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Principal Investigator Discusses LuPIN-1 Study

- **Lu-PIN-1 Study two-thirds enrolled**
- **Study testing ability of Veyonda® to boost effect of Novartis experimental drug**
- **Noxopharm to initiate LuPIN-2 study.**

SYDNEY, January 14, 2019: Noxopharm (NOX: ASX) today releases an interview with Associate Professor Louise Emmett, the co-Principal Investigator of the LuPIN-1 Study being conducted at St Vincent's Hospital, Sydney.

LuPIN-1 is being conducted in men with late-stage prostate cancer and involves combination therapy of Veyonda® and an experimental radiopharmaceutical drug, ¹⁷⁷Iutetium-PSMA-617 (Lu-PSMA), previously owned by Endocyte Inc but now owned by Novartis following that company's recent US\$2.1 billion acquisition of Endocyte Inc.

Lu-PSMA treatment is being developed for men with metastatic, castrate-resistant disease who have exhausted all standard treatment options and have limited remaining survival prospects.

The Interview

St Vincent's Hospital and Dr Emmett have been at the forefront of the development of this form of treatment, establishing that when men do respond, they obtain a meaningful survival benefit.

The goal of combining Veyonda® with Lu-PSMA is to raise the response rate by boosting the anti-cancer benefit of Lu-PSMA without causing unacceptable increases in side-effects.

LuPIN-1 is an Investigator-Initiated study, meaning that the study was initiated by the academic team led by Dr Emmett, with both Noxopharm and Endocyte cooperating to make their drugs available. This means that the Hospital has discretion over when it will release the data and has chosen to do so at a major conference mid-year in the U.S. Hospital ethics prevent clinicians revealing interim clinical data before then that could be regarded as market-sensitive.

To date the study has 24 men (of a final enrolment target of 32) under treatment. The combination treatment has proven to be well tolerated, consistent with other clinical studies using Veyonda where there has been a lack of any dose-limiting toxicity. Efficacy is being measured by a number of end-points including maximum PSA responses, pain reduction, the proportion of men who complete their full treatment course, and time to disease progression.

Company comments

Whilst very promising, the effectiveness of current Lu-PSMA therapy is limited by a number of factors such as the amount of ¹⁷⁷lutetium taken up by each cancer cell. Veyonda[®] is being used to convert the effect of even low levels of ¹⁷⁷lutetium into a more potent anti-cancer effect.

Important outcomes being targeted by the Company are (i) an increase in the number of men who will be able to complete their full 6 cycles of treatment, and (b) greater depth of response (>90% reduction in PSA levels). The Company regards both outcomes as key factors in the successful uptake of Lu-PSMA treatment by doctors and patients, as well as the establishment of Veyonda[®] + Lu-PSMA as a standard treatment combination in late-stage prostate cancer.

Dr Greg van Wyk, Noxopharm Chief Medical Officer, said, "As a result of LuPIN-1, we have entered into discussions with our partners about initiating the next stage of the LuPIN program. This will be a Phase 2, randomised, controlled study where we will aim to show a definitive survival advantage compared to Lu-PSMA treatment alone."

"Whilst we are very excited about the progress of the LuPIN program, it is only one of two approaches we are pursuing with Veyonda[®] in radiation therapy. Our DARRT program is another major commitment wherein we are studying the use of Veyonda[®] to boost the anti-cancer effect of externally delivered radiotherapy. In both programs prostate cancer is our key focus, but this year we are accelerating our efforts to study Veyonda[®] in sarcomas, where Veyonda[®] is going to be used in combination with radiotherapy or chemotherapy."

The interview: <https://www.finnewsnetwork.com.au/MediaCenter/MediaCenterMobile.aspx?Site=FNN1441>
can also be found on the Noxopharm website www.noxopharm.com Latest News section

About Lu-PSMA

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

Lu-PSMA therapy has been used in over 3000 men to date on an experimental basis mainly in Germany and Australia. Endocyte is conducting a Phase 3 registration study of ¹⁷⁷lutetium-PSMA-617 in men with progressive, metastatic, castrate-resistant prostate cancer (VISION Study) in the U.S., Canada and Europe in approximately 750 men.

The standard way of using Lu-PSMA is by intravenous injection every 6 weeks for 30 weeks. The reported general outcome is that less than 50% of men complete the full course of 6 injections before suffering relapse.

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 specifically inhibits the ability of a cancer cell to respond to stress such as that induced by radiation, leading to the death of the cancer cell and activation of the body's innate immune system e.g. natural killer (NK) cells.

About Noxopharm

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

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