Biotech Daily

Wednesday September 3, 2014

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: IMPEDIMED UP 31%, GENETIC TECH DOWN 8%**

*** ANTISENSE ATL1103 PHASE II 'SUCCESS' FOR ACROMEGALY**

*** WEHI SHOWS ANTIBIOTIC EMETINE BLOCKS MALARIA PROTEINS**

*** IMPEDIMED JUMPS 49% ON CPT CATEGORY 1 REIMBURSEMENT CODE**

*** CYNATA BEGINS EURO PROCESS, LISTED OPTION TRADING**

*** ORTHOCELL TO FILE FOR JAPAN, EU APPROVAL IN 2015**

*** ATCOR WINS FRENCH TRIAL FOR SPHYGMOCOR**

*** NASDAQ NON-COMPLIANCE LETTER FOR GENETIC TECHNOLOGIES**

MARKET REPORT

The Australian stock market eased 0.04 percent on Wednesday September 3, 2014 with the S&P ASX 200 down 2.4 points to 5,656.1 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and two were untraded.

Impedimed was the best, climbing as much as 19 cents or 48.7 percent to 58 cents before closing up 12 cents or 30.8 percent at 51 cents with 4.3 million shares traded, followed by Living Cell up 12 percent to 5.6 cents with 151,500 shares traded.

Osprey climbed 6.5 percent; Circadian was up 5.6 percent; Oncosil was up 4.35 percent; Mesoblast, Neuren, Pharmaxis and Viralytics were up more than three percent; both GI Dynamics and Medical Developments rose 2.8 percent; Atcor, Psivida, Sirtex and Tissue Therapies climbed one percent or more; with Resmed up by 0.7 percent.

Genetic Technologies led the falls, down 0.2 cents or eight percent to 2.3 cents with 897,666 shares traded, followed by Universal Biosensors down 7.9 percent to 17.5 cents with 35,000 shares traded.

Benitec and Cellmid lost more than five percent; Compumedics fell 4.55 percent; Admedus and Anteo were down more than three percent; Analytica, Bionomics and Phosphagenics shed more than two percent; Acrux, Clinuvel and Ellex were down more than one percent; with Cochlear and CSL down by less than one percent.

ANTISENSE THERAPEUTICS

Antisense says that significant efficacy in its phase II trial of ATL1103 for the growth disorder acromegaly positions it for a phase III trial and partnering.

Antisense said that the 26 adult patient, randomized, parallel group, phase II trial met its primary efficacy endpoint showing a statistically significant average reduction in the serum insulin-like growth factor-I (sIGF-I) levels of 26 percent from baseline ($p < 0.0001$) at week 14, one week past the last dose, at the 400mg per week dose tested.

The company said that all patients treated with 400mg per week of ATL1103 had a reduction in sIGF-I levels from baseline at week 14.

Antisense said that greater reductions in sIGF-I were observed in patients with lower body weights, receiving a relatively higher dose per kilogram, with a correlation of $p = 0.0001$, with the patients who received more than 5.5mg/kg per week showing a 36 percent average reduction in their sIGF-I levels.

The company said that the results positioned ATL1103 to move into phase III development and it would accelerate out-licencing activities to secure a pharmaceutical development partner for the drug's further development.

The chief investigator for the study and professor of endocrinology at the Manchester, UK-based Christie NHS Foundation Trust Prof Peter Trainer said there were limited therapeutic options for patients with acromegaly and a need for new therapies.

"The results achieved in this phase II trial suggest ATL1103 with appropriate dose adjustment should be capable of achieving disease control in a significant proportion of patients with acromegaly," Prof Trainer said.

"ATL1103's profile as a potentially efficacious and well-tolerated conveniently dosed therapy strongly supports its move into phase III stage of development," Prof Trainer said.

Antisense managing director Mark Diamond said the results "greatly enhance our partnering prospects for the drug and we expect a number of interested pharmaceutical companies to enter formal due diligence on ATL1103 in coming months".

The company said that two regimens were tested, 200mg three times in the first week then once weekly, or 200mg/week, and 200mg three times in the first week then twice weekly, or 400mg/week.

