



## **ASX RELEASE**

**10 August 2016**

### **ASX: NOX**

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## **NOXOPHARM PROVIDES UPDATE ON INAUGURAL CLINICAL STUDY**

Noxopharm has completed putting in place the required logistics to enable it to conduct a clinical study of its lead pipeline drug candidate, NOX66, in Europe, commencing before the end of 2016.

The study is designed as a progressive Phase 1a/Phase 1b and prospective Phase 2a and is being conducted at two clinical sites in Tbilisi, Georgia. Georgia has been selected because of the speed with which the study can be recruited, and therefore completed.

UK-based contract research organisation (CRO), Clinical Accelerator, has been appointed to manage the study. Clinical Accelerator specialises in clinical trials management in Central and Eastern Europe.

Data management and statistics will be conducted by Australian CRO, Datapharm Australia Pty Ltd.

A Sydney-based oncologist will act as senior Medical Monitor.

Overall management is in the hands of Dr Marinella Messina, Noxopharm Clinical Affairs Manager.

### **About the Phase 1a/1b/2a Study.**

The Study is designed in 3 steps of NOX66 alone (Phase 1a) and various dosage combinations of NOX66 + carboplatin (Phase 1b) in a range of cancer types involving 15 patients, followed by a specific dosage combination of NOX66 + carboplatin in specific types of cancer (Phase 2a). Using this adaptive design, patients progress through the Phase 1a and Phase 1b arms providing they can tolerate the treatment and are deemed to be receiving a benefit from the treatment. Phase 2a is triggered by meaningful clinical responses in the Phase 1b arm and involves the immediate recruitment of an additional 20 patients involving a maximum of 2 specific tumour types.

All patients will have solid cancers that are unresponsive to standard cytotoxic chemotherapy. The primary objectives of the three progressive studies are (a) to determine the safety and tolerability of NOX66 alone and in combination with carboplatin, (b) to determine if NOX66 is able to reverse resistance to carboplatin in heavily drug-resistant cancers, and (c) to determine if NOX66 will allow the dosage of carboplatin to be lowered to a safer level without compromising its efficacy.

## **About NOX66**

NOX66 is an innovative dosage formulation of idronoxil, a compound that down-regulates pro-survival mechanisms in cancer cells, including the cell's ability to establish and maintain a range of drug-resistance mechanisms. The primary target of idronoxil is tumour-specific external NADH oxidase 2 (or ENOX2), the protein responsible for maintaining the transmembrane electron potential in the cancer cell's plasma membrane. Loss of this potential inhibits the ability of the cancer cell to maintain a wide range of pro-survival mechanisms. NOX66 has been developed specifically to protect idronoxil from Phase 2 metabolism in the human body, thereby intended to increase the bio-availability of idronoxil to cancer cells. The primary clinical indications to be sought for NOX66 are (a) the ability to provide meaningful clinical response to frontline chemotherapies in cancers with high levels of drug resistance, and (b) the ability to lower the dosage of frontline chemotherapies to safer levels.

## **About Noxopharm**

Noxopharm is an Australian drug development company with offices in Melbourne and Sydney. 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.

## **About Clinical Accelerator**

Clinical Accelerator is an independent clinical trial management organisation operating principally in Central and Eastern Europe, Russia, Ukraine and CIS countries. The organisation offers a broad range of clinical trial services together with dedicated patient enrolment support to worldwide clients in the pharmaceutical, biotechnology, nutraceutical and medical device industries. Clinical Accelerator's model of operation is designed to achieve cost-effective and time-efficient implementation of clinical studies for its clients with a firm focus on the quality of clinical trial data.

## **About Datapharm Australia**

Datapharm Australia is Australia's original full service contract research organization, celebrating 30 years in 2017. Services include: clinical trial management, set-up, monitoring, data management, statistical analysis and programming, medical writing, pharmacovigilance and auditing for Phase I to IV studies in over 35 therapeutic areas. Their electronic CRF system facilitates FDA-compliant data collection and smooth study conduct at sites globally.

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## **Forward Looking Statements**

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as "aim", "anticipate", "assume", "believe", "continue", "could", "estimate", "expect", "intend", "may", "plan", "predict", "project", "plan", "should", "target", "will" or "would" or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections and assumptions made by Noxopharm about circumstances and events that have not yet taken place. Although Noxopharm believes the forward-looking statements to be reasonable, they are not certain. Forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond the Company's control that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement. No representation, warranty or assurance (express or implied) is given or made by Noxopharm that the forward-looking statements contained in this announcement are accurate and undue reliance should not be placed upon such statements.