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Promising Data Leads to Expansion of LuPIN Trial

- **LuPIN trial to recruit additional 24 patients**
- **Additional patients to be treated with Veyonda® 1200 mg**
- **The objective is to see whether the dose-response effect seen to date will lead to even greater response rates**
- **Data from total of 56 patients expected to lay foundation for pivotal registration trial.**

SYDNEY, 23 May, 2019: Noxopharm (ASX: NOX) **('Noxopharm'** or the **'Company'**) in collaboration with St Vincent's Hospital, Sydney, are pleased to announce that the LuPIN trial, which is investigating ^{177}Lu-PSMA-617 in combination with Veyonda® in men with late stage metastatic castration-resistant prostate cancer (mCRPC), is to be expanded to include an additional dose cohort. This dose cohort will comprise 24 men who will be treated with Veyonda® 1200 mg daily for 10 days in combination with ^{177}Lu-PSMA-617. The decision to proceed with the expansion was based on the encouraging results observed in respect to tolerability and interim clinical responses with the 400 and 800 mg dosages in the 32 patients enrolled in the trial to date.

Dr. Greg van Wyk MBBCh, Chief Executive Officer of Noxopharm, commented, "Veyonda® 1200 mg has proven to be well tolerated in combination with external beam radiotherapy, as has the combination of Veyonda 800 mg and ^{177}Lu-PSMA-617 in the LuPIN trial to-date. Combined with the reputation of St Vincent's Hospital, Sydney, as leaders in the field of theranostics, supporting them to be able to expand the trial represents a big step forward in our efforts to ultimately bring Veyonda® to market as a versatile adjunct to radiotherapy in prostate cancer".

A/Prof Louise Emmett, Director of Theranostics and Nuclear Medicine at St Vincent's Hospital, Sydney, "The nominal difference in response rates between Veyonda 400 mg and 800 mg encouraged us to explore the dose effect more robustly by adding a 1200 mg cohort."

The encouraging results materialising from LuPIN are expected to lay the foundations for a pivotal Phase II/III registration trial that the Company hopes will see Veyonda® become a standard of care adjunct to ^{177}Lu-PSMA-617.

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 a cancer cell 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 innate immune system.

About ^{177}Lu-PSMA-617

Lu-PSMA is a peptide that attaches to prostate cancer cells 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.

^{177}Lu-PSMA-617 therapy has been used in over 3,000 men to date on an experimental basis mainly in Germany and Australia. Endocyte 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 in approximately 750 men.

Standard use of ^{177}Lu-PSMA-617 is intravenous administration once every six weeks for 6 cycles. The reported general outcome is that less than 50% of men complete the full course of 6 injections before suffering relapse.

About LuPIN-1

LuPIN-1 is a dose escalation and dose expansion trial of men with mCRPC progressing despite having received docetaxel, cabazitaxel and either abiraterone or enzalutamide. All men enrolled are being administered up to 6 cycles of ^{177}Lu-PSMA-617 at six-weekly intervals. The first eight men received 400 mg of Veyonda® daily on days 1-10 of each cycle. Following a safety data review, the dose for patients 9-16 was escalated to 800 mg of Veyonda®. Once the next safety data review of these 8 patients treated with 800 mg was concluded, an additional 16 patients were recruited at this dose, bringing the total patients recruited to 32 (8 x 400 mg, 24 x 800 mg). The trial now will enroll 56 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 innate immune cell function.

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Forward Looking Statements

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