Biotech Daily

Monday June 5, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRIMA UP 16%, CYCLOPHARM DOWN 12%**

*** MONASH, JANSSEN COLLABORATE ON RHEUMATOID ARTHRITIS**

*** MELBOURNE UNI: 'STOP 'FLU BEFORE REACHING LUNGS'**

*** PRIMA: 'IMP321 IMMUNE RESPONSE FOR BREAST CANCER'**

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*** MEDICAL DEVELOPMENTS, CSIRO WORK ON DRUG MANUFACTURE**

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*** LBT APPOINTS MATTHEW MICHALEWICZ DIRECTOR**

*** PRANA APPOINTS DR DAVID STAMLER CMO FOR HUNTINGTON'S**

*** BURNET NANJING BIOPOINT LIVER TEST WINS CHINA GONG**

MARKET REPORT

The Australian stock market fell 0.57 percent on Monday June 5, 2017 with the ASX200 down 33.2 points to 5,754.9 points. Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and four were untraded. All three Big Caps were up.

Prima was the best, up half a cent or 16.1 percent to 3.6 cents with 26.1 million shares traded. Impedimed, Medical Developments and Osprey climbed more than five percent; Acrux improved four percent; Benitec and Cellmid were up more than three percent; Prana rose 2.1 percent; Admedus, Avita and Cochlear were up more than one percent; with CSL, Nanosonics, Pro Medicus and Resmed up by less than one percent.

Cyclopharm led the falls, down 12 cents or 12 percent to 88 cents with 30,333 shares traded. Psivida lost 5.6 percent; Airxpanders, Living Cell, Neuren and Oncosil fell more than four percent; Bionomics, LBT, Orthocell, Polynovo and Sirtex shed two percent or more; Opthea, Starpharma and Viralytics were down more than one percent; with Mesoblast down by half a percent.

MONASH UNIVERSITY, JANSSEN BIOTECH

Monash University says it has signed a research and commercialization deal with Janssen Biotech for the detection and prevention of rheumatoid arthritis.

Melbourne's Monash University said that Janssen was a Johnson & Johnson subsidiary and the drug discovery agreement would employ 10 researchers for four years with an option to licence any resulting drug.

The University said that rheumatoid arthritis was a debilitating autoimmune disease affecting more than 400,000 Australians and more than 24.5 million people worldwide.

Monash University vice-chancellor Prof Margaret Gardner said the partnership between the Monash Biomedicine Discovery Institute and Janssen demonstrated the potential for world class research excellence and industry expertise to deliver health and economic benefits on a global scale.

"Monash is recognised internationally for its expertise in biomedical innovation and this important collaboration opens up the possibility to transform the lives of rheumatoid arthritis sufferers," Prof Gardner said.

Monash University said that research led by Prof Jamie Rossjohn had been investigating the impact of therapeutics on immune systems affected by rheumatoid arthritis.

"This collaboration is a great opportunity to take our advances in basic biomedical science and translate them to the market for the betterment of the Australian population and worldwide," Prof Rossjohn said.

THE UNIVERSITY OF MELBOURNE

The University of Melbourne says that its researchers hope to stop influenza spreading to the lungs by immunizing the upper respiratory tract.

The University said research by the Peter Doherty Institute for Infection and Immunity entitled 'Resident memory $CD8^+$ T cells in the upper respiratory tract prevent pulmonary influenza virus infection' was published in Science Immunology. An abstract is at: http://immunology.sciencemag.org/lookup/doi/10.1126/sciimmunol.aam6970.

The University said the finding "could be the key to preventing complications such as pneumonia and take scientists closer to developing a one-shot 'flu vaccine".

Doherty Institute researcher Dr Linda Wakim said that previous influenza research had focused on the influenza-fighting powers of immune cells in lung tissue, but those cells decayed too quickly to be useful in developing a vaccine.

"We took a step back and thought, 'What if we could stop the virus in the nose before it made it to the lungs?'" Dr Wakin said.

"We moved our focus to investigating immune responses in nasal tissue, which is where the body first encounters 'flu viruses, a kind of nasal border patrol," Dr Wakim said.

