Biotech Daily

Tuesday June 21, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ATCOR UP 12.5%; ADMEDUS DOWN 6%**

*** WEHI: 'DENOSUMAB STOPS BREAST CANCER IN MICE', HUMAN TRIAL**

*** FRANCE APPROVES MEDICAL DEVELOPMENTS PENTHROX**

*** RESAPP INTERIM ADULT DATA SHOWS ALGORITHM ACCURACY**

*** IMMURON, WALTER REED SHIGELLA COLLABORATION**

*** CYNATA PHASE I GVHD APPLICATION DELAYED UNTIL JULY**

*** US PATENT FOR ORTHOCELL TENOCYTES, COLLAGEN SCAFFOLD**

*** CYCLOPHARM $1.3m CHINA DEAL, H1 REVENUE EXPECTED UP 21%**

*** INDIA APPROVES GENERA RTI-PLEX DIAGNOSTIC**

*** RECCE: '327 ANTIBIOTIC PRECLINICAL STUDIES BY MARCH 2017'**

*** ITL FAILED MALAYSIA AIR-CONDITIONING PROFIT WARNING**

*** UP TO 18% OPPOSE UNIVERSAL BIOSENSORS DIRECTORS, PAY**

*** BARD1 DIRECTOR DR IRMGARD IRMINGER-FINGER TAKES 19.6%**

*** GENETIC TECHNOLOGIES: PROF SUSAN GROSS MEDICAL DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.33 percent on Tuesday June 21, 2016 with the ASX200 up 17.6 points to 5,274.4 points. Nineteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Atcor was the best, up 1.5 cents or 12.5 percent to 13.5 cents with 133,043 shares traded, followed by Universal Biosensors up 12 percent to 28 cents with 409,475 shares traded. Actinogen and Pharmaxis climbed more than five percent; Prima rose 4.4 percent; Bionomics, Cellmid and Living Cell were up more than three percent; Acrux, Anteo, Medical Developments, Neuren and Resmed rose two percent or more; Airxpanders, Cochlear, Ellex, Impedimed, Orthocell and Viralytics were up more than one percent; with Clinuvel, CSL and Sirtex up by less than one percent.

Admedus led the falls, down two cents or 6.35 percent to 29.5 cents with 787,829 shares traded. Osprey fell 4.55 percent; Biotron, Compumedics, Mesoblast and Polynovo lost more than three percent; Antisense, Avita, Factor, IDT and Starpharma shed more than two percent; with Reva down 0.95 percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that mouse data shows that denosumab could prevent breast cancer in women carrying the BRCA-1 gene mutation.

The Institute said that a human clinical trial was underway.

WEHI said that denosumab was currently used to treat osteoporosis and breast cancer that had spread to the bone, and women who had the BRCA-1 gene mutation were at high risk of developing aggressive breast cancer.

The Institute said that many women with the gene mutation chose surgical removal of breast tissue and ovaries to reduce their chance of developing cancer.

WEHI said that by identifying the cells that gave rise to breast cancers in women who inherited the mutated BRCA1 gene, its researchers identified denosumab as having the potential to prevent breast cancer from developing.

The research article, entitled 'RANK ligand as a potential target for breast cancer prevention in BRCA1-mutation carriers' was published in Nature Medicine and an abstract is at: http://www.nature.com/nm/journal/vaop/ncurrent/full/nm.4118.html.

The abstract said that "Taken together, these findings identify a targetable pathway in a putative cell-of-origin population in BRCA1-mutation carriers and implicate RANKL blockade as a promising strategy in the prevention of breast cancer".

The research said that "inhibition of RANKL [or tumor necrosis factor superfamily member 11] in a BRCA-1-deficient mouse model substantially curtailed mammary tumorigenesis".

The Institute said that if the mouse data was confirmed in human studies, it would provide a non-surgical option to prevent breast cancer in women with elevated genetic risk.

Researcher Emma Nolan said that cancer precursor cells in BRCA-1-mutant breast tissue had similarities to aggressive forms of breast cancer.

"These cells proliferated rapidly and were susceptible to damage to their DNA, both factors that help them transition towards cancer," Ms Nolan said.

"We were excited to discover that these pre-cancerous cells could be identified by a marker protein called RANK," Ms Nolan said.

