Biotech Daily

Thursday May 24, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PATRYS UP 12%, GENETIC TECHNO DOWN 12%**

*** BIONOMICS STARTS 134-PATIENT BNC105 OVARIAN CANCER TRIAL**

*** WEHI DRUG COULD PREVENT MALARIA BRAIN DAMAGE**

*** HEARTWARE BTT RESULTS PUBLISHED; EUROPE LABEL EXTENDED**

*** US LDL PATENT FOR PATRYS PAT-SM6**

*** STUDY SHOWS IMPEDIMED COULD SAVE US $1m A YEAR**

*** RESMED, BIANCAMED, OMRON SLEEP MONITOR LAUNCHED IN JAPAN**

*** PRIMA COO MATTHEW LEHMAN TO REPLACE CEO MARTIN ROGERS**

*** DRILL INVESTMENTS BELOW 5% OF IMMURON**

*** CHAIRMAN ANDREW KROGER TAKES 12% OF CRYOSITE**

MARKET REPORT

The Australian stock market fell 0.28 percent on Thursday May 24, 2012 with the S&P ASX 200 down 11.2 points to 4,055.8 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and seven were untraded.

Patrys was the best, up 0.3 cents or 11.5 percent to 2.9 cents with 269,045 shares traded.

Viralytics climbed 7.1 percent; Antisense was up 6.7 percent; Circadian was up 5.9 percent; Prana and Reva were up more than three percent; Acrux, Avita and QRX rose more than two percent; CSL and Impedimed were up more than one percent; with Cochlear and Heartware up by less than one percent.

Yesterday's 51 percent best, Genetic Technologies, led the falls, easing 1.5 cents or 11.5 percent to 11.5 cents with 1.25 million shares traded.

Prima fell 9.1 percent on board and management changes (see below); Cellmid, Genera and Sunshine Heart were down more than six percent; Neuren Pharmaxis and Phylogica fell more than four percent; Tissue Therapies was down three percent; Sirtex shed 2.3 percent; Anteo and Bionomics were down more than one percent; with Biota, Mesoblast and Starpharma down by less than one percent.

BIONOMICS

Bionomics says it has started a phase I/II clinical trial of its vascular disrupting agent BNC105 in women with ovarian cancer.

Bionomics said that it expected that up to 134 women would be enrolled at 18 sites across Australia, New Zealand and the US to evaluate BNC105 in combination with current standard therapies carboplatin and gemcitabine.

The company said the trial would be conducted by the Australian and New Zealand Gynaecological Oncology Group and the National Health and Medical Research Council Clinical Trials Centre in Australia and the Hoosier Oncology Group in the US.

Bionomics chief executive officer Dr Deborah Rathjen said the design of the clinical trial was based on “robust preclinical data demonstrating synergy between BNC105 and platinum-based therapies in improving survival rates of animals with solid tumors”.

“There is extremely promising data around this compound and we anticipate this trial will establish further potential of BNC105 in this new indication - to help women suffering ovarian cancer,” Dr Rathjen said.

Bionomics said that despite modest improvements in patient outcomes as a result of surgery or chemotherapy, the majority of ovarian cancer patients relapse and die from their disease and there was a clear unmet medical need for more effective therapies.

The company said that ovarian cancer was the fifth leading cause of cancer-related death among women and was often diagnosed at an advanced stage after the cancer had spread beyond the ovary.

Bionomics said that in 2010 there were an estimated 21,880 new cases and 13,850 deaths from ovarian cancer in the US and about $2.2 billion was spent in the US each year on treating ovarian cancer.

The company said that in 2006 in Australia 1,226 ovarian cancer cases were diagnosed and the number of ovarian cancer cases in Australia increased by 47 percent between 1982 and 2006.

Bionomics said that it was expected that the number of new cases would continue to increase with an estimated 1,434 women expected to be diagnosed with ovarian cancer in 2015.

Bionomics said that drugs used to treat ovarian cancer had reported sales of more than $US2 billion in 2011.

Bionomics said that BNC105 was a vascular disruption agent and rapidly shut down existing and new tumor blood vessels with no effect on normal blood vessels.

The company said that the preclinical data indicated that all solid tumor types, including breast, prostate and lung cancers, were susceptible to BNC105 and that BNC105 also potently inhibited the growth of a broad range of cancer cells in culture.