The University said that Dr Wakim's team found that nasal resident memory CD8 T-cells in animal models were "highly effective in protecting against several different strains of flu and lived long enough to fight off the virus".

"We found a population of these cells that, unlike their cousins in the lung, persisted for a very long time and that they could block inhaled virus particles from reaching the lung, preventing severe 'flu-related lung infections," Dr Wakim said.

"We stopped influenza at the gates," Dr Wakim said.

She said the findings highlighted the potential of targeting the cells in new influenza vaccines.

"We are now trying to work out the best way to lodge these 'flu-fighting resident memory T cells in the nasal tissue, with the ultimate goal of developing a new vaccine that can provide long term protection against 'flu viruses," Dr Wakim said.

PRIMA BIOMED

Prima says that 13 of 15 patients in its phase IIb, IMP321 with paclitaxel for breast cancer trial showed disease control and a sustained increase in antigen presenting cells.

Last year, Prima said that interim data from the 15-patient safety run-in for the active immunotherapy paclitaxel (AIPAC) trial, showed that IMP321 was "safe and well-tolerated" at both the 6mg and 30mg doses and immune monitoring data confirmed that IMP321, as an antigen presenting cell activator, was working to generate the desired immune responses and the data showed an increased level of blood monocytes, dendritic cells and CD8 T-cells (BD: Dec 22, 2016).

Today, Prima said that the 15-patient data from the 226-patient trial was presented at the American Society of Clinical Oncology meeting in Chicago, Illinois, with the poster presentation, entitled 'Combination of paclitaxel and LAG-3Ig (IMP321), a novel MHC class II agonist, as a first-line chemoimmunotherapy in patients with metastatic breast carcinoma (MBC): Interim results from the run-in phase of a placebo controlled randomized phase II' delivered by Dr Francois Duhoux.

The abstract is available at: http://abstracts.asco.org/199/AbstView_199_189892.html.

Prima said the higher 30mg dose demonstrated a stronger immune response, and was determined to be the recommended phase II dose.

The company said IMP321 led to a sustainable increase and activation of antigen presenting cells for more than six months with an increase in CD8 T-cell and natural killer cell numbers, together with an improved pre-dose T-helper cell status.

Prima chief medical officer Dr Frédéric Triebel said the "very positive data is a major milestone for our AIPAC trial".

"It further supports previous clinical data in metastatic breast cancer, which led to Prima designing and starting AIPAC along with scientific advice from the European Medicines Agency," Dr Triebel said.

"The similar disease-free rate to that 30 patient trial and stronger immune response from the higher 30mg dose further underpins the randomised phase for AIPAC currently underway," Dr Triebel said.

"The increase of [antigen presenting cells] numbers in the blood and their activation, which stimulate the body's immune response to fight cancer cells, has not previously been seen with other immune checkpoint inhibitors as IMP321 has a broader mode of activation, not restricted to T cells," Dr Triebel said.

"Furthermore, the increased numbers of CD8 T cells and natural killer cells, and corresponding baseline Th1 status is a very positive indicator of the potential efficacy of IMP321 as these are known to be related to anti-tumour efficacy in patients," Dr Triebel said.

Prima climbed half a cent or 16.1 percent to 3.6 cents with 26.1 million shares traded.

CYCLOPHARM

Cyclopharm says it expects to raise $7 million, through a fully-underwritten one-for-6.8 rights issue at 80 cents a share.

Cyclopharm said the entitlements offer was underwritten by Bell Potter Securities and the funds would be used to complete recruitment of the 240 patients for the approved US Food and Drug Administration trial of Technegas, including a preliminary 40-patient trial for submission to the FDA by April 2018.

The company said that the record date would be June 8, the offer would open on June 14 and close on June 23, 2017.

Cyclopharm fell 12 cents or 12 percent to 88 cents.

RHS (FORMERLY REPRODUCTIVE HEALTH SCIENCE)

RHS says it has raised $1.5 million in a placement of 10,714,285 shares at 14 cents a share an 8.1 percent discount to the 15-day volume-weighted average price.
RHS said the funds would assist expansion of marketing and business development activities.
The company said that through Taylor Collison was the lead broker.
RHS was up two cents or 12.9 percent to 17.5 cents.

