NOXOPHARM NEWSLETTER

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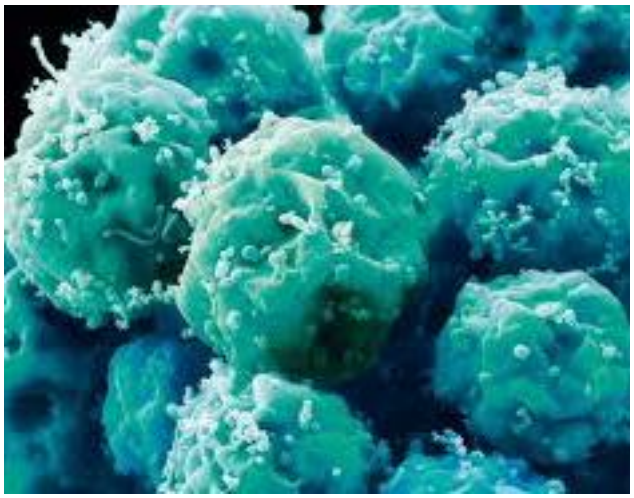
Welcome to the Noxopharm August Newsletter, distributed during the week of the Company's 1st Anniversary since listing on the ASX. The past 12 months have been very productive, and this Newsletter provides a summary of some of that progress, written by members of the Noxopharm staff.



TARGETING RARE CANCERS

By Ian Minns, Director Clinical Dev & Medical Affairs

It is estimated that more than 50,000 Australians will be diagnosed in 2017 with one of the 200 or so cancers classified as "rare or less common (RLC) cancer". These cancers account for only about 25% of all cancers diagnosed, but more than 40% of patients who die from cancer. One of the main reasons for this is that these cancers are under-represented in clinical trials. Individually, the numbers are small, making it more difficult to run clinical trials.

To overcome this, Noxopharm Limited is developing a clinical trial on patients with rare cancers where they can add NOX66 to their standard therapy. This will allow us to collect information on how different rare cancers react to NOX66. We expect this study to take longer than the other trials we are running, but we hope that the data we collect will help rare cancer patients when NOX66 is approved for use for a more common cancer.

NOX wishes to thank our office neighbours McCain Foods Aust/NZ (Kitchens of Sara Lee) for their kind donation of office furniture to NOX, saving the Company a significant amount of money. NOX has made a donation to Rare Cancers Australia by way of a thank you.

www.rarecancers.org.au

WHAT IS GMP?

By Dr Phillip Coghlan, Director of Manufacturing

GMP stands for Good Manufacturing Practice and is a mandatory system for ensuring that drug substances and drug products are consistently produced and controlled according to the highest quality standards. It is designed to minimize the risks involved in the production of a product that cannot be eliminated through testing the final product. GMP is enforced by a wide set of regulations, codes, and guidelines and is enforced by licencing of premises and regular auditing. The regulations cover manufacturing, facilities and controls for the manufacturing, processing, packaging or holding of a drug product.

What does GMP means for Noxopharm?

The Company soon will commence Phase 3 clinical trials of NOX66. GMP means that all the raw materials that go into manufacturing the product need to be of a minimum standard and be verified before they are used. The manufactured NOX66 product will be required to be tested and meet appropriate quality standards that we establish for it.

Regulatory authorities such as the FDA will require that the product used in these trials is manufactured in accordance with current GMP standards (cGMP). Accordingly, NOX will be working closely with its suppliers to ensure that they have all appropriate GMP licensing in place, and with on-site audits in a regular basis by ourselves.

UNDERSTANDING CLINICAL TRIALS: 101. SPONSORED OR INVESTIGATOR LED?

By Dr Marinella Messina, Clinical Operations Manager

The process of planning and running a clinical trial is complicated. It typically takes anything from 4 to 12 months from the time when the planning process starts to when the first patient is recruited. However, if we get the planning right, the study will run more smoothly and effectively – because once the study starts, it is hard to change things!

The clinical team will be using this column over the coming editions to shed some light on what is involved in clinical trials. I am going to start with one of the first questions you need to ask – is the trial going to be 'Sponsored' (*we have 5 of these*) or 'Investigator Led' (*we have 2 of these*)?