Bionomics said that in addition to the phase I/II ovarian cancer trial, BNC105 was under evaluation, in combination with the mTOR inhibitor everolimus (Afinitor), in a US multi-centre phase II clinical trial in patients with metastatic renal cell carcinoma, with more than 30 US-based clinical trial sites actively recruiting patients to the trial.

The company said that results from the initial stage of the clinical trial demonstrated that the combination of BNC105 and Afinitor was safe and well tolerated, with several phase I patients achieving at least disease stabilization.

The company said that five patients had received at least 10 cycles of the combination and enrolment in the trial was due for completion at the end of the year.

Bionomics said that data from the renal cell carcinoma trial and the ovarian cancer trial could enable consideration by the FDA of fast track designation for BNC105 adding substantial value to the BNC105 licencing package.

Bionomics fell half a cent or 1.5 percent to 32.5 cents.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says an anti-inflammatory drug could prevent irrevocable brain and tissue damage in severe cases of malaria.

A WEHI media release said its researchers had shown that a new class of anti-inflammatory agents, called innate defense regulator (IDR) peptides, could help increase survival from severe clinical malaria when used in combination with anti-malarial drugs.

The Institute said that a research team led by Prof Louis Schofield with Dr Ariel Achtman and Dr Sandra Pilat-Carotta published the study, entitled 'Effective Adjunctive Therapy by an Innate Defense Regulatory Peptide in a Preclinical Model of Severe Malaria' in the journal Science Translational Medicine.

An abstract is at: http://stm.sciencemag.org/content/4/135/135ra64.

Dr Achtman said that many drugs that prevent malaria infections were not effective in sick patients at preventing tissue damage from the inflammatory immune response.

"The most severe forms of malaria, such as cerebral malaria which causes brain damage, are actually the result of the immune system trying to fight infection and causing collateral damage," Dr Achtman said.

Dr Pilat-Carotta said the team used a treatment approach combining drugs that suppressed potentially harmful inflammation with anti-malarial agents that fought the parasite, in mouse models infected with the malaria parasite Plasmodium berghei.

"In this study, we showed that a new class of drugs could prevent inflammation in the brains of mice with malaria and improve their survival," Dr Pilat-Carotta said."

"This is an example of a 'host-directed' therapy - a treatment intended to act on the host not the parasite," Dr Pilat-Carotta said.

The Institute said that malaria killed up to one million people worldwide every year, particularly children under five years and pregnant women, who often developed severe clinical symptoms such as brain damage and multiple organ failure.

Prof Schofield said up to 25 percent of severe clinical malaria cases were fatal even with access to the best health care.

"Anti-malarial drugs are very effective, but only if they are given before serious clinical symptoms develop," Prof Schofield said.

"On their own, anti-malarial drugs fail in approximately one out of every four cases of severe clinical malaria, because by the time the patient arrives at a hospital they are already very sick and inflammation caused by the immune response to the parasite is causing major organ damage," Prof Schofield said.

Prof Schofield said that innate defense regulator peptides were a new class of anti-inflammatory agent developed by Prof Robert Hancock and colleagues at the University of British Columbia, Canada, which enhanced beneficial aspects of the initial immune response, while dampening harmful inflammation,.

"IDR peptides are also relatively cheap to produce and easy to use, making them a good option for medical treatments in developing countries," Prof Schofield said.

Dr Achtman said the development of preclinical models of severe malaria could improve pre-clinical drug screening and potentially prevent some of the drug failures that happened at the human clinical trial stage.

Dr Achtman said that the WEHI bioinformatics division's Prof Gordon Smyth and Charity Law used sophisticated analyses to identify early changes to inflammatory processes, days before the mice showed visible changes in malaria symptoms.

"Host-directed therapies are a good treatment option because parasites are less likely to evolve resistance and we believe they will eventually increase the number of successful treatment interventions in the short time-window between hospitalization with severe malaria and death," Dr Achtman said.

HEARTWARE INTERNATIONAL

Heartware says the results of its US 140 patient bridge-to-transplant clinical trial evaluating its ventricular assist system have been published in the journal Circulation.

