



Biotech Daily

Thursday June 16, 2011

Daily news on ASX-listed biotechnology companies

Circadian VGX-100 Ready For Cancer Trials, Eye Indications

Circadian says it has \$25 million to take its VGX-100 cancer drug candidate targeting vascular endothelial growth factor C through phase I and into phase II trials.

In a two-hour presentation to investors, scientists and the biotechnology media in Melbourne, Circadian executives mapped out the evidence for using vascular endothelial growth factor C (VEGF-C) as a target, citing elevated levels associated with cancer patients resistant to Avastin, which targeted VEGF-A.

Circadian's head of preclinical research and development Dr Megan Baldwin said that VEGF-C induced both blood and lymph system vessel growth and VGX-100 was a fully-human monoclonal antibody for VEGF-C for both cancer and eye disease.

Dr Baldwin said Avastin had a 30-50 percent response rate across tumor types and 25-50 percent of responders became resistant.

She said the likely reasons were that tumor growth could be through pathways other than VEGF-A or other factors turned on when VEGF-A was blocked, namely VEGF-C.

Dr Baldwin said a 42-patient trial at the MD Anderson Cancer Centre reported circulating levels of VEGF-C were elevated in patients treated with Avastin and the chemotherapy regime of folinic acid, fluorouracil and irinotecan (Folfiri) prior to disease progression.

"VEGF-C may indicate resistance to Avastin," Dr Baldwin said.

She said that mouse models for a range of cancers showed that VGX-100 alone did little to stop tumor progression, but in combination with Avastin and chemotherapy drug docataxel, VGX-100 significantly delayed tumor regrowth in prostate cancer, non-small cell lung cancer and ovarian cancer; and in combination with Avastin alone delayed glioblastoma tumor regrowth (BD: Apr 15, 2010).

Circadian's head of development Mark Sullivan said the investigational new drug application would request VGX-100 be co-administered with Avastin and chemotherapy.

Mr Sullivan said Circadian would target glioblastoma, colorectal cancer and one of breast, lung and renal cancer and possibly ovarian cancer.

Mr Sullivan said the company had a pre-investigational new drug application meeting with the US Food and Drug Administration “and we are extremely comfortable with that”.

He said the IND could be granted and the phase I trials could begin this year, with the strong Australian dollar an advantage for running the trials at two centres in the US.

Mr Sullivan said the dose-ranging phase I trials of 27 to 33 patients, would simultaneously examine the safety and tolerability of VGX-100 as a monotherapy and in combination.

He said the subsequent phase II glioblastoma trial of more than 100 patients could become a pivotal registration trial.

Mr Sullivan said that Avastin’s key patents expired in 2017 and “it could be very attractive to companies looking for something to combine with generic Avastin”.

Dr Baldwin said that all the pre-clinical work on VGX-100 was applicable for front-of-eye indications, which would require some advanced toxicology studies.

Dr Baldwin said a large number of front-of-eye diseases were typified by vascularization and inflammation and VGX-100 had shown efficacy in mouse studies of reducing both angiogenesis and lymphangiogenesis.

She said trials for eye indications were not likely to start before July 2013.

Circadian chief executive officer Robert Klupacs said the company’s \$25 million in cash “takes us a hell of a long way to generate clinical data” through the phase I cancer trials and into the phase II cancer trials.

Mr Klupacs said he would prefer to take the compound all the way to registration but it was more likely the company would partner the drug or raise capital and there were also potential non-dilutive alternatives.

Circadian was up half a cent or 0.8 percent to 60 cents.

David Langsam
Editor

** David Langsam has an indirect interest in Circadian through Australian Ethical Superannuation.*

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053
email: editor@biotechdaily.com.au www.biotechdaily.com.au