Biotech Daily

Wednesday May 25, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ADMEDUS UP 9%, MESOBLAST DOWN 7%**

*** LA TROBE UNI $5m STRATEGIC INNOVATION FUND**

*** ADMEDUS TO SUPPLY ROYAL ADELAIDE HOSPITAL INFUSION PUMPS**

*** STARPHARMA DEP CABAZITAXEL ELIMINATES NEUTROPENIA IN RATS**

*** VICTORIA BACKS DELEGATES TO SAN FRANCISCO BIO 2016**

*** INVITROCUE: '3-D SCAFFOLDS ENHANCE STEM CELL LIVER CELLS'**

*** MEDICAL DEVELOPMENTS US, PORTUGAL SPACER DISTRIBUTORS**

*** MGC: 'FDA OKAYS CBD COSMETICS, $1.85m CALIFORNIA DISTRIBUTOR'**

*** IMMURON PHASE II IMM-124E NASH TRIAL 50% ENROLLED**

*** MULTIPLE DOSES OF RECCE 327 ANTIBIOTIC SAFE IN MICE**

*** BENITEC FOCUS ON SCIENCE, HEP B, AMD VECTOR, US DIRECTOR**

*** RHINOMED RECRUITS INPEAP SLEEP APNOEA TRIAL RECRUITMENT**

MARKET REPORT

The Australian stock market climbed 1.45 percent on Wednesday May 25, 2016 with the ASX200 up 76.9 points to 5,372.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and two were untraded. All three Big Caps were up.

Admedus was the best for the second day in a row, up three cents or 9.2 percent to 35.5 cents with 1.2 million shares traded. Antisense and Viralytics climbed more than six percent; Genetic Technologies, Medical Developments and Universal Biosensors were up five percent or more; Acrux, Living Cell and Osprey improved four percent or more; Pharmaxis was up 3.9 percent; Anteo, Prima and Starpharma rose more than two percent; CSL, Opthea, Prana and Resmed were up more than one percent; with Cochlear and Psivida up by less than one percent.

Mesoblast led the falls, down 14.5 cents or 7.2 percent to $1.875, with 1.3 million shares traded. Factor Therapeutics and Impedimed shed more than two percent; Actinogen, Bionomics, Biotron, Nanosonics, Orthocell, Polynovo, Pro Medicus, Reva and Sirtex were down more than one percent; with Ellex down 0.6 percent.

LA TROBE UNIVERSITY

La Trobe University says it has created a $5 million strategic innovation fund “to fast track the translation of research findings into successful business ventures”.
La Trobe media and communications head Tim Mitchell told Biotech Daily the university conducted research across a range of disciplines including biotechnology through the La Trobe Institute of Molecular Science as well as through other departments.
La Trobe vice-chancellor Prof John Dewar said the dedicated fund was sourced from returns on the University’s long term investments and would be available to University researchers “to help unleash the full impact of their work”.
“A core role of universities is to generate new ideas and find new discoveries that have a positive economic, social or cultural impact on our society,” Prof Dewar said.
“We recognise the importance of promoting and supporting innovation within our organisation and the communities we support,” Prof Dewar said.
“By dedicating a portion of our investment returns into a strategic investment fund, we have the opportunity to re-invest in the research conducted at La Trobe,” Prof Dewar said.
Former Pfizer executive and now La Trobe industry engagement pro vice-chancellor Dr Dan Grant said the fund would help emerging La Trobe technologies bridge the ‘valley of death’ between research findings and commercialisation.
“This seed funding will help support the establishment of spin-out companies from intellectual property developed within La Trobe University,” Dr Grant said.
“The fund will also allow us to develop promising early-stage research to the point where it is attractive to commercial partners for licencing or venture investment,” Dr Grant said.
Dr Grant said the University would launch an accelerator program “which would act as a launch pad for innovative business ideas” and act as a pipeline to the innovation fund.
“The La Trobe Accelerator Program will leverage our campuses located in key regional centres in Victoria and in metropolitan Melbourne to attract talent, align knowledge translation with priority areas, generate commercial activity through job growth and strengthen our economy,” Dr Grant said.
“As a world-class university with a proven track record in innovation and discovery, La Trobe University is uniquely positioned to bring an innovation culture to regional Victoria and the communities of Bendigo, Shepparton, Wodonga and Mildura,” Dr Grant said.
“By unlocking the innovation that exists within our university communities we hope to create an innovative ecosystem in regional Victoria,” Dr Grant said.
The La Trobe Accelerator will accept its first intake in May 2017.