Prof Geoff Lindeman said the discovery of RANK as a marker of cancer precursors was an important breakthrough, because inhibitors of the RANK signalling pathway, including denosumab, were in clinical use.

"We therefore investigated what effect RANK inhibition had on the cancer precursor cells in BRCA-1-mutant breast tissue," Prof Lindeman said.

WEHI said that RANK inhibition switched-off cell growth in breast tissue from women with the BRCA-1 gene mutation and curtailed breast cancer development in mice.

"We think this strategy could delay or prevent breast cancer in women with an inherited BRCA-1 gene mutation," Prof Lindeman said.

"A clinical trial has already begun to investigate this further," Prof Lindeman said.

Prof Lindeman said that an Austrian study had also identified the importance of RANK and complementary approaches were used.

"They deleted the RANK gene during development [and] we switched off the RANK pathway using an inhibitor to recapitulate a breast cancer prevention study in humans," Prof Lindeman said. "Both studies suggest that targeting RANK offers hope to women at high genetic risk for breast cancer."

"This is potentially a very important discovery for women who carry a faulty BRCA1 gene, who have few other options," Prof Lindeman said.

"Current cancer prevention strategies for these women include surgical removal of the breasts and/or ovaries, which can have serious impacts on people's lives," Prof Lindeman said. "To progress this work, denosumab would need to be formally tested in clinical trials in this setting as it is not approved for breast cancer prevention."

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that France has approved Penthrox for the emergency relief of moderate to severe pain in conscious adults with trauma and associated pain.
Medical Developments chief executive officer John Sharman said the approval was “an exciting achievement … [and] with French approval we can begin to sell product in France and Belgium”.
“Preparations for the launch of Penthrox in France and Belgium are well advanced,” Mr Sharman said.
“The approval triggers another milestone payment of $US3.0 million from Mundipharma, our partner in Europe,” Mr Sharman said.
Medical Developments chairman David Williams said that “French approval is a red-letter day … not because we can now sell in France, but because it also signals the start of our quest for the approval in 28 other countries in the EU that we will seek as part of the decentralised approval process.”
Medical Developments was up 12 cents or two percent to $6.08.

RESAPP HEALTH

Resapp says that interim data from 143 of 322 patients in its cough algorithm respiratory diagnostic trial shows accuracy ranging from 83 percent to 100 percent.
Resapp said the algorithm demonstrated 89 percent accuracy in differentiating asthma from chronic obstructive pulmonary disease (COPD) on cough sound alone, increasing to 96 percent when the history of smoking or non-smoking was included in the algorithm.
The company said that the diagnostic demonstrated 83 percent accuracy in differentiating between pneumonia and asthma on cough sound alone, rising to 95 percent when the presence of fever was included.
Resapp said the algorithm demonstrated between 92 percent and 100 percent accuracy in distinguishing adult patients with COPD, asthma and pneumonia from subjects with no discernible respiratory disease.
The company said the diagnostic demonstrated 94 percent accuracy for distinguishing COPD or asthma from subjects with no discernible respiratory disease.
Resapp said that the accuracy rates increased when clinical signs and symptoms and patient history were considered with the algorithm’s primary cough test.
The company said it had enrolled 322 of the targeted 400 adult patients and the data demonstrated “similarly high levels of sensitivity, specificity and accuracy as previously reported in [the] paediatric study (BD: Mar 2, 31, 2016).
Resapp chief executive officer Dr Tony Keating said the results provided “an excellent indication that the algorithms which Dr Abeyratne’s team originally developed for children are equally accurate in adults”.
“These results begin to build the foundation for our adult diagnostic clinical and regulatory strategy and significantly increase the addressable market for our technology,” Dr Keating said.
Resapp said that the algorithm was evaluated using the method of leave-one-out cross-validation against the clinical diagnosis provided by the clinical team, with the diagnosis based on clinical presentations, auscultation findings, or listening to chest sounds using a stethoscope, and imaging as well as laboratory test results.
The company said that smoking was a factor in adult respiratory disease, so the control group was split into smokers and non-smokers, but larger datasets and prospective studies would be needed to produce results with higher statistical validity.
Resapp was up six cents or 16.2 percent to 43 cents with 12.3 million shares trades.

