Karen Jagoda: Welcome to the Empoweredpatientpodcast.com show. I'm Karen Jagoda, and my guest today is Dr. Greg van Wyk. He's the CEO and CMO of Noxopharm. That's N-O-X-O-P-H-A-R-M.com. They're a clinical-stage drug development company headquartered in Australia, and I'm delighted to get you on the show today, Greg, to give us a little bit of an update about what Noxopharm has been up to.

Greg van Wyk: Thanks, Karen. It's a pleasure to be here. Yeah, it's been an exciting time for Noxopharm, so good time to have an update.

Karen Jagoda: Let's just start by giving our audience a little bit of insight about why Noxopharm has chosen to work on therapies in the oncology space.

Greg van Wyk: Great. Our founder, Graham Kelly, has a long track record in working on a type of molecule called isoflavonoids. They're derived from plants. Plant materials, plant steroids, such as soybeans, etc. He worked out some time ago, how to make these substances, and turning them into ever more synthetic or modified forms of these drugs. He found that he was able to create quite nice anti-cancer effects.

Greg van Wyk: It's really the continuation of his legacy, having brought these molecules into cancer treatment, and the challenge that faced those before Noxopharm, is that it's very hard to actually get these substances to the cells where they need to do their work. We think in Noxopharm, that we've figured out the secret to that, and that's essentially why Noxopharm exists and why we're in the cancer space.

Karen Jagoda: I did have a chance to talk to Dr. Kelly earlier this year. You have taken over his job as CEO as well as the chief medical officer. Is that an opportunity for you to talk to different kinds of people, perhaps, than you were talking to just as the CMO?

Greg van Wyk: Yeah, absolutely. I'm definitely more involved in the business development side of our business, the general communications side of our business, where we're really looking to reach out and speak to the broader community about who we are as a company.

Greg van Wyk: I still have a big role to play in the clinical side of the business, but there I'm in a very fortunate position where we have a global medical director, a person by the name of Gisela Mautner. She's an exceptional talent and really does help us to deliver a very strong clinical plan.

Greg van Wyk: I'm also fortunate in that, whilst Graham has moved out of the CEO role, he still is very much engaged in leadership within the organization, as he's now the
executive chair. He really does a lot of the work speaking to the investment community, and currently very much so in the US.

Greg van Wyk: I have the opportunity to obviously learn from his leadership, and have him mentor me as I take on this new opportunity.

Karen Jagoda: Tell us a little bit about your lead clinical drugs there. It's Veyonda. Is that the pronunciation?

Greg van Wyk: Yeah.

Karen Jagoda: Tell us what's going on there, because it's really intriguing.

Greg van Wyk: Yes, it is. It's a very exciting project to work on. In essence, it's a suppository form of an active compound called idronoxil. It's been around for some time. As I mentioned, Graham synthesized this way back in the '90s already, but many have tried and failed to bring it into the clinic. It's always shown lots of promise in pre-clinical models in a range of cancers, such as prostate cancer and sarcoma.

Greg van Wyk: It's been very difficult to actually get the substance to the cells. We feel that by formulating it in a suppository formulation, using a technology that we believe enables it to be absorbed into the system in its active form, we're starting to see some clinical effects that we believe may well be the beginnings of these substances finally living up to their promise.

Greg van Wyk: Yes, we're in the clinic. We're also doing a lot of pre-clinical work to characterize the formulation and really explore some of the new frontiers of science in cancer care that weren't there 10, 15 years ago, such as the role of the immune system in treating cancer. We're finding some interesting effects of our medicine as an immuno-oncology agent.

Greg van Wyk: We are in the clinic already, looking really specifically at prostate cancer and sarcoma, two very different types of cancer, but both with a huge unmet need. In the case of prostate cancer really, there's so many men that are affected by prostate cancer in their lifetime, and unfortunately 1 in 40 American men lose their life every year to prostate cancer.