The article entitled 'Use of an Intrapericardial, Continuous Flow, Centrifugal Pump in Patients Awaiting Heart Transplantation' was co-authored by co-principal investigator and director of the Mechanical Assist Device and Heart Transplant Program at the University of Louisville Prof Mark Slaughter and an abstract is at: http://circ.ahajournals.org/.

The top-line results were published in 2010, showing that 92 percent (126 patients) of the 137 investigational device patients met the primary endpoint and 94 percent of the investigational device patients achieved a survival endpoint at 180 days and the study projected one-year survival of 91 percent using the Kaplan-Meier analysis (BD: Nov 15, 2010).

Today, co-principal investigator and the University of Michigan's medical director of the Heart Transplant Program Prof Keith Aaronson said that with the publication of the results in Circulation, "cardiologists and cardiac surgeons treating advanced heart failure will now have the opportunity to thoroughly review the excellent results our investigators obtained using the [Heartware Ventricular Assist Device] to bridge their patients to transplant".

Heartware said the authors noted high rates of 180-day success and survival and improvements in quality of life and functional capacity for patients with end-stage heart failure that were similar to those seen with cardiac transplantation.

The company said that success was achieved for the primary endpoint by establishing non-inferiority between the investigational device and comparator arm of the study, which was derived from contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support [$p < 0.0001$].

The company said that the most common adverse events were typical of those previously reported for an axial design, continuous-flow pump, and included bleeding, infections, stroke and peri-operative right heart failure.

Heartware chief executive officer Doug Godshall said the "high rates of success and survival, as well as improvements in quality of life and functional capacity detailed in the publication, support our belief that, if approved, the HVAD would offer patients with advanced heart failure a valuable new treatment option"

Mr Godshall said that the company was working closely with the US Food and Drug Administration as it reviewed the application for the Heartware ventricular assist system as a bridge to heart transplant.

"As we showed at our FDA panel meeting last month, some of the more challenging adverse events we observed in this initial study cohort have improved measurably in our continued access cohort by refining post-operative management techniques and by introducing sintered inflow cannulas which appear to be contributing to decreased thromboembolic complications," Mr Godshall said.

Heartware said its system was FDA's Circulatory System Devices Advisory Committee voted nine to two that the benefits outweigh the risks and while not binding, would be considered by the FDA in its review of the pre-market approval application.

Separately, Heartware said it had received an expanded European label for long-term use of its ventricular assist system in all patients at risk of death from refractory, end-stage heart failure.

Mr Godshell said the label extension was similar to the destination therapy indication in the US and the designation provided international customers with additional flexibility as they treated patients who might not be eligible for heart transplantation.

Heartware was up two cents or 0.9 percent to $2.28.

PATRYS

Patrys has been granted a US patent covering its PAT-SM6 antibody binding to low-density lipoprotein (LDL) and components of LDL believed to be involved in the mode of action for the product.

Patrys chief executive officer Dr Marie Roskrow told Biotech Daily that binding to low-density lipoproteins, commonly known as bad cholesterol, was just one of PAR-SM6's modes of action.

Dr Roskrow said that intravenous PAT-SM6 bound to low-density lipoproteins in the bloodstream and then traveled to the targeted tumor, in turn binding with the tumor.

In its media release, Patrys said it was the second granted US patent covering the PAT-SM6 through to at least 2024 with the possibility of an extension of term.

Dr Roskrow said the PAT-SM6 patent was "an endorsement of the novelty of our products and reinforces the commercial value of Patrys' pipeline".

"This patent is a key component of our intellectual property portfolio and provides long term market exclusivity for Patrys' PAT-SM6 product for the treatment of cancer," Dr Roskrow said.

Patrys said that PAT-SM6 was a natural human antibody that had shown promise as a potential treatment for multiple types of cancer including melanoma and multiple myeloma.

In February 2012, the company announced successful data from a phase I clinical trial in patients with in-transit melanoma (BD: Feb 9, Mar 20).

Patrys said it was preparing a phase I/IIa clinical trial using PAT-SM6 in patients with relapsed and multi-resistant multiple myeloma.

The company said it expected the trial would begin at the University of Würzburg by December 2012.

Patrys was up 0.3 cents or 11.5 percent to 2.9 cents.