Put simply, a Sponsored trial is managed, led and paid for by Noxopharm – while we may not do all of the activities ourselves, the responsibility for all aspects of the study remains with us. This means, for example, that we have the final decision in how a protocol is written (we'll explain that one in the future!), how data are collected and how we review the outcomes of a study. For investigator led studies, the responsibility for all of that lies with the investigator – a clinician who has his or her own research idea and asks Noxopharm for support. Normally we support this by providing NOX66 and may also provide some limited funding for some aspects of the trial. This means that we get to see how our drug performs relatively cheaply, but the balance is

that we do not have the final say in the design or planning of the study, and we are in the hands of the investigator on when we can announce the outcome.

Both types of study provide important information, with investigator led trials allowing the research dollar to be stretched that much further, particularly in early-stage testing where broadening the way the drug is used maximizes the chance of identifying the optimal way of using the experimental drug.

BRAIN CANCER R&D

By Dr Frederic Delebecque, Manage, Pre-clinical (Oncology)

When biotech companies speak about developing drugs to treat brain cancer, they almost always are referring to *primary* brain cancer, or cancers that arise within the brain. And as serious a problem as these are for both adults and children, an even bigger problem is *secondary* brain cancer, or cancers that start somewhere else in the body and then spread to the brain. No-one is exactly sure just how big a problem this is, with estimates ranging from 4 to 8-times more secondary brain cancer than primary brain cancer. But what is agreed on is that secondary brain cancer is invariably fatal and with few treatment options. Melanoma, lung, breast and bowel cancers are the most common sources of secondary brain cancer, but every cancer has the potential to spread to the brain.

At Noxopharm we are targeting both forms of brain cancer. Animal studies have shown that NOX66 reaches the brain in relatively high levels, so we are confident that NOX66 will reach cancers within the human brain no matter what their origin. We have already shown in the laboratory that NOX66 can kill or injure brain cancer cells whether they come from brain tissue or breast or lung or prostate. We now are working in animal models to confirm that we can use NOX66 to sensitise brain cancers to radiotherapy or chemotherapy, regardless of the type of cancer. Our ultimate aim is to use NOX66 to sensitise cancer cells to radiation to the extent that a low dose of radiotherapy will deliver a potent anti-cancer effect while sparing normal brain cells.

FROM THE WIDER WORLD OF CANCER

By Dr Graham Kelly CEO

If the average man-in-the-street wonders in what odd directions scientific research can end up going, then here is further proof. **Camels and llamas may hold an answer in the ongoing fight against human cancer.**

The story starts with enzymes known as matrix metalloproteinases, or MMPs. This is a common family of enzymes within our bodies that play a big role in how our tissues are remodeled, eg how a uterus shrinks after pregnancy. And scientists have known for some time that these enzymes also play a role in how

cancer tissue uses MMPs to remodel healthy tissues to accommodate the rapid growth and spread of a cancer. As a result, MMPs tend to be abundant in rapidly growing cancers.

This has set MMPs up as potential drug targets in the hope of being able to slow down the growth and spread of cancers. But developing standard drugs against MMPs has proven difficult because of the wide range of different MMPs, resulting in unacceptable toxicity. This has led scientists to look at developing antibodies against specific MMP types, an approach thought more likely to succeed.

But here is the problem. Human antibodies have the wrong sort of shape to bind to MMPs….they simply won't stick to the MMP. Camels and llamas to the rescue…it turns out that their antibodies have the right sort of shape that allows them to stick to MMPs.

A group of scientists at the University of California, Riverside now have fashioned human-like antibodies in the shape of camel antibodies and hope to have them in the clinic shortly. The strange world of science.

We will have more information to share with you on our website that we will be adding to as we progress. Please do drop by the website to find more about our story, our science, and our plans for the future.

www.noxopharm.com

info@noxopharm.com
Email:info@noxopharm.com
Phone:(+61) 2 9144 2223
Address: PO Box 824, Turramurra 2074 NSW AUSTRALIA

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