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Dr Megan Baldwin Sharpens Circadian Focus

Dr Megan Baldwin has been the chief executive officer of Circadian for 54 weeks and in that time has reviewed the company's programs, changed priorities to her own field of ophthalmic indications and with a market capitalization of $9.5 million, raised $17.4 million.

Dr Baldwin says the company's vascular endothelial growth factor (VEGF) phase II-ready asset in oncology, VGX-100, is to be partnered or licenced and there are no plans to take the VGX-100 program for metastatic cancer and solid tumors cancer any further, without a partner or licencee.

Dr Baldwin said that a 43-patient phase I dose escalation trial of VGX-100 as a monotherapy and in combination with Avastin had been completed and apart from the published results, the company was completing biomarker analyses.

She said Circadian's focus was on OPT-302, formerly known as VGX-300, with a phase I dose escalation trial for wet age-related macular degeneration, planned to start by July 2015.

Dr Baldwin said the trial would be robust with more than 20-patients and would begin with a combination of OPT-302 and the existing drug Lucentis and at the top dose OPT-302 would be tested as a monotherapy and in combination with Lucentis, with each patient dosed monthly over three months.

Dr Baldwin said that "a large randomized controlled study of OPT-302 and Lucentis would be compared to Lucentis alone", pending the results of the phase I trial expected by April 2016.

She said the phase II trial was expected to begin within three months of the phase I results, by July 2016, and would recruit naïve patients and it was expected that some patients in the Lucentis-alone arm would not respond to Lucentis alone and they would be eligible for the combination treatment.

Dr Baldwin said that the rationale for the combination treatment was that Lucentis, like Avastin targeted VEGF-A, but OPT-302 was a soluble form of VEGF Receptor 3 (VEGFR-3) targetting VEGF-C and VEGF-D and therefore used in combination, provided “a more complete inhibition of blood vessel formation and a reduction of leakage into the eye”.

Dr Baldwin said that wet age-related macular degeneration was the focus for Circadian but she expected the drug could have efficacy in other indications including diabetic macular oedema, diabetic retinopathy and retinal vascular occlusion.

Late last year Circadian appointed a scientific advisory board for the OPT-302 program that includes Arizona’s Retinal Consultants Prof Pravin Dugel, the University of Sydney’s Prof Mark Gillies, Johns Hopkins Wilmer Eye Institute’s Prof Peter Campochiaro and Harvard Medical School’s Prof Kameran Lashkari.

Dr Baldwin said at that time that the “internationally recognized key opinion leaders ... [would] be instrumental in assisting us move this important clinical program forward”.

The change of focus reflects the dynamic Dr Baldwin’s own background in both VEGF research and opthalmics.

Having won the award of Dux of her high school, Coomoora Secondary College in South Springvale, the then Megan Baldwin studied for a Bachelor of Science at the University of Melbourne, undertaking honors in type 2 diabetes at the Royal Melbourne Hospital and earning an award for “most outstanding Bachelor of Science honors research” in the Department of Medicine.

Having also made the University of Melbourne Dean’s Honour Roll, Megan was accepted into the Ludwig Institute for Cancer Research and completed a Doctorate of Philosophy in Medicine working in the angiogenesis laboratory on VEGF-D, winning an Australian postgraduate award and a travel award to present at a diabetes conference in Finland, as well as the 2002 Anti-Cancer Council of Victoria Postdoctoral Research Fellowship.

From 2002 until 2007, Dr Baldwin was employed by Genentech in San Francisco as a post-doctoral researcher, supervised by Prof Napoleone Ferrara, who discovered VEGF-A and made the first VEGF antibody leading to the development of bevacizumab, or Avastin, and later ranibizumab, or Lucentis.

Genentech appointed Dr Baldwin market planning manager in its commercial division and she continued work on angiogenesis at the same time.

Returning to Australia, Dr Baldwin was appointed scientific affairs manager at Circadian in 2008, then head of preclinical research and development and in 2012 was appointed chief executive officer of the newly-created Opthea subsidiary, containing the company's ophthalmic assets.

A year ago, Dr Baldwin was appointed the chief executive officer of Circadian and began the reorganization of Australia's oldest ASX-listed biotechnology company.

Circadian has been through several guises, from its origins as a developer of the anti-jet lag drug melatonin, to an incubator for a raft of other biotechnology companies including Metabolic (later Calzada and now Polynovo), Antisense, Avexa and Optiscan, Dr Baldwin has clarified its narrative to a company specializing in ophthalmic indications.

She said that the $17.4 million capital raising was an exciting and complex operation meeting with US biotechnology, healthcare and life sciences specialist investors including the New York-based Baker Brothers and the San Francisco, California-based BVF Partners, who "saw we were undervalued with a molecule that is a selective protein hitting a VEGF pathway".

"It is a really exciting time to have the funding to execute what we told people we would do," Dr Baldwin said.

Circadian was unchanged at 16 cents.

David Langsam
Editor