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NOXOPHARM PROVIDES UPDATE ON NOX66 CLINICAL TRIAL PROGRAM

- **shortened clinical development program**
- **marketing approval and revenue stream targeted for 2021**
- **prostate cancer likely indication for initial marketing approval.**

6 July 2017, Sydney: The Company's NOX66 clinical development timetable and strategy has undergone significant development over the past 6 months. The change is regarded as material, obliging the Company to inform shareholders as well as the broader market.

Key change
The key change is an accelerated timetable built around an aim to be generating a commercial return within 5 years (by 2022). This is possible through a considerably shortened clinical trial program of 4 years.

A 4-year program contrasts with the 8-plus years normally required to bring an anti-cancer drug from the time of treatment of the first Phase 1 patient through to marketing approval. This shortened timetable follows the safety review of patients receiving NOX66 in the first clinical study, combined with growing understanding of the anti-cancer function of NOX66.

It parallels a decision by the Company to manage independently the development of the drug through to marketing approval, thereby optimising the efficiency of development and maximizing the value of its asset.

Shortened 4-year timetable
Generally, drug development involves 3 discrete, consecutive phases:
- Phase 1 (safety; understanding behaviour of drug in the body);
- Phase 2 (indicative evidence of efficacy; provide guidance on design of the final clinical trial);
- Phase 3 (final clinical trial; data submitted for marketing approval).

The NOX66 timetable has been shortened into a 2-step program, with current clinical activities (Step 1) designed to provide combined Phase 1 and Phase 2 evidence.

Step 1 commenced earlier this year when the first patient was treated with NOX66. Over the course of 2017 a further five clinical studies will commence, with these six studies in total recruiting a combined total of 120 patients and providing the early evidence of safety to direct the Step 2 (Phase 3) program. These studies will each progressively complete from February 2018, however the design of the trials and pre-determined analysis points allow for review of data on an ongoing basis. This means that evaluation of clinical evidence will occur at points before the last patient completes a study.

The key milestones in the shortened timetable are as follows:

- end of Q4 2017: preliminary clinical data to provide guidance on the preferred clinical indication
- end of Q1 2018: confirm preferred clinical indication
- end of Q2 2018: complete planning of study in agreement with regulators in key territories; advanced recruitment of sites and investigators.

The Company will report to the market on these milestones as they occur.

Prostate cancer primary target.

The Company has identified metastatic, castrate-resistant prostate cancer as the preferred clinical target for an initial marketing approval, with NOX66 being used as a radio-sensitiser. The aim is to show that NOX66 in combination with a palliative dose of radiation (which normally is provided to offer a patient temporary relief from the pain and symptoms of cancer) can shift the effect of the radiotherapy from a temporary, moderate response, to a stronger, longer-lasting and more meaningful response.

Three of the proposed six clinical studies in Step 1 are focused on this indication. Two of these studies involve radiation delivered externally either by stereotactic body radiotherapy or external beam radiotherapy. The third study combines NOX66 with brachytherapy (internally-delivered radiation) using the experimental product ^{177}lutetium-PSMA.

These 3 studies will enrol collectively up to 60 patients with metastatic, castrate-resistant prostate cancer that has no remaining standard treatment options, but where palliative radiotherapy is able to be used. All 3 studies are well advanced in their approval and set-up processes and are anticipated to commence treatment by the end of August 2017. These 3 studies will be conducted at centres in NSW and Queensland, including 2 teaching hospitals in Sydney.

As an ultimate approved indication, late-stage prostate cancer represents a large market of significant unmet medical need. As the subject of a clinical trial, it is expected that patient enrolment will be relatively rapid. Furthermore, a short duration of treatment (2-3 weeks in the case of external beam radiotherapy) and follow-up within 1-3 months to assess clinical response, means that a clinical trial of up to 20 patients can be completed within 6-9 months.

A successful outcome in late-stage patients also offers the opportunity to test NOX66 as a radio-sensitiser in early-stage patients where radiotherapy is standard first-line treatment following diagnosis of inoperable prostate cancer. Moving the drug into early-stage cancer treatment as quickly as possible is a key strategy of the Company because of its considerable commercial potential.