IMMURON

Immuron says it has a research and development collaboration with the Walter Reed Army Institute of Research for the development of a Shigella vaccine.
Immuron said that Shigella was a gram-negative bacteria that caused shigellosis, also known as bacillary dysentery, which was manifested by symptoms of diarrhoea, often with blood, fever and stomach cramps starting a day or two after exposure.
The company said Shigella caused 165 million cases of severe dysentery, with one million deaths, a year, mostly children in the developing world with no approved vaccines.
Immuron said that the collaboration with the Silver Spring, Maryland-based Walter Reed Army Institute of Research would investigate the anti-Shigella activity of antibodies in the formulation of Travelan, assess their protective capacity in preclinical studies and develop a Shigella-specific bovine immunoglobulin product using Walter Reed antigens and Immuron's cow colostrum-derived oral immunotherapy platform.
The company said the efficacy of the vaccines would be tested in-vitro and the goal of the collaboration was to develop therapeutics for commercial and government use.
Immuron said that clinical trials under an investigational new drug application with the US Food and Drug Administration would open the door for the approval of a Shigella vaccine for both military and civilian populations.
Immuron was up half a cent or 1.9 percent to 26.5 cents.

CYNATA THERAPEUTICS

Cynata says it expects to file an application for a phase I UK trial of CYP-001 Cymerus mesenchymal stem cell product for graft-versus-host disease in July 2016.
Earlier this year, the company said it expected to begin the trial by July 2016, but today, Cynata chief executive officer Dr Ross Macdonald told Biotech Daily there had been a small delay as the company collated data from the proof of concept mouse study at the University of Massachusetts Amherst (BD: Jan 28, Apr 7, 2016).
Cynata said the UK application would be for a CYP-001 phase I trial in patients with steroid-resistant graft-versus-host disease.
The company said that interim data from the proof-of-concept mouse study showed that CYP-001 resulted in a strong, statistically significant, survival benefit in the study animals and confirmed biological activity of the Cymerus product and the additional data was expected "to provide a more robust data package for clinical trial approval".
Cynata was up 3.5 cents or 12.3 percent to 32 cents.

ORTHOCELL

Orthocell says it has been granted a US patent covering the combination of its tenocytes, or tendon derived stem cells, and collagen scaffolds.
Orthocell said that the patent, entitled 'Tenocyte containing Bio-scaffolds and treatments using the same' protected the combination of tendon stem cells seeded onto collagen based scaffolds for the repair of torn rotator cuff tendons within the shoulder and provided intellectual property protection until 2028.
The company said that tenocytes were "the building blocks of tendons, which along with growth factors, facilitate tendon regeneration".
Orthocell said the patent complemented its patent family covering the expansion of tendon cells for Ortho-ATI, the method of manufacture of Celgro SMART Graft scaffold and the combing of the tenocyte cells and scaffolds.
Orthocell was up half a cent or 1.5 percent to 34 cents.

CYCLOPHARM

Cyclopharm says it has secured a $1.3 million China contract and expects revenue for the six months to June 30, 2016 to be up 21 percent to $6.1 million.

Cyclopharm said that the sales included an increase in the number of Technegas generators sold and a 24 percent increase in the sales of consumable patient administration sets used with the Technegas generators.

The company said that sales in the six months to June 30, 2015 were adversely affected by a timing anomaly in order patterns from a major European customer.

Cyclopharm said it had received its largest single order for Technegas generators and associated consumables from its Chinese distributor, worth $1.3 million, for 50 Technegas generators and 250 patient administration sets.

Cyclopharm managing-director James McBrayer said the company had been "systematically building our presence in the Chinese market over the past five years".

"This single order for 50 Technegas generators nearly doubles our full year average Technegas generator demand seen in the past few years," Mr McBrayer said.

Cyclopharm said that Technegas was recognised as the leader in functional lung ventilation imaging and was cited by name as the agent of choice in the European guidelines in the diagnosis of pulmonary embolism.

The company said it had been providing financial, technical and clinical support for Technegas trial in China for the diagnosis and management of chronic obstructive pulmonary disease.

Cyclopharm was up eight cents or 11.1 percent to 80 cents.

GENERA BIOSYSTEMS

Genera says that India has approved the import and sale of its RTI-plex upper respiratory tract multiplex molecular diagnostic.