ADMEDUS

Admedus says it has an undisclosed five-year contract to install and supply the new 800-bed Royal Adelaide Hospital with the Arcomed Chroma infusion pump systems.
Admedus said that the Regensdorf, Switzerland-based Arcomed AG Chroma pumps provided a “whole-of-hospital system with smart pump technology”.
The company said that the infusion pumps had liquid crystal display (LCD) touch screen, drug error reduction system and on-screen color-coding of medications to increase patient safety and enhance clinical workflow and the agreement included technical and clinical support and consumable products for use with the systems over the coming five years.
Admedus chairman and interim managing-director Wayne Paterson said the company was “encouraged by the uptake of Arcomed Chroma infusion pump systems”in Australia.
“The Admedus team remains focused on providing hospital-wide infusion solutions across the Australian and New Zealand healthcare systems,” Mr Paterson said.
Admedus was up three cents or 9.2 percent to 35.5 cents with 1.2 million shares traded.

STARPHARMA HOLDINGS

Starpharma says that its dendrimer enhanced (DEP) cabazitaxel eliminated neutropenia typical of cabazitaxel treatment, in rats.

Starpharma said that neutropenia was a common and life-threatening side-effect of currently available chemotherapy drugs including cabazitaxel, marketed as Jevtana.

The company said the study followed similar findings with other DEP candidates and the findings showed that DEP cabazitaxel outperformed Jevtana with respect to the level and duration of anticancer activity and overall survival.

Starpharma said that DEP cabazitaxel was a detergent-free version of Jevtana for advanced prostate cancer, which had sales of about $US430 million in 2015.

The company said that Jevtana, like docetaxel (marketed as Taxotere) was formulated using the detergent polysorbate 80 due to its poor solubility and was associated with anaphylaxis and neutropenia.

Starpharma said that Jevtana had a US Food and Drug Administration warning regarding neutropenia and severe hypersensitivity to polysorbate 80.

Starpharma said that DEP cabazitaxel was water soluble and detergent-free.

The company said that neutropenia was characterised by low neutrophil, or white blood cell, levels in the blood, was a sign of bone marrow toxicity and was the most important dose limiting toxicity of Jevtana.

Starpharma said that severe neutropenia was a life-threatening and potentially fatal toxicity that occurred in more than 80 percent of patients treated with Jevtana and could necessitate anti-cancer treatment modification, interruption or discontinuation.

The company said that Jevtana was used in the treatment of advanced prostate cancer that has worsened or pregressed after treatment with docetaxel, and was under clinical development for breast cancer and other cancers.

Starpharma chief executive officer Dr Jackie Fairley said that the results were “very pleasing … as they show the platform benefits of our DEP dendrimers in enhancing the therapeutic window, decreased bone marrow toxicity and enhanced efficacy, of drugs”.

“The combination of these benefits for DEP cabazitaxel provide compelling commercial advantages,” Dr Fairley said.

“The fact that these results are similar to those seen previously with DEP docetaxel and other classes of DEP enhanced therapeutics demonstrates the platform nature of the DEP technology,” Dr Fairley said.

Starpharma said that the relative toxicities of DEP cabazitaxel and Jevtana were compared in a pre-clinical study where equivalent doses, based on cabazitaxel 2.5mg/kg, were administered to rats intravenously.

The company said that blood samples were taken at prior to dosing, then at days five, seven, 14 and 21 and cell counts were undertaken.

Starpharma said that the neutrophil counts, expressed as the mean absolute count across all animals in the dose group with three rats per group at each time point were measured.

The company data showed a significant fall in mean neutrophil count for Jevtana at day five, before recovering at day 20, while the DEP cabazitaxel outperformed the vehicle group, except at day seven.

Starpharma said that rats treated with a single dose of DEP cabazitaxel showed a lack of neutropenia, while Jevtana-treated rats exhibited severe neutropenia within the first week following drug treatment.