Other indications

While prostate cancer remains the preferred and most likely indication for initial marketing approval, the Company has adopted a prudent, risk-reduction strategy of testing NOX66 across a range of different types of cancer patients and using it as a sensitiser of both radiotherapy and chemotherapy. This will optimise any decision about the nature of a final Phase 3 study. This approach also creates the opportunity to take NOX66 into a second Phase 3 study to deliver potentially 2 marketing approvals.

An additional 3 studies have already been announced and they remain:

- combining NOX66 with chemotherapy (carboplatin) in patients with solid cancers (breast, lung, ovarian, prostate, head & neck). This study currently has 8 patients under treatment, with the remaining 8 patients in this study scheduled to be recruited by the end of July, 2017;
- combining NOX66 with external beam radiotherapy in patients with solid cancers other than prostate cancer;
- combining NOX66 with both radiotherapy (palliative) and chemotherapy (various types) in patients with solid cancers.

A further study addressing the high, unmet medical need of patients with cancers classified as rare cancers also will commence in late 2017. This study will provide NOX66 in addition to standard therapy (radiotherapy or chemotherapy). The purpose of this study is to provide supportive information for the Company to seek an extended indication for the use of NOX66 for treatment of rare cancers which account for nearly 25% of all newly diagnosed cancers.

The Company also believes that NOX66 represents a significant opportunity to be used in the treatment of primary and secondary brain cancers, and is working with Australian and overseas hospitals with Phase 1 clinical studies in mind. It is anticipated that any clinical studies in this area would commence in 2018.

Available resources

The necessary in-house personnel to plan and run this shortened clinical program are in place, along with the appropriate medical advice. The Company is confident that it has the necessary experience and competencies to deliver on its objectives.

In keeping with all successful drug development biotechnology companies, Noxopharm will require additional funding over the course of the next 12 months to complete this program. The $6M raised in 2016 at the IPO was done on the basis of running 2 Phase 1 studies through to completion in 2018, with a follow-up capital raising at that time to allow the Company to embark on a Phase 2 program.

However, the Company's growing confidence in the safety and efficacy of NOX66 has led the Board to determine that the potential to put the Company on a commercial footing within 5 years more than justifies the expanded clinical trial program and, with it, the need to bring forward the raising of additional capital.

The Company is sufficiently funded to maintain the current level of clinical activity, noting that 2 of the studies are Investigator-Initiated studies that are funded largely by the participating hospitals. However, additional funding will need to be sought before the end of 2017.

The Board also recognises that an accelerated program brings the opportunity of news of clinical data, which, if successful, has the potential to re-rate the Company's market valuation, minimising the dilutive effect of such raising.

About Phase 3 registration studies
A Phase 3 registration study is one that is designed in conjunction with regulatory bodies such as the FDA (in the US), EMA (in Europe) and the TGA (in Australia), where clinical and statistical end-points are agreed on that, if met, normally lead to marketing approval.

About NOX66
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 including sphingosine kinase and PI3 kinase that regulate cell pro-survival mechanisms and which are over-expressed in cancer cells, as well as inhibiting external NADH oxidase Type 2 (ENOX 2) which is responsible for maintaining the transmembrane electron potential (TMEP) in the plasma membrane of cancer cells and whose expression is limited to cancer cells. Inhibition of these enzymes results in disruption of key downstream pro-survival mechanisms including resistance mechanisms, sensitizing the cancer cell to the cytotoxic effects of chemotherapy drugs and radiotherapy.

About Noxopharm
Noxopharm is an Australian drug development company with offices in Sydney, Melbourne and Hong Kong. The Company has a primary focus on the development of drugs to address the problem of drug-resistance in cancer cells, the major hurdle facing improved survival prospects for cancer patients. NOX66 is the first pipeline product, with later generation drug candidates under development. The Company also has initiated a pipeline of non-oncology drugs.

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