Biotech Daily

Tuesday August 15, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRIMA UP 9.5%, DIMERIX DOWN 9%**

*** MORE DATA BACKS OPTHEA OPT-302 WITH LUCENTIS FOR WET AMD**

*** WESTMEAD OKAYS CLARITY SARTATE FOR NEUROBLASTOMA TRIAL**

*** IMAGION HIRES STARFISH TO DEVELOP MAGSENSE IMAGING**

*** ACTINOGEN LOSES FOUNDING DIRECTOR DR ANTON UVAROV**

MARKET REPORT

The Australian stock market was up 0.47 percent on Tuesday August 15, 2017 with the ASX200 up 27.1 points to 5,757.5 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and two were untraded. All three Big Caps were up.

Prima was the best, up 0.2 cents or 9.5 percent to 2.3 cents with 5.6 million shares traded.

Neuren climbed 6.8 percent; Starpharma was up 5.1 percent; Opthea improved 4.4 percent; Acrux, LBT and Universal Biosensors were up more than three percent; Admedus, Reva and Viralytics rose more than two percent; Bionomics and Osprey were up more than one percent; with Cochlear, CSL, Resmed and Sirtex up by less than one percent.

Yesterday's best, Dimerix, led the falls, down 0.1 cents or 9.1 percent to one cent with 4.6 million shares traded.

Actinogen lost 7.1 percent; Atcor, Compumedics and ITL fell more than five percent; Cellmid fell four percent; Benitec was down 3.85 percent; Mesoblast and Polynovo shed more than two percent; Clinuvel, Oncosil, Orthocell, Pro Medicus and Psivida were down more than one percent; with Airxpanders, Ellex and Nanosonics down by less than one percent.

OPTHEA

Opthea says that further data from its phase I/IIa trial of OPT-302 with Lucentis shows further benefits for wet age-related macular degeneration.

Opthea said that among the 18 treatment-naïve patients in the 51 patient trial, there was an average 73 percent reduction in choroidal neovascularisation (CNV) area from baseline at week-12 with nine (50%) of the patients having no detectable CNV at week-12.

Opthea chief executive officer Dr Megan Baldwin told Biotech Daily that historical data on Lucentis alone indicated that choroidal neovascularisation (CNV) stayed the same or had a very small reduction in area.

Dr Baldwin said that “OPT-302 and Lucentis had a marked effect”.

“You would not expect that with Lucentis alone,” Dr Baldwin said.

Dr Baldwin said that treating the lesion meant that the combination was treating the wet age-related macular degeneration.

She said that on a new secondary endpoint of reduction of sub-retinal hyper-reflective material the combination showed a decrease at week-12 from baseline.

Dr Baldwin said that sub-retinal hyper-reflective material included the debris released into the eye which could lead to irritation and inflammation, so a reduction in material confirmed the combination of OPT-302 with Lucentis “is having a benefit”.

In a media release Opthea said that sub-retinal hyper-reflective material was a morphological feature observed as hyper-reflective material on optical coherence tomography that could contain exudate, haemorrhage, fibrosis or other cellular material and has been associated with worse visual acuity.

The company said that the additional data showed that sub-retinal hyper-reflective material height and width decreased in treatment-naïve patients at week-12 by 65.7 percent and 55.9 percent, respectively.

“This further demonstrates benefits for morphological aspects of the disease,” Dr Baldwin said.

In April, Dr Baldwin and study investigator Prof Pravin Dugel said the trial met its safety and efficacy endpoints of improvements in visual acuity and retinal swelling, including biological activity at the low dose of 0.3mg of OPT-302 (BD: Apr 3, 2017).

Today, Opthea said that the study results were presented for the first time by Dr Dugel at the American Society for Retinal Specialists meeting in Boston, on August 14, 2017.

Dr Dugel said “the results of OPT- 302 combination therapy on these two anatomical measures add to the totality of previously reported data providing further evidence of directional improvement across multiple patient outcomes”.

