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FIRST NOX66 CLINICAL TRIAL TO COMMENCE

Sydney, 31 January: Noxopharm Limited announces that its first NOX66 Phase 1a/1b clinical study involving NOX66 has received approval from the Georgian Ministry of Health to begin recruitment.

This first-in-human formal study involves patients with late-stage cancer (breast, ovary, prostate, lung and head and neck) who have failed standard therapies including carboplatin and who have no remaining standard treatment options. NOX66 is being assessed for its ability to overturn the drug-resistance mechanisms developed by cancer cells that enable them to resist all chemotherapy drugs including carboplatin. Apart from seeking to make carboplatin chemotherapy generally more effective, the ultimate objective is to lower chemotherapies such as carboplatin dosages to safer but highly effective levels. The aim is to provide an effective treatment option for patients considered too frail or too elderly to undergo chemotherapy, or for the significant number of cancer patients who currently chose not to undergo further chemotherapy.

This study is an amended version of the study originally meant to start in late-2016. The amendment came about because of data suggesting that it was not necessary to test a third, high-dose of NOX66 as originally proposed. Although causing a 2-month delay to the commencement of the study, the amendment and consequent delay were considered warranted in terms of patient convenience and overall conduct of the study including a potentially earlier completion date. The amendment necessitated re-submission to the Georgian drug regulatory authority, with that approval received today. Recruitment is planned for the last week of February following shipment of drug.

About the Study
Patients will run-in with a 3-week safety and pharmacokinetic Phase 1a arm of NOX66 alone before progressing to the Phase 1b arm of NOX66 in combination with carboplatin. The Phase 1b arm comprises 3 months of low-dose carboplatin, followed if necessary by 3 months of standard-dose carboplatin.

The hypotheses being tested are that:

- NOX66 alone will be well tolerated
- NOX66 will not exacerbate carboplatin toxicity
- NOX66 will reverse resistance to carboplatin, providing meaningful tumour responses where none would be expected, and
- NOX66 will restore carboplatin effectiveness to the point where its dosage can be reduced to a well-tolerated level.

The study also has an adaptive design component that will allow it to be expanded immediately into a Phase 2a study in the event that the above hypotheses are confirmed.

The study is being conducted at 2 hospitals in Tbilisi. A total of 16 patients are to be enrolled in the Phase 1a/1b arms using 2 dosages of NOX66 (2 cohorts each of 8 patients), and potentially a further 20 patients in the Phase 2a arm.

Enrolment is expected to be complete by 3Q 2017. Phase 1 completion milestones to be reported in 2017/2018 are (i) Phase 1 a, (ii) Phase 1b low-dosage carboplatin, and (iii) Phase 1b standard dosage carboplatin.

The study is being managed by UK-based CRO, Clinical Accelerator, and Australian-based CRO, Datapharm Australia.

About NOX66
NOX66 is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to protect idronoxil from being inactivated in the human body by Phase 2 metabolism. The purpose is to ensure that most idronoxil administered remains in an active form rather than as inactive Phase 2 metabolites.

Idronoxil works by cancelling mechanisms (such as PARP 1/Akt) in cancer cells that allow those cells to resist the killing effects of chemotherapies and radiotherapy. Idronoxil targets an external NADH oxidase, ENOX 2, responsible for maintaining the transmembrane electron potential (TMEP) in the plasma membrane. Inhibition of this enzyme causes loss of TMEP and disruption of key downstream pro-survival mechanisms such as PARP 1/Akt/PI3 kinase. ENOX2 is an oncogene whose expression is restricted to cancer cells.

About Noxopharm
Noxopharm is an Australian drug development company with offices in Sydney and Melbourne. 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 in an R&D program.

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