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NOX MEETS WITH ADVISORS TO CONSIDER INTERIM NOX66 RADIOTHERAPY CLINICAL DATA

- **DARRT-1 provides evidence of more abscopal responses**

- **Meeting of US Advisory Board in Philadelphia**

Sydney, 8 August 2018 : Noxopharm (ASX: NOX) today provides a shareholder update on the Company's DARRT clinical program.

The company convened a meeting of a US Medical Advisory Board in Philadelphia on Monday August 6th. The Board comprised 10 leading medical and radiation oncologists from major US hospitals. The purpose of the meeting was to consider the early clinical data relating to the DARRT program, and to provide guidance on a strategy of bringing DARRT to market.

DARRT Program

The DARRT program involves using NOX66 to boost the effect of radiotherapy in patients with late-stage cancer who are undergoing palliative radiotherapy. Palliative radiotherapy is where a relatively low dosage of radiation is directed at 1 or 2 tumours to relieve symptoms such as pain or pressure on vital organs. These are patients with metastatic disease who have no remaining standard treatment options, generally have limited survival time, and generally are not expected to gain any significant survival advantage from the treatment.

The DARRT program is studying whether a combination of NOX66 + palliative radiotherapy will lead to a significant anti-cancer effect resulting in a partial or complete response involving the whole body, beyond just the 1 or 2 irradiated tumours, delivering both a significant improvement in survival and quality of life.

The partial or complete response of non-irradiated tumours is referred to as an abscopal response, which the Company regards as the ultimate goal in cancer therapy for patients with metastatic disease, particularly if it is complete and permanent. The Company believes that its DARRT program offers the potential to achieve this without the rigours of chemotherapy, with minimal discomfort to the patient, and to be highly cost-effective.

The Company previously has reported on the first two patients with late-stage cancer to receive NOX66 on a compassionate use basis, one of whom had a complete abscopal response and the other a partial abscopal response. The DARRT program is based on those early promising clinical signals.

DARRT-1 Design

DARRT-1 involves 24 men with late-stage (metastatic castrate-resistant) prostate cancer receiving palliative radiotherapy. The study is being conducted in 2 steps. The first step is a dose-response study with cohorts of 4 men receiving different dosages of NOX66 (400, 800 and 1200 mg daily 2 weeks). The Company anticipates (based on anticipated drug levels in blood) that the therapeutic dose will be between 800 and 1200 mg. In the second step, a final cohort of 12 patients then are to receive the selected NOX66 dosage.

Patients are scanned at 0, 6, 12 and 24 weeks to determine tumour response. An abscopal response is defined as a reduction in the size and number of tumours outside the field of irradiation, with 12-weeks expected to be the time of maximum response; the 24-week scan will provide guidance on the likely durability of the response. Safety is determined on an ongoing basis.

DARRT-1 Results

The first 2 cohorts (400 mg and 800 mg) have completed their 12-week scans; in the 3rd cohort (1200 mg), only the first patient had reached his 6-week scan by the time of the meeting.

- In the 400 mg cohort, no patients are showing an abscopal response at 12-weeks.
- In the 800 mg cohort, 1 patient is showing a partial abscopal response at 12-weeks.
- In the 1200 mg cohort, the first patient in this cohort has reached the 6-week point. This patient is showing a partial abscopal response and with a halving of the PSA count suggestive of a significant decrease in tumour load.

No drug-related toxicity has been reported to date.

The remaining 15 patients are expected to be recruited over the next 2-3 months, with all 6-week scans and PSA results expected to be available by the end of the year.

Comments

Noxopharm CEO, Graham Kelly, said, “So far we have treated 7 patients (2x compassionate use and 5 DARRT-1 patients) with the DARRT treatment program using our anticipated therapeutic dose of 800-1200 mg of NOX66. Four of those 7 patients have shown an abscopal response varying from partial to complete. We now are at the dose we consider our therapeutic dose, with the first patient at that dose showing early signs of a strong anti-cancer effect and an abscopal response, so we have good reason to believe we are on track to achieve the first evidence of this being possible in a reasonable proportion of prostate cancer patients.”

The final 24-week scans in all 24 patients are expected in April 2019, but the Company anticipates having 12-week scans on most patients before the end of this year, allowing the Company to keep its anticipated timetable of commencing a multinational Phase 2 adaptive study in about mid-2019. The Philadelphia meeting was conducted with that timetable in mind. The Company’s projected timetable of gaining marketing approval in 2022 remains.

The meeting also led to a recommendation to extend the DARRT program into additional cancer types including pancreatic cancer, head and neck cancer and primary brain cancer, all cancers associated with aggressive cancers and poor survival outcomes, and where, like prostate cancer, immuno-oncology drugs are proving generally ineffective. The Company now will undertake a strategic review of these opportunities, with investigator-initiated studies and clinical study grants likely to be used to pursue such indications.

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 radiotherapies. Idronoxil also is an immuno-oncology drug, increasing the activity of human mononuclear cells including NK cells.

About DARRT

The Company's DARRT (Direct and Abscopal Response to Radiotherapy) Program aims to test the ability of NOX66 to increase tumour response to palliative dosages of radiotherapy. DARRT patients are those with late-stage cancer that has metastasized, where palliative radiotherapy is being applied to between 1-2 separate tumours to provide relief from symptoms such as pain. The radiotherapy (20-30 Gy) is being applied in 5 fractionated dosages, and the NOX66 administered daily over the course of radiotherapy + 1 additional week.

Two outcomes are being sought: the first is more complete response in the irradiated tumours (direct response); the second is a response in non-irradiated tumours (abscopal response).

About Noxopharm

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney and Hong Kong. The Company has a primary focus on the development of drugs to sensitise cancer cells to radiotherapy and chemotherapy.

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