Antisense said that an average reduction in sIGF-I of 36 percent was achieved in the five of 13 patients who received more than 5.5 mg/kg per week, supporting the expectation that higher dosing should result in higher sIGF-I reductions and time-course data over the 13 weeks of dosing at the 400mg/week dose showed a progressive reduction in sIGF-I over the dosing period and maintenance of the effect well past the last dose, suggesting that continued dosing for longer than 13 weeks in a phase III study could result in additional reductions in sIGF-I.

The company said that at the 200mg/week dose, no reduction in average sIGF-I levels was observed at week 14, although there were reductions in four of 13 patients and the 200mg dose might be therapeutically effective for some patients, particularly with the view to a longer dosing period.

Antisense said that there were no patient withdrawals or reports of any serious adverse events related to dosing and ATL1103 was assessed as generally well tolerated, with the most common adverse event of injection site reactions, no flu-like symptoms, no abnormalities in renal function and no clinically meaningful changes in other laboratory values reported as adverse events, suggesting the drug may be tolerated at higher doses.

The company said it planned to conduct a small study at a higher dose than 400mg per week for potential use in a phase III clinical trial.

Antisense said that final safety data assessment was expected in November 2014.

Antisense climbed as much as 23.3 percent to 18.5 cents, closing unchanged at 15 cents.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its staff have shown how the antibiotic emetine blocks the molecular machinery producing proteins required for malaria parasite survival.
The Institute said that although emetine was effective against malaria it was not used as a preventive drug due to its significant side effects, but researchers Dr Wilson Wong, Dr Jake Baum and their colleagues had opened new approaches for anti-malarial drug development by showing how emetine attached to and blocked the molecular machinery that made the proteins required for malaria parasite survival.
WEHI said that the study, with collaborators at the Medical Research Council Laboratory of Molecular Biology in Cambridge, UK and the Bio21 Institute in Melbourne, was entitled 'Cryo-EM structure of the Plasmodium falciparum 80S ribosome bound to the anti-protozoan drug emetine' and was published in the Cambridge UK-based journal Elife.
The full article is available at: http://elifesciences.org/content/3/e03080.
Elife described itself as "non-profit collaboration between the funders and practitioners of research to improve the way important results are presented and shared" and said it was supported by the Howard Hughes Medical Institute and the Wellcome Trust.
WEHI said that malaria infected hundreds of millions of people worldwide every year and caused more than 600,000 deaths.
The Institute said that the Plasmodium falciparum malaria parasite had developed resistance to anti-malarial drugs.
Dr Wong said the study examined the parasite cell's protein-making machinery, or ribosome, visualizing for the first time the structure of the protein complex in the malaria parasite.
"The ribosome is responsible for constructing all proteins inside the cell, based on the DNA blueprint," Dr Wong said.
"Antibiotics such as emetine kill the malaria parasite by binding to its ribosome and preventing the parasite from building the proteins it needs to produce energy, grow, reproduce and evade the immune system," Dr Wong said.
Dr Wong said knowledge of emetine and related antibiotics such as pactamycin could be used as the basis for developing new anti-malarial drugs.
"Our structure is an exciting discovery as it gives a clear path forward in developing new drugs to tackle this deadly disease," Dr Wong said.
"We have found features of the parasitic ribosome that are not found in the human form," Dr Wong said.
"Drug makers could exploit these features in order to specifically target the production of proteins within the malaria parasite," Dr Wong said.
"We are now working with our colleagues from the Institute's ...chemical biology division to develop new molecules based on emetine and pactamycin," Dr Wong said.
"Knowing exactly how these antibiotics work will enable development of new anti-malarial drugs that replicate the active component of these antibiotics while changing the parts that make it toxic to patients," Dr Wong said.
Dr Baum said the study used cryo-electron microscopy (cryo-EM) to create the structure of the malaria parasite's ribosome.
"Cryo-EM is an exciting technique that allows us to visualize the structure of protein complexes directly from cellular material, instead of having to crystallize them which is often difficult to do and requires huge amounts of material," Dr Baum said.
"The images of the parasite ribosome revealed how emetine binds to the ribosome, stopping it from reading the recipe for malaria proteins," Dr Baum said.
"We can use this knowledge to design better forms of emetine that could be used to tackle malaria," Dr Baum said.