“In particular, the reduction in CNV size observed in treatment-naïve patients receiving OPT-302 and Lucentis combination therapy, together with the eradication of CNV in half the patients as assessed by an independent reading centre, is a very exciting finding,” Dr Dugel said. “This observation was made at the relatively early week-12 time point and considering that selective [vascular endothelial growth factor-A] VEGF-A inhibitors tend to stabilize the neovascular complex rather than cause regression, we look forward to assessing CNV area in Opthea’s upcoming 350-patient phase IIb clinical study with OPT-302 which will dose patients for a longer duration,” Dr Dugel said.

Dr Baldwin said the “additional encouraging findings provide support to further advance the planned clinical development of OPT-302 in retinal neovascular diseases where there is a large unmet medical need”.

The presentation, entitled ‘A Phase I/IIa study of intravitreal OPT-302, a novel VEGF-C/D inhibitor, alone or in combination with ranibizumab in patients with wet AMD’ is available at: http://bit.ly/2i1mIdz.

Opthea was up 3.5 cents or 4.4 percent to 83 cents.

CLARITY PHARMACEUTICALS

Clarity says that Sydney's Westmead Children's Hospital has approved its trial of Sartate for neuroblastoma, expected to begin next month.

Clarity said it was completing centralized product manufacturing validation and was planning to complete site set-up by the end of August, followed by trial recruitment in September 2017.

The company said that Sartate was copper-64 labelled octreotate, or 64Cu-Sartate, a positron emission tomography diagnostic used for the localization of somatostatin receptor-positive cancers such as neuroblastomas.

Clarity said it completed a first-in-human trial of 64Cu-Sartate in neuro-endocrine tumor patients at Melbourne's Peter MacCallum Cancer Centre in 2015.

The company said that the trial results and research suggested that 64Cu-Sartate "would be an ideal diagnostic for neuroblastoma and the data from this trial will help pave the way for the use of copper-67 labelled Sartate for therapy in this patient population".

Clarity said that 67 labelled Sartate was shown to be efficacious in pre-clinical models and was "an ideal candidate for therapeutic treatment in this patient population".

The company said that neuroblastoma was the most common type of cancer to be diagnosed in the first year of life and accounted for about 13 percent of paediatric cancer mortality.

Clarity said that malignant cells formed in early nerve tissue, or neuroblasts, of the sympathetic nervous system and could be found anywhere along this system, including the adrenal glands, neck, chest, or spinal cord.

Clarity executive chairman Dr Alan Taylor said the ethics approval was "an important milestone in our clinical trial process".

"This step will enable us to progress further in our aspiration to develop treatments for children with cancer that would not only lead to better efficacy in fighting the disease, but also potentially reduce the significant side-effects of current treatments and provide a higher quality of life post treatment for these children," Dr Taylor said.

Clarity is a public unlisted company.

IMAGION BIOSYSTEMS

Imagion says that Canada's Starfish Medical will assist in the design and development of its nano-magnetic Magsense cancer diagnostic for clinical applications.

The Albuquerque, New Mexico-based Imagion said that its Magsense systems had been developed "specifically to detect cancer and other diseases earlier and with higher specificity" than existing diagnostics.

The company said that with the Victoria, British Columbia-based Starfish it would "establish the clinical instrument design specifications and Starfish will provide Imagion with a mock-up of the instrument before committing to the building of prototypes for human studies and market development".

Imagion said that Starfish was Canada's "largest medical device design, development and contract manufacturing company" which would translate its prototype systems into a product that could meet regulatory requirements for use in first-in-human testing.

Imagion chief executive officer Robert Proulx said that building a clinical prototype instrument for human studies was "an important step for us".

"We chose Starfish because of their depth in medical device engineering and experience in magnetic imaging systems," Mr Proulx said. "I am convinced they can help us turn our technology into a commercial product."

Imagion fell one cent or 6.45 percent to 14.5 cents.

ACTINOGEN MEDICAL

Actinogen says that Dr Anton Uvarov has resigned as a non-executive director, effective from today.

Actinogen said that Dr Uvarov joined the company in December 2013 prior to the acquisition of Xanamem and was “particularly involved in shaping the drug’s ongoing development, leading to the successful enrolment this year of the first patients into [the] Xanadu …phase II study of Xanamem in Alzheimer’s disease”.

The company said it “would like to thank Anton for his invaluable contribution … and takes this opportunity to wish him well in his future endeavors”.

Actinogen fell 0.4 cents or7.1 percent to 5.2 cents.