SIRTEX MEDICAL

Sirtex says Asian patients treated non-resectable advanced hepatocellular carcinoma had better tumor response rates that with SIR-Spheres than sorafenib.
Last month, Sirtex said the 360-patient phase III Singapore-based trial of Sirt versus sorafenib in locally advanced hepatocellular carcinoma (Sirvenib) study concluded that "there were no statistically significant differences in [overall survival] between Y90 and sorafenib"
The Sirvenib abstract at that time concluded that "Asian patients with locally advanced [hepatocellular carcinoma] without extra-hepatic metastasis treated with Y90 have statistically significant better [tumor response rates] and fewer [serious adverse events] when compared with those treated with sorafenib".
Today, Sirtex said that Singapore-based Sirvenib trial data was presented at the American Society of Clinical Oncology meeting.
Sirtex chief medical officer Dr David Cade said that the data "verifies the important role of SIR-Spheres as an alternative treatment to sorafenib for advanced [hepatocellular carcinoma] in an Asian population, given the significant safety and toxicity benefits conferred, with no significant difference in median overall survival outcomes".
Sirtex principal investigator Prof Pierce Chow said that "the comparative data on side effects reported in the Sirvenib study unequivocally favoured Y-90 resin microspheres over sorafenib".
Prof Chow said that the SIR-Spheres group had about one quarter the number of adverse events and fewer serious adverse events.
The Spain-based Clinica Universitaria de Navarra liver unit director Prof Bruno Sangro, said the Sirvenib study results "confirm those from the Sarah study, in terms of the good safety profile of Sirt using Y-90 resin microspheres, which was significantly better tolerated than sorafenib".
Prof Sangro said that two large, prospective, randomized controlled trials showed that SIRT was safe for live cancer patients with cirrhosis.
In April, Sirtex said that the French head-to-head 459-patient SIR-Spheres versus sorafenib 800mg daily, liver cancer trial failed to meet its primary endpoint of overall survival, but "SIRT was more effective than the sorafenib systemic treatment in controlling tumor progression in the liver" (BD: Apr 24, 2017).
"Although this is a negative primary endpoint, as Sirvenib was designed to show superiority in overall survival, it shows that for centres that treat [hepatocellular carcinoma], it is worth having SIRT as an alternative to sorafenib so that the multidisciplinary tumor boards can consider the most appropriate treatment option for their patients," Prof Sangro said.
Sirtex fell 24 cents or two percent to $11.78 with 654,703 shares traded.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says the Australian Therapeutic Goods Administration has included its Mente Autism technology on the Australian Register of Therapeutic Goods.
Neurotech said that inclusion on the Regsiter was “a significant milestone for the company”.
The company said the Mente Autism electro-encephalogram (EEG) based diagnostic and training system was registered as a biofeedback system as a medical device class IIa.
Neurotech was up 2.5 cents or 10.2 percent to 27 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL, CSIRO

Medical Developments says it will work with the Commonwealth Scientific and Industrial Research Organisation to develop new drug manufacturing technologies.
Medical Developments said the agreement extended the existing partnership with the CSIRO and the pharmaceutical technologies developed in that partnership.
The company said that the collective ambition was to develop the next generation of manufacturing technologies to make small molecule pharmaceutical products at a significantly reduced cost and improved quality, compared with traditional processes.
Medical Developments said that it would invest $3 million over three years in the project and preliminary results were “very encouraging”.
The company said that it would pay 60 percent of costs in cash or shares to be issued at the 7-day volume-weighted average price and the balance in cash, which CSIRO agreed to invest in the unlisted 10-year options, which could “only be exercised [or] vested when a developed technology has been proven to be commercially viable” and would be issued at a 10 percent discount to the 7-day volume-weighted average price at the date of invoice.
Medical Developments chief executive officer John Sharman said the company was “confident we can build on the success of the Penthrox project which delivered significant improvements to our existing manufacturing process”.
CSIRO Biomedical Manufacturing Group director Dr Paul Savage said the Organisation was “delighted to partner with Medical Developments International to develop this new technology”.
“We are confident that the approach used to develop [Medical Developments’] production technology for Penthrox can be extended to other pharmaceutical products,” Dr Savage said.
“By introducing transformative processing technologies, CSIRO aims to further assist the global competitiveness and growth of the Australian pharmaceutical manufacturing industry,” Dr Savage said.
Medical Developments was up 26 cents or 5.1 percent to $5.33.