Genera said that the Indian Central Drugs Standard Organisation Medical Device and Diagnostic Division approved the test and the licence had a term of three years to 2019 before requiring renewal.

The company said that with its India distribution partner Genecell Diagnostics to would complete a submission for its Paptype human papillomavirus test for India-wide regulatory and importation approval.

Genera said it had a non-exclusive distribution agreement with Genecell to supply its Ampasand-based molecular diagnostic assays to two pathology groups in India.

Genera was untraded at 21 cents.

RECCE

Recce says it expects to complete pre-clinical testing of its Recce 327 antibiotic with results by March 2017.

Recce detailed a timetable of in-vitro and in-vivo efficacy, safety and chemistry testing including safety in mice, rats and dogs, as well as efficacy for sepsis, colon cancer, leukaemia and anti-viral in mice.

The company said that "all tests to date have confirmed Recce's unique potential as a human antibiotic and theoretical considerations also indicate potential strengths in new markets as a drug against human cancers and/or viruses".

Recce said that the pre-clinical program was directed at filing an investigational new drug application with the US Food and Drug Administration for the compound.

Recce was untraded at 29 cents.

ITL

ITL says an air-conditioning breakdown in its Malaysia cleanroom has resulted in significant costs as well as a loss of production and deferred sales.

ITL said that it previously advised the start-up operating costs of its Myhealthtest and a margin squeeze in the medical supplies business would constrain the financial results for the six months to June 30, 2016 (BD: Feb 17, 22, 2016).

Today the company said that the air conditioning failure “resulted in significant costs in terms of manufacturing inefficiencies, hiring of temporary equipment, replacement chiller and maintenance work, which all meant a loss of production and deferred sales”.

ITL said that the cause was being investigated by technical engineering experts and insurance assessors, with some of the cost likely to be recoverable from the building contractor, the equipment manufacturer or the insurance company but this was “unlikely to be resolved for some time”.

The company said the full year profit before tax was expected to be about $250,000.

ITL said that during the last five years it had returned to profitability and has increased returns to shareholders through franked dividends and share buybacks and it would use the existing business to fund its transition “to pursue high margin opportunities in emerging healthcare growth markets, accelerating development of innovative patented products for the global healthcare markets and steering Myhealthtest to reach its commercial potential”.

ITL was unchanged at 15.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors annual general meeting passed all three but with up to 17.6 percent opposition to the election of two directors and executive pay.

Universal Biosensors shareholders voted 11,099,404 votes (17.6%) against the re-election of director Marshall Heinberg with 51,841,748 votes (82.4%) in favor, with director David Hoey re-elected by a slightly wider margin.

The company said that the resolution to approve named senior executive remuneration was opposed by 11,489,283 votes and supported by 63,076,460 votes.

The company’s most recent Appendix 3B said that Universal Biosensors had 175,688,273 shares on issue meaning that the opposition to executive pay amounted to 6.5 percent of the company’s shares on issue, sufficient to requisition extraordinary general meetings.

Universal Biosensors was up three cents or 12 percent to 28 cents.

BARD1

Bard1 executive director Dr Irmgard Irminger-Finger says she has become a substantial shareholder with 108,252,420 shares (19.61%).

The Geneva, Switzerland-based Dr Irminger-Finger said she held the shares in escrow for 24 months and held a further 108,252,420 unquoted performance shares in escrowed for 24 months.

Bard1 fell 0.1 cents or 4.2 percent at 2.3 cents with 1.2 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has appointed Prof Susan Gross as its senior medical director, effective from June 20, 2016.

Genetic Technologies said that Prof Gross was New York's Albert Einstein College of Medicine professor of clinical obstetrics and gynaecology, women's health, paediatrics and genetics and was previously the Montefiore Medical Centre's division of reproductive genetics director and founder of the Jacobi Medical Centre human genetics laboratory.

The company said that Dr Gross had worked in research, medical education and patient care, as well as guideline committees and was previously Natera Inc's chief medical officer and was currently SJG Advisors LLC president.

Genetic Technologies said that Dr Gross held a Doctor of Medicine from the University of Toronto, Ontario.

Genetic Technologies was untraded at 1.8 cents.