The company data showed tumor regrowth in Jevtana-treated rats and “complete tumor regression in DEP cabazitaxel treated rats.

Starpharma was up two cents or 2.9 percent to 72 cents.

VICTORIA GOVERNMENT

The Victoria Government says that more than 70 medical technology, pharmaceutical and biotechnology delegates will go to San Francisco today for BIO 2016.

The Government said that it had supported a trade delegation to the conference for the past 15 years, “highlighting Victoria’s reputation as a global leader in medical technologies, pharmaceuticals and biotechnology”.

A media release from the Minister for Small Business, Innovation and Trade Philip Dalidakis said that a focus of the delegation included Victoria’s “capabilities across infectious disease and diagnostics, cancer, neurology and regenerative medicine, development of medical devices, drug development and clinical trials”.

The media release said that Victoria was home to more than 180 biotechnology companies, 10 major medical research institutes, 10 major teaching hospitals and nine universities, with medical technologies and pharmaceuticals one of the key growth sectors employing more than 20,000 people and generating more than $12.7 billion in revenue for the state.

INVITROCUE

Invitrocue says it has shown that pluripotent stem cell-derived hepatocyte-like cells are “functionally enhanced by culturing the cells in [three-dimensional] cellulosic scaffolds”.

Last week, Invitrocue chief executive officer Dr Steven Fang told Biotech Daily that the company began by growing liver cells in its scaffold system for response to chemicals and had used the same system to grow cancer cells for testing anti-cancer drugs.

Today, the company said the research, entitled ‘Functionally Enhanced Human Stem Cell Derived Hepatocytes in Galactosylated Cellulosic Sponges for Hepatotoxicity Testing’, had been published in the journal Molecular Pharmaceutics, with an abstract available at: http://pubs.acs.org/doi/abs/10.1021/acs.molpharmaceut.6b00119.

Invitrocue said that the pluripotent stem cell-derived hepatocyte-like cells (hPSC-HLCs) “were functionally enhanced by culturing the cells in 3-D cellulosic scaffolds”.

The company said the research showed that the cells could be maintained and differentiated in the three-dimensional (3-D) cellulosic scaffolding technology due to the physical properties of the scaffolds and optimised media conditions.

Invitrocue director Prof Hanry Yu was a co-author along with researchers Dr Abhishek Anathanarayanan and Yinghua Qu.

“Previous journals have shown that there are advantages in growing stem cell derived hepatocytes in 3D culture but in this study we have demonstrated the utility of our 3D cellulosic scaffolding technology for growing stem cell derived hepatocytes and evaluated it for drug testing applications,” Dr Anathanarayanan said.

Invitrocue was untraded at 10 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that Amerisourcebergen will distribute its asthma spacer range in the US and Overpharma Lda will distribute them in Portugal.

Medical Developments said the Chesterbrook, Pennsylvania-based Amerisourcebergen would distribute its range of anti-static compact space chamber devices in the US and the Mortágua Portugal- based Overpharma Lda would have the exclusive sales and marketing rights to the anti-static space chamber plus range in Portugal.

Medical Developments was up 35 cents or 5.9 percent to $6.37.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says the US Food and Drug Administration has approved its cannabinoid-based MGC Derma Anti-Ageing cosmetic range, allowing sales in all US States.
MGC said that it had applications pending for similar approvals in Canada and Australia.
The company said that the FDA approval meant that the 16 products could be imported and sold in states where medicinal cannabis was not yet legal, and followed European Union approval earlier this month (BD: May 11, 2016).
The company said it had signed C&M CBD Holding LLC as an exclusive distributor of the cosmetic products in California with a first year order for more than 60,000 units of its anti-aging cosmetic products, worth EUR1.2 million ($A1.85 million) a year, to be paid in monthly instalments in advance.
Biotech Daily was unable to find any internet presence for C&M CBD Holding LLC and no one from the company was available to help locate the company.
MGC said that the cosmetics would be produced in its Slovenian facilities, with monthly shipping to begin in September 2016 and on Californian shelves by October 2016.
MGC was up 0.4 cents or 7.7 percent to 5.6 cents with 131.4 million shares traded.

