

NEWSLETTER



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FROM THE CLINIC



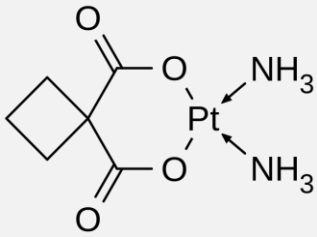
We now are in a position to proceed without our first clinical trial of NOX66. This trial is being conducted at 2 cancer clinics in Tbilisi, Georgia. It involves patients with late-stage cancers (lung, prostate, breast, ovarian, head & neck) who have exhausted all standard treatment options.

What is the purpose of the trial? Simply, to see if NOX66 can combine with the common chemotherapy drug, carboplatin, to provide a strong anti-cancer response, with the ultimate aim of seeing if the potency of the combination is great enough to allow the carboplatin dosage to be lowered to a non-toxic level.

Do we really think that NOX66 is capable of meeting these goals? Yes. In the test-tube, idronoxil (the active component of NOX66), makes carboplatin work some tens of thousands of times greater. That is an extraordinarily exquisite level of sensitisation, well beyond any other drug combination that we are aware of. Importantly, for the sorts of patients in this trial, this effect extends to cancer cells that are highly resistant to all drugs including carboplatin, with idronoxil allowing these highly resistant cells to be killed by very low levels of carboplatin.

Why the confidence given that idronoxil gave disappointing clinical results earlier? Because earlier clinical trials conducted by another company delivered idronoxil in a way that we now believe led to it being ineffective. NOX66 addresses that problem, delivering idronoxil to humans in a way designed to preserve its anti-cancer activities. The promise of this trial is that for the first time, idronoxil will have the capacity to work in the body in the same potent way that it works in the laboratory.

What type of patients are we recruiting? The patients will for the most part have been treated extensively with a variety of chemotherapy drugs (including carboplatin, plus radiotherapy in some cases), but where their cancer finally has stopped responding to therapy. Experience shows that further chemotherapy in these cases typically is unjustified, producing



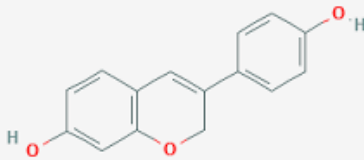
carboplatin

nothing more at best than a temporary halt to the growth of the cancer, and even then, only after using dosages of chemotherapy likely to be unacceptably toxic.

Why lung, prostate, breast, ovarian and head & neck? Because if we are successful in achieving a major response to the combination therapy, then we want to move immediately into a larger Phase 2 (and possibly registration) study, and that process will be assisted by recruiting patients with one or two of the most common forms of cancer.

Why carboplatin? In the test-tube, idronoxil makes all frontline chemotherapy drugs work some thousands of times better. But we had to choose one, and carboplatin has been chosen because of its common use in solid cancers.

How will we measure success? First, in terms of safety. We want to make sure that NOX66 is well tolerated on its own and then does not make carboplatin any more toxic when used together. Given that idronoxil only targets cancer cells, we are not expecting any unpleasant surprises on that front, but that remains to be confirmed.



idronoxil

Second, in terms of efficacy. We are looking for meaningful responses in the patients. By 'meaningful' we mean significant shrinkage of all the cancerous lesions (and not just stopping their growth) for periods considerably longer than the usual few months. At this stage we simply want to see whether we can shrink tumours where shrinkage would not normally be expected, and whether we can achieve that with a lower-than normal dosage of carboplatin.

The end-points we are using in this study (and all our other Phase 1b studies) are shrinkage of the tumours (by RECIST criteria) and quality of life (ECOG score). Tumour response will be measured by scanning and will be expressed as either complete disappearance of all lesions (complete response) or at least a 30% reduction in the size of target tumours (partial response).

How long will the trial last? The Phase 1a/1b arms comprise 16 patients. Enrolment is projected to run March – July 2017. The trial theoretically concludes 8 months following recruitment of the last patient.

When will we be reporting? The 3 scheduled reporting points are at the conclusion of the (i) Phase 1a, (ii) Phase 1b low-dose carboplatin arm and (iii) Phase 1b standard-dose carboplatin arms.

FROM THE LAB

Brain cancer project

This project is a collaboration with The University of Hong Kong, chosen because of the resources of a neurosurgery group there in the field of drug-resistance within brain cancer cells.

