of this data has been published on the SNMMI website and will shortly be published in the *Journal of Nuclear Medicine*.

Details of the oral presentation are as follows:

Title: Interim results of a Phase I/II prospective dose escalation trial evaluating safety and efficacy of combination ^{177}Lu-PSMA-617 and NOX66 in men with mCRPC post-androgen signaling inhibition and 2 lines of taxane chemotherapy (LuPIN trial)

Presenter:	Associate Professor Louise Emmett
Date:	25 June 2019
Time:	8:30am-8:40am
Oral presentation #:	1560
Poster/Abstract #:	465

Summary

The aim of the LuPIN study is to see if Veyonda® can increase the response rate to ^{177}Lu-PSMA-617 in men with late-stage mCRPC, where more than 50% of men on ^{177}Lu-PSMA-617 alone reportedly show disease progression (relapse) before completing the full course of treatment.

With tumour shrinkage or stablisation and improvement of quality of life the primary objectives in end-stage disease, Veyonda® is being used to see if its radio-enhancing and immuno-stimulatory properties will increase both the rate of response (more men able to complete the full course of treatment) and the durability of the response (longer time before disease progression), end-points that the Company believes are key to this radiopharmaceutical treatment being widely adopted by patients and the medical profession.

The data reported in the abstract is an interim report on the first 16 subjects, all of whom have received $\geq$ 2 doses of ^{177}Lu-PSMA-617, with 4/16 having already completed the planned 6 cycles. The first eight men received 400 mg of Veyonda®, and following a safety data review, the dose for patients 9-16 was escalated to 800 mg of Veyonda®.

At this interim stage of the trial, the effect of Veyonda® is being measured by its effect on the PSA response rate (a standard FDA-recognised measure of response in prostate cancer, defined as a >50% overall reduction in PSA) and its tolerability and safety profile.

The PSA response rates for 400mg (8 patients) and 800mg (8 patients) dosages of Veyonda® were 62.5% and 75%, respectively, producing an overall PSA response rate of 69% across the 16 patients. The response rate overall (69%) and particularly the response rate in the 800 mg cohort (75%) compare favourably with PSA response rates of ^{177}Lu-PSMA-617 alone, ranging between 31 and 61%, in 10 published trials[1,2,3,4].

To date, this apparent increased response rate has been achieved in a generally well-tolerated way, with only one severe adverse event (pneumonitis) being reported.

Background and comments

^{177}Lu-PSMA-617 is an experimental radiopharmaceutical comprising a peptide that delivers the radioactive isotope, ^{177}lutetium, to prostate cancer cells. Radiopharmaceuticals are a means of delivering radiotherapy broadly throughout the body.

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[1] The Lancet Oncology Jun 2018, 19 (6) 825-833; DOI: 10.1016/S1470-2045(18)30198-0

[2] Journal of Nuclear Medicine Aug 2016, 57 (8) 1170-1176; DOI: 10.2967/jnumed.115.171397

[3] Journal of Medical Radiation Sciences Mar 2017, 64 (1) 52-60; DOI: 10.1002/jmrs.227

[4] Clinical Genitourinary Cancer Feb 2019, 17 (1) 15-22; DOI: 10.1016/j.clgc.2018.09.014

^{177}Lu-PSMA-617 has been under assessment on an experimental basis over the past 5 years, mainly in Germany and Australia, in several thousand men with end-stage prostate cancer with no remaining treatment options. A/Professor Emmett and St Vincent's Hospital have played a key role in that assessment process. ^{177}Lu-PSMA-617 is the subject of a US$6 billion series of acquisitions in 2018 by Novartis.

The LuPIN Study is a Phase 1b study in 32 men with mCRPC where the disease is end-stage and progressing despite treatment with docetaxel, cabazitaxel and either abiraterone or enzalutamide. The men are receiving up to 6 courses of treatment with Veyonda® and ^{177}Lu-PSMA-617 at six-weekly intervals. ^{177}Lu-PSMA-617 is delivered as a single intravenous injection and Veyonda® administered daily on days 1-10 of each cycle.

Greg van Wyk MBBCh, Chief Executive Officer of Noxopharm, commented, "^{177}Lu-PSMA-617 is an exciting investigational therapeutic candidate that enables radiation to reach prostate cancer cells throughout most of the body. While PSA response rates in patients treated with ^{177}Lu-PSMA-617 alone are good, Veyonda is being added to ^{177}Lu-PSMA-617 to explore whether it can increase both the rate of response and the durability of responses. The data released today deals with the first of these two questions and is looking positive, as the patients in the first two LuPIN cohorts appear to be deriving benefit beyond that which would be expected with ^{177}Lu-PSMA-617 alone. We eagerly await results from the next 16 patients in the 800 mg dose expansion cohort to see how all of these patients do over the longer-term."

Graham Kelly PhD, Executive Chairman of Noxopharm, added, "We are developing Veyonda® as an enhancer of radiotherapy across all its forms, including radiopharmaceuticals. One of the main challenges of radiopharmaceuticals is the limit on the amount of radio-isotope that is taken up by the target cancer cells, restricting their anti-cancer effectiveness. Veyonda® is designed to boost that effectiveness, which we are confident will work across the broad use of radiopharmaceuticals in many forms of cancer."

About Veyonda®

Veyonda® (previously known as NOX66) is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil. 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 also activates the body's immune system related to fighting cancer cells.

About ^{177}Lu-PSMA-617

Lu-PSMA is a peptide that attaches to prostate cancer cells via their prostate surface membrane antigen (PSMA) and carries a radioactive mineral isotope (^{177}lutetium) that enters and seeks to kill the cancer cell. An advantage of ^{177}-Lu-PSMA-617 therapy is that it is able to reach prostate cancer cells throughout the body and to deliver radiotherapy in a highly targeted way.

Endocyte Inc (now owned by Novartis) is conducting a Phase 3 registration study of ^{177}Lu-PSMA-617 in men with progressive mCRPC (VISION Study) in the U.S., Canada and Europe involving approximately 750 men.

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® as a dual-acting radio enhancer and stimulator of

immune cell function. Noxopharm also is the major shareholder in a subsidiary company, Nyrada Inc, focused on the development of a number of non-oncology drug assets.

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Forward Looking Statements

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