Greg van Wyk: Sarcoma is a really debilitating form of cancer, for which there really hasn't been much advance in natural medical treatment, medicine treatments of these patients, since the late '60s when doxorubicin was brought to market.
Greg van Wyk: We feel that if we can make a difference in the lives of patients with prostate cancer and patients with sarcoma, then we really will have made a significant contribution to the treatment of people with cancer.

Greg van Wyk: Indeed, we have a patient in Australia who has been treated on and off with Veyonda over the last three years, in what we call a special access scheme, or a compassionate access scheme.

Greg van Wyk: She’s done remarkably well, really pleasing. I mean, it’s one patient but when you work for the company, any patient that we can have an impact on is just a fantastic lift for everyone that works in the company. Yeah, we’re really excited about the opportunities that we have in those spaces.

Karen Jagoda: The one thing you didn’t mention, and my understanding was that this drug sort of enhances the effect of chemotherapy or radiotherapy. It’s not a replacement for something, but it’s an enhancer, it’s a multiplier. Can you say a little bit about that interaction?

Greg van Wyk: Yes. You’re absolutely correct, Karen. Thanks very much for raising that. This molecule has gotten multiple effects. It has effects within the cell where it promotes cell death of cancer cells specifically. It has mechanisms that prevent the cancer cell that has been damaged from being able to repair itself.

Greg van Wyk: Really, those two actions play a key role in augmenting or helping the effect of certain chemotherapy agents, as well as augmenting the effect of radiotherapy.

Greg van Wyk: We’re now starting to understand that there’s also this downstream immuno-oncological effect of the drug, so it truly is a versatile drug, where it does have some anti-cancer properties of its own, but we find that those properties that it has make it a really great partner to some chemotherapies, as well as to radiotherapy, because it has a synergistic effect in terms of what it does to the cancer cells.

Greg van Wyk: Yes, it is a really great partner for these treatments, but I think the really key thing that makes it a great partner is the fact that it’s quite well-tolerated. You can add it into various regimens, such as radiotherapy or chemotherapy, get that added benefit, but not see dramatically increased toxicities. I think that’s what makes it quite a unique value proposition in the cancer treatment landscape.

Karen Jagoda: Might it reduce the need for chemotherapy, or the length of time that radiotherapy is necessary?
Greg van Wyk: We are using it already in combination with a low does of radiotherapy. We’re really using radiotherapy as the spark to the system, so to speak. We try and damage the DNA and then by using idronoxil and Veyonda in combination with that, we prevent the cancer cells from being able to repair. We also, having set off the immune system, are able to ramp up the immune system's response to those cancer cells.

Greg van Wyk: Already in radiotherapy, we're seeing that we're using lower doses of radiotherapy, which is really well-tolerated. In chemotherapy, we have a couple of options available to us, and we're exploring both. The first being if we use the same dose of chemotherapy and add Veyonda in, can we go for a pure efficacy play where we improve the actual efficacy of that combination for patients?

Greg van Wyk: There is the alternative option as well, which is can we reduce the doses of these chemotherapy agents so that there are less toxicities? Ultimately, our goal would be to give clinicians and patients both of those options and put them in a position where they can decide what's most important to them, and perhaps initially go with a very strong or high-dose combination.

Greg van Wyk: If we see side effects emerging, then we have the option to lower the does of the chemotherapeutic. That would be a really great outcome for us and for patients, and commissions as well, because it puts them in control.

Karen Jagoda: That really sounds promising and exciting at the same time. More on that in the near future, I suspect. I'm wondering if you can give us a little sense of what some of Noxopharm's upcoming milestones are. It sounds like you're touching on so many different opportunities, so what lies ahead in the near term?

Greg van Wyk: We have many opportunities and we're very much focusing those opportunities on prostate cancer and on sarcoma, using a combination of chemotherapy and radiotherapy, specifically within those two cancer types in the initial setting.