MGC PHARMACEUTICALS

MGC says it has a agreement with Slovenia’s University of Ljubljana, which has been issued a full medical cannabis license for a breeding and cultivation program.
MGC said the goal of the strategic research program was to create medicinal cannabis strains tailored for specific medical indications, including epilepsy, chronic pain, as well as the side effects of oncology.
The company said that the agreement hoped to produce new genetic intellectual property, giving it “a strong competitive advantage for future production operations”.
MGC was up 0.4 cents or 9.3 percent to 4.7 cents with 73.5 million shares traded.

NOXOPHARM

Noxopharm says its data safety monitoring committee has approved the completion of recruitment of the remaining patients in its phase Ib trial of NOX66 for cancer.
Noxopharm said that the review concluded that the drug did not cause any untoward side-effects and 14 continuous days of NOX66, or idronoxil 400mg daily, was not associated with any adverse events.
The company said that the study was trialling NOX66 for late-stage breast, lung, ovary, prostate or head and neck cancer, not responding to chemotherapy and who had no remaining standard treatment options.
Noxopharm said that study's aim was the study to see if NOX66 could overcome cancer resistance to chemotherapy.
The company said the phase Ia safety run-in had been completed and the phase Ib safety and efficacy arm would trial NOX66 with carboplatin, which was expected to be fully enrolled by end of July 2017.
Noxopharm said that an interim analysis could be conducted when all patients in each of the two dose cohorts of 400mg and 800mg completed three and then six cycles of combination therapy.
Noxopharm fell 2.5 cents or 6.4 percent to 36.5 cents.

BENITEC BIOPHARMA

Benitec has filed a US Securities and Exchange Commission F-3 shelf registration form to raise up to $US20 million ($A26.8 million).
Benitec said that when declared effective by the SEC, the registration would allow the company to issue up to US$20 million of various types of securities, including ordinary shares, preferred shares and/or warrants over a period of three years.
The company said that any shares issued would trade as American depositary shares on the Nasdaq under the code BNTC.
Benitec said that a shelf registration meant it could come to market more quickly and efficiently, but the company had "no immediate plans to issue securities under the registration statement".
Benitec chief executive officer Greg West said that when the capital markets had a strong appetite for gene therapy "we need to be ready to access the markets".
Mr West said that a shelf registration was common capital management practice for dual-listed companies and was standard industry practice, providing "more efficient access to US capital markets to facilitate our on-going development and growth".
Benitec was up half a cent or 3.45 percent to 15 cents.

AIRXPANDERS

Airxpanders says that the equivalent to 35,500,503 Chess depository instruments (CDIs) and 9,023,796 options will be released from escrow on June 22, 2017.
Airxpanders said that 827,758 US shares equivalent to 2,483,274 CDIs would be released from ASX escrow with 10,774,730 US shares equivalent to 32,324,190 CDIs and 693,039 CDIs to be released from voluntary escrow.
The company said that options over the equivalent of 8,569,356 CDIs would be released from ASX escrow with options and warrants over the equivalent of 454,440 CDI's would be released from voluntary escrow.
Airxpanders said that following the release no further securities would be held in escrow.
Airxpanders fell 3.5 cents or 4.7 percent to 71.5 cents.