The aim of the collaboration is to show that idronoxil (as NOX66) will make brain cancer cells more responsive to the standard front-line chemotherapy drug for glioblastoma (GBM) known as temozolomide (TMZ). If we can do that in the laboratory, then that clears the way for the Hong Kong group to go directly into a Phase 1b clinical study.

This work is able to proceed because we have shown that our NOX66 delivery technology delivers idronoxil across the mammalian blood-brain barrier in high amounts.

While the early part of this project will focus on GBM (the major primary form of brain cancer in adults), eventually we will be extending the study to look at the effect of idronoxil + TMZ on aggressive paediatric brain cancers and on adult secondary brain cancers including lung and breast cancer and melanoma. That is, we see a NOX66 + TMZ combination as a potential standard therapy across a broad range of both primary (from within the brain) and secondary (from outside the brain) cancers.

FROM THE STAFFROOM



Ian Minns joins the Company this month as its Director of Clinical Development and Medical Affairs. Ian is a scientist who has made his career in major pharmaceutical companies (Janssen-Cilag, Novo Nordisk, Bristol-Myers Squibb) with responsibilities variously for drug trials, product launches, training medical representatives, identifying and working with KOLs, and developing branding and marketing strategies. Ian joins the team of Professor Paul de Souza (Medical Advisor) and Dr Marinella Messina (Clinical Affairs Manager) who together will oversee the running of the NOX66 development program. Ian will have carriage of the overall drug development program, working with our regulatory affairs consultants to develop the strategies that we need to meet our aim of achieving marketing approval for NOX66 as quickly as possible.



David Franks joins the Company as Company Secretary and CFO. David replaces Melbourne-based Phillip Hains and his team who provided an experienced hand on the tiller during the listing process. But with the Company now being based in Sydney, the need for a Sydney-based company secretarial and financial officer service became necessary.

FROM THE WIDER WORLD

In each issue we will feature a news item from the world of **oncology. It doesn't necessarily need to be relevant immediately to what Noxopharm is doing.... just something that** might be of broader interest.

In this issue we feature the sacred cow of the cost of treating cancer. 'Sacred cow' because the word 'cancer' seems to evoke a higher level of fear than many other diagnoses, the result being that as a society we have developed a 'save at all costs' approach when it comes to cancer in particular.

When, as a society, we are prepared to countenance spending considerable sums of money to save a dozen or so people each year being mauled by sharks, or mount expensive searches for some hundreds of people lost at sea, then it looks petty to be having a conversation about the cost of saving someone from cancer. But that is exactly a conversation that the world is beginning to have because unlike isolated shark attacks, 1 in 2 men and 1 in 3 women are going to develop a life-threatening cancer in their lifetime, with 40% of those people dying from the cancer. That's a lot of people and a lot of money.

When cancer therapy involved off-patent, generic chemotherapy drugs and simple old-fashioned radiotherapy, cancer therapy was still a costly exercise, but not that much different to the cost of treating other chronic or life-threatening illnesses. Federal health budgets were strained, but still coped.

Then along came the new generation of anti-cancer drugs, the so-called immunotherapies, extending the lives of patients with end-stage lung cancer or melanoma and in the process being hailed as 'game-changers' and 'breakthrough' drugs. The reality, however, is somewhat different... a typical cost of a course of treatment of immunotherapies is in the vicinity of US\$150,000 – 250,000 depending on the length of treatment required. If the majority of patients were 'cured' and did so without experiencing any serious side-effects, then the completely dispassionate view of a health economist would probably be that it was worth it in cold, hard economic terms.

The problem is that anti-cancer drugs rarely 'cure' cancer. In the case of the newer batch of immunotherapeutic anti-cancer drugs, somewhere between only 10-20% of patients receiving the drugs respond to the point of complete remission, with growing evidence that that remission is not necessarily all that long-lived. So, if we can't predict up-front who is going to respond (and at the moment generally we can't) meaning that 8 or 9 patients out of 10 are not going to respond in any meaningful way with many of these non-responders experiencing side-effects requiring hospitalisation, then health economists start asking questions. And so the conversation among those writing the cheques is coming around to asking the question.... *should the cost of an anti-cancer drug be according to the benefit it provides?*

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.



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