Greg van Wyk: In the case of sarcoma, we're in dialogue with the FDA at the moment, with the intent of beginning a Phase I clinical trial of idronoxil and/or Veyonda in combination with doxorubicin in patients with soft tissue sarcoma. That's a near-term milestone that we're working very hard on achieving.

Greg van Wyk: Then in the case of our prostate work, next week there's a publication at a conference called the SNMMI in Anaheim, where an investigator from Australia will be presenting data of Veyonda in combination with Lutetium PSMA, which is this injectable form of radiotherapy. A very exciting technology, and the combination potentially, even has the opportunity to be even more exciting. She'll be presenting some data from that.
Greg van Wyk: Then our DARRT study, which is the low dose external beam radiotherapy, in combination with Veyonda, we will be releasing top-line results, interim results from that in October. Then we expect a final top-line data from that 24-man study in November.

Greg van Wyk: Yes, lots of news to come, both in terms of clinical results, and also in terms of interactions with regulatory authorities about initiating the next wave of clinical trials.

Greg van Wyk: Then finally, we have a number of advisory boards coming up with experts in prostate specifically, both in the US and in Australia, that will really inform what are the studies that we want to do beginning next year, that come after DARRT, and really take us into that next stage of developing Veyonda for treating men with prostate cancer in combination with radiotherapy. Very exciting times ahead.

Karen Jagoda: You were saying that things have changed over the last 10 or 15 years as we've learned more about immunology. I also get the sense that there are less silos out there, and that there's more of an interest in doing partnerships and trying to find two or three drugs or therapies that work together, instead of developing each thing more on its own.

Karen Jagoda: Do you get the sense that the industry has changed, given your own background in the pharmaceutical industry, that there is more interest in collaboration and breaking down the old silos?

Greg van Wyk: Yes, absolutely. The mergers and acquisition space is extremely busy, but as you mentioned, what's also really exploded, particularly in the oncology space, is the understanding that there are many mechanisms that might be complementary, and very few companies own more than one or two of those mechanisms.

Greg van Wyk: We're seeing that very much in the oncology space, where the owner of a molecule that potentially targets one component of the immune system or of cancer biology, is partnering with another that owns another mechanism.

Greg van Wyk: What's been really interesting to see is how some of the really big players, such as the companies that have brought the likes of the program, death ligand inhibitors to market, are partnering with some smaller companies with very early-phase emerging technologies and studying those.

Greg van Wyk: I think we'll see more of scenarios where those partnerships are initiated, then they mature, and then perhaps the bigger partner takes a big stake in that asset, or even acquire the company.
Enhancing Chemo and Radiation for Prostate Cancer
With Dr. Greg van Wyk, CEO CMO Noxopharm
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Greg van Wyk: It's interesting to see that a lot of Big Pharma is no longer going straight in and acquiring the smaller biotech. They're working with them for a period of time, seeing how that asset emerges, and then making a business development decision from there.

Greg van Wyk: It's a very fluid environment, and of course, that's just talking about pharma. When you bring academia and other groups into the mix, oftentimes you have three or four different entities, all with an interest in one or more molecules coming together, to work on combinations of agents that they hope will increase the efficacy or improve the tolerability of treatment regimens for patients.

Greg van Wyk: Those treatment regimens are getting ever more sophisticated and complicated, and that's what makes working in oncology so exciting, is we're really pushing the frontiers of medicine very quickly. At the end of the day, it's patients and society that are reaping the benefits of that innovation, so a very exciting place to be working.

Karen Jagoda: Thanks to my guest today, Dr. Greg van Wyk, CEO and CMO of Noxopharm. That's N-O-X-O-P-H-A-R-M.com. Follow them on Twitter at Noxopharm. I'm Karen Jagoda, and you've been listening to the Empoweredpatientpodcast.com show. Follow me on Twitter at Karen Jagoda. Like us on Facebook at Empowered Patient Radio. Thanks for listening and we'll see you next time.

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