MEDIBIO

Medibio says it has appointed “Michael Phelps the most decorated swimmer in history and mental health advocate” as a director.
Medibio said that since retiring from competitive swimming in 2016, Mr Phelps has sought to raise awareness around mental health and prior to the appointment worked with its team of doctors to explore ways in which the cardiac rhythm technology could address the identification and treatment of mental health issues.
The company said that Mr Phelps used the technology to analyze his own datasets.
Medibio said that Mr Phelps established the Michael Phelps Foundation in 2008 with the focus on promoting swimming and healthy and active lifestyles, especially for children.
According to the Olympics website, Mr Phelps was the highest ranked Olympian, holding 28 Olympic medals, of which 23 were gold, three silver and two bronze.
Medibio was up three cents or 10 percent to 33 cents with 1.8 million shares traded.

LBT INNOVATIONS

LBT says it has appointed artificial intelligence entrepreneur Matthew Michalewicz as a non-executive director, effective from September 1, 2017.
LBT said that Mr Michalewicz had more than 20 years’ experience in starting technology companies, particularly in predictive analytics and optimization software.
The company said Mr Michalewicz was currently the chief executive officer of Complexica Pty Ltd a provider of artificial intelligence software applications that assisted “organizations [to] increase revenue, margin and customer engagement through automated analytics”.
LBT said that Mr Michalewicz had experience as a business executive, specializing in start-ups, raising capital, technology commercialization, sales and marketing strategy, international expansion, corporate governance and mergers and acquisitions.
The company said that prior to co-founding Complexica, Mr Michalewicz was the chief executive officer of Solveit Software Pty Ltd and was currently a director of Comops, Prophecy International and Complexica.
LBT said that Mr Michalewicz held a Bachelor of Science in Business Administration from the University of North Carolina.
LBT fell half a cent or 2.1 percent to 23.5 cents.

PRANA BIOTECHNOLOGY

Prana says that it has appointed Dr David Stamler as its chief medical officer and head of clinical development, to be based in San Francisco, California.
Prana said that Dr Stamler previously worked for Teva Pharmaceuticals as head of clinical development and therapeutic head of movement disorders, following its acquisition of Auspex Pharmaceuticals and was responsible for clinical and regulatory interactions leading to the approval of Austedo, or deutetrabenazine, for the treatment of chorea associated with Huntington’s disease in 2017.
The company said that Dr Stamler led the development of a new drug for Huntington’s disease, which was approved by the US Food and Drug Administration in April 2017, the second neurological agent Dr Stamler led through the FDA approval process.
Prana said the appointment followed a review of its assets and strategy and “marks a refocus on prioritising PBT434 for the treatment of Parkinsonian movement disorders”, with PBT434 expected to begin a phase I trials this year.
Prana was up 0.1 cents or 2.1 percent to 4.9 cents.

THE BURNET INSTITUTE

The Burnet Institute says spin-off Nanjing Biopoint Diagnostic Technology has been recognized as an example of China Good Technology.

The Burnet said that award from the China Association of Productivity Promotion Centres was for its point-of-care test for liver disease.

The Institute said the test for the alanine aminotransferase (ALT) enzyme which indicated liver disease or damage was one of seven biotechnology or medical technology innovations among the final list of 108 products across China for 2016.

The Burnet said that the test had earlier been recognised as one of 50 Jiangsu Good Technology innovations and was then selected from a shortlist of 286 products for national level recognition.

The Institute said that simple methods to detect liver disease at the point-of-care were "urgently needed as part of the worldwide effort to eliminate hepatitis C and hepatitis B infection".

The Burnet Institute said that point-of-care tests would be useful for other diseases, including the detection of non-alcoholic fatty liver disease, the monitoring of pre-eclampsia in pregnancy, and drug toxicity in tuberculosis therapy.

Burnet Institute deputy director and Nanjing Biopoint Diagnostics chief executive officer Prof David Anderson said the need for a point-of-care test for alanine aminotransferase was "an important stimulus for Burnet's establishment of Nanjing Biopoint in 2013".

"This project has been the focus of our collaborative [research and development] since that time and includes laboratory teams and clinical collaborators in Melbourne and Nanjing, Jiangsu Province," Prof Anderson said.

"This test posed very significant challenges during development, so we are excited to bring it to reality, combining Australian and Chinese expertise, and now supported with our own manufacturing capability established at Nanjing Biopoint," Prof Anderson said.