IMPEDIMED

Impedimed says the upgrading of its L-Dex US current procedural terminology (CPT) code to category 1 for all cancer-related lymphoedema is “transformational”.
Impedimed said that the American Medical Association decision opened a $US350 million potential market.
Impedimed chief executive officer Richard Carreon told Biotech Daily that the CPT 3 was a “technical code and rarely do insurers allow them”.
“Category 1 is the highest level and the most sought after,” Mr Carreon said.
“Medicare pays on category 1 and they are extraordinarily difficult to obtain and a unique one is even harder,” Mr Carreon said.
Mr Carreon said that of 183 category 1 code applications, 19 were granted, with just six for a unique code, of which Impedimed’s lymphoedema test was one.
Impedimed said that its CPT category 1 code with the specific number 93702 for bioimpedance spectroscopy described the L-Dex procedure for the assessment of lymphoedema, encompassing all cancer related lymphoedema.
The company said that the clinician description was ‘Bioimpedance-derived spectroscopy for extracellular fluid analysis’.
The company said that the decision was “a transformational event for Impedimed”.
Impedimed said that the category 1 code descriptor meant that reimbursement for L-Dex was not limited to specifically breast cancer patients, but expanded the market opportunity for L-Dex to all cancer patients at risk of developing lymphoedema.
The company said that the new addressable market was about 940,000 patients each year in the US alone and estimated to be more than US$350 million a year.
“This is a real game-changer for Impedimed,” Mr Carreon said.
“Securing a unique CPT 1 code is a significant achievement, and one that very few Australian companies have managed,” Mr Carreon said.
“We are now increasing our focus on the wider oncology market to positively impact a far greater number of patients,” Mr Carreon said.
Impedimed said that the reimbursement rates for all new codes would be determined by the Centers for Medicare and Medicaid Services and published in November 2014, effective from January 1, 2015.
Impedimed climbed as much as 19 cents or 48.7 percent to 58 cents before closing up 12 cents or 30.8 percent at 51 cents with 4.3 million shares traded.

CYNATA THERAPEUTICS

Cynata said that it had begun a scientific advice procedure with the European Medicines Agency, the first formal engagement with the EMA for its Cymerus stem cell technology.
Cynata said that the EMA regulatory process enabled advice to be provided to a company on the appropriate tests and studies in the development of a medicine and was designed to facilitate the development and availability of effective and acceptably safe medicines.
Cynata product development vice president Dr Kilian Kelly said the start of the first clinical study of the Cymerus mesenchymal stem cell product was “an important event”.
Dr Kelly said that the company had not been a decision about the location of trial sites for the phase I trial.
Separately, Cynata said that a group of investors led by John King had acquired a block of the company’s listed options expiring in December 2014.
The company said it was responding “to investor queries about recent trading activity in its December 2014 options”.
Cynata fell two cents or 4.8 percent to 40 cents.

ORTHOCELL

Orthocell says it expects to complete registration filings for its Ortho-ATI or autologous tenocyte implantation technology in Europe and Japan in 2015.
Orthocell managing director Paul Anderson told an investor meeting in Melbourne that the company had three separate and complementary platforms, with Ortho-ATI the lead product for tendon repair.
Mr Anderson said that Ortho-ATI was Australian Therapeutic Goods Administration approved and available for sale in New Zealand, Hong Kong, Singapore and Malaysia.
Mr Anderson said that the company had published 4.5 year data from a 17 patient open-label, pilot study showing that grip strength scores of patients with chronic lateral epicondylitis, a severe form of tennis elbow, improved by an average 84 percent at one year after treatment and 207 percent at an average of 4.5 years after they underwent the Orthocell procedure (BD: Aug 25, 2014).
Mr Anderson said that the company also had two-year data from a 15 patient gluteal tendon, or hip, study and one-year data from a 90 patient ankle study.
Mr Anderson said that the treatment groups were selected from the difficult to treat mid-to-late stage and treatment-resistant patients.
He said that Orthocell took between four and six weeks to harvest healthy tendon tissue from the patient, expand it at the company's Perth, Western Australia facility and implant the tendon stem cells into the damaged tendon tissue.
Mr Anderson said the company's second product was the Celgro pig-based collage scaffold for the repair of soft tissue injuries or degeneration, including ear drum, cartilage and tendon repair, hernia, vaginal wall and other general surgical repairs.
Mr Anderson said he expected to file for TGA approval for Celgro by July 2015.
He said that the third product was the Ortho-ACI autologous chondocyte implant for knee and ankle cartilage