IMPEDIMED

Impedimed says a US study supports the economics of early detection and treatment of secondary lymphoedema in breast cancer patients, saving $3 million in three years.

Impedimed said that the publication compared the financial impact based on the clinical outcomes of a theoretical population of one million covered lives in the US.

Impedimed said the article entitled 'Economic Evidence of BIS-Aided Assessment of Post-Breast Cancer Lymphedema in the United States' was published in the May 2012 issue of the American Journal of Managed Care and "represents the output of an extensively detailed model commissioned by Impedimed in order to assess the health economic impact of L-Dex U400 testing".

Impedimed said the savings identified by the model were primarily due to the reduction of the more costly interventions required to treat lymphoedema when it was found at the more advanced stages associated with conventional assessment methods.

The company said that additional savings resulted from the higher specificity of bio-impedance spectroscopy, leading to fewer non-lymphoedema patients being treated unnecessarily.

Impedimed's senior vice-president of North American managed care Jack Butler said that using a prospective model of care, on a population of one million covered lives, at an L-Dex reading price of $300, and an efficacy score of 80 percent, the saving would be $US3.1 million over three years.

"Additionally, quality of life for these breast cancer survivors would be improved," Mr Butler said.

Impedimed was up half a cent or 1.5 cents to 34.5 cents.

RESMED

Resmed says its recently acquired subsidiary Biancamed has launched the Omron Sleep Design HSL-101 using Resmed technology in Japan.
Resmed said the HSL-101 was launched by Biancamed partner Omron Healthcare and was a wireless sleep monitoring device.
The company said the device used Resmed technology for wireless, non-contact sleep monitoring which in turn connected to health care support services in Japan.
Resmed said the device was placed beside the patient's bed and non-contact sensing technology measured sleep throughout the night and could report key sleep quality metrics, such as sleep onset time and total sleep time.
The company said that in the morning, users could generate a full report on the night's sleep and when the data was connected to the internet cloud, a full picture of sleep was provided, alongside a customized summary of health tips and advice.
Resmed was unchanged at $3.25 with 7.6 million shares traded.

PRIMA BIOMED

Prima says chief operating officer Matthew Lehman will replace chief executive officer Martin Rogers from September 1, 2012.
Prima said Mr Rogers would remain a non-executive director and Mr Lehman had been appointed a director, effective immediately, and would be the acting chief executive officer during Mr Rogers' nuptial leave until the end of July 2012.
Prima chairman Lucy Turnbull said the company thanked Martin Rogers "for his tireless work in transforming Prima over the past four and a half years".
"Under his leadership, Martin consolidated Prima's research activities to focus on development of CVac, he brought together a strong management team and board of directors and he has overseen the globalization of Prima's development activities with key operations in the US and Germany," Ms Turnbull said.
Ms Turnbull said that Mr Lehman had "extensive experience in product development and clinical trial execution" and would serve Prima well.
Prima said that Mr Lehman would relocate from Germany to San Francisco, where the company planned to concentrate its longer-term operational expansion.
Prima said that executive director Dr Neil Frazer had resigned, assuring "consistency with the corporate governance principles and recommendations of the Australian Securities Exchange such that the independent non-executive directors maintain a majority on the Company board".
The company said Dr Frazer continued as chief medical officer, Dr Sharron Gargosky had been promoted to chief technical officer and Marc Voigt had been promoted to general manager of the German subsidiary and chief business officer.
Prima fell 1.5 cents or 9.1 percent to 15 cents with 7.8 million shares traded.

IMMURON

Drill Investments says it has ceased its substantial holding in Immuron.
Drill said in its substantial shareholding that it had reduced its holding from the previous notice of 20,710,000 shares (5.56%) to 15,000,000 shares (4.02%) (BD: May 14, 2012).
The company said it sold the 5,710,000 shares for $104,270 or 1.83 cents a share.
Immuron was untraded at two cents.

CRYOSITE

Cryosite chairman Andrew Kroger has become a substantial shareholder in his company with the acquisition of 5,434,276 shares or 11.65 percent.

The initial substantial shareholder notice said the shares were acquired by Andrew Kroger, Daltonvale Pty Ltd and Colfax Bay Pty Ltd for $733,379 or an average price of 13.5 cents a share

Cryosite was untraded at 15.5 cents.