IMMURON

Immuron says its phase II trial of IMM-124E for non-alcoholic steato-hepatitis (NASH) has recruited 56 patients or almost half percent of its intended cohort of patients.
Last year Immuron announced it was 25 percent of the way in recruitment with 33 of the 120 patients enrolled in the trial, with 13 US sites and six Australian sites initiated and more to be added in the US and Israel (BD: Jul 2, 2015).
The company began the randomized, double-blind, placebo-controlled phase II study in 2014 (BD: Nov 27, 2014).
Today, Immuron said four more patients would be randomized this week and to date, 25 patients had completed treatment, with no significant treatment adverse events reported.
Immuron said that it expected full recruitment by the end of 2016, with 28 active clinical study sites across the US, Australia and Israel, with two more US sites targeted.
Immuron's head of medical Dan Peres said that the half-way mark was "a significant milestone for the company, and a great achievement by the team".
Immuron was up one cent or 3.1 percent to 33 cents.

RECCE

Recce says that a safety study of the Recce 327 antibiotic in mice shows no signs of toxicity, and was the third favorable safety result.
Recce said Recce 327 was therapeutic with a single dose and the five mice were injected with Recce 327 at 70mg/kg, every second day over a 10 day period.
The company said that no mice died, all mice remained visually healthy and body weights remained substantially stable.
Recce said that a single dose was efficacious in curing mice infected with methicillin-resistant Staphylococcus aureus and the dose was shown to be capable of repeating, without toxicity.
Recce executive chairman Dr Graham Melrose said the study was "great news".
"It opens the way for us to continue our progress through the pre-clinical studies in pursuit of [investigational new drug application] status with the [US Food and Drug Administration]," Mr Melrose said.
Recce was up half a cent or 2.3 percent to 22 cents.

BENITEC BIOPHARMA

Benitec says its focus is science and business development, building a macular degeneration drug delivery vector and will appoint a director for Nasdaq compliance.

Benitec acting chief executive officer Greg West told Biotech Daily that today's quarterly update and conference call was primarily aimed at the company's 20 percent of US investors, who expected quarterly updates.

Mr West said that the company as looking for a new director with accounting qualifications to meet Nasdaq compliance.

Mr West said it was important for all shareholders to know the company had "reduced its head count significantly except for research and development staff" along with other cost savings, but its focus was on science and business development, particularly in the US.

In February and March, Benitec said that competition from other hepatitis C treatments forced the close of its phase I/IIa trial of DNA-directed RNA interference (ddRNAi) drug TT-034 and it would change focus to hepatitis B (BD: Feb 26, Mar 1, 2016).

Last year, then chief executive officer Dr Peter French left the company prior to completion of the hepatitis C trial (BD: Dec 16, 2015).

Today, the company said that it was collaborating with the Emeryville, California-based 4D Molecular Therapeutics to build a delivery vector for its age-related macular degeneration DNA constructs.

Benitec chief scientific officer Dr David Suhy said that the company had developed a DNA-directed RNA interference (ddRNAi) genetic construct that targeted validated members of the vascular endothelial growth factor pathway that, when up-regulated in the diseased condition, caused the breakthrough of blood vessels into the eye and destroyed the field of vision in the affected patient.

"Although the ddRNAi expression cassette has been validated for some time, we have been working towards developing a corresponding viral delivery technology which can be administered into the eye via an intra-vitreal injection," Dr Suhy said.

Dr Suhy said the 4D Molecular methodology screened complex libraries of adeno-associated virus (AAV) particles to identify and isolate the variants that were able to transduce nearly all of the cells within the retina from a single intra-vitreal injection.

Dr Suhy said the company was validating the AAV capsid to visualize expression within multiple cell types of the retina and screening to ensure that the selected vectors reduced immunogenicity when administered into the eye.

Dr Suhy said he expected to complete studies with the new capsid and the ddRNAi payload by the end of 2016.

Benitec was unchanged at 10.5 cents.

RHINOMED

Rhinomed says it has completed recruitment in the phase I pilot trial of its intra-nasal positive expiratory airway pressure (Inpeap) technology for obstructive sleep apnoea.

Rhinomed said that the 20-patient trial at Monash Health began in 2015 and the lead investigators were collating the data for analysis (BD: Jun 15, 2015).

Rhinomed was up 0.2 cents or eight percent to 2.7 cents with 8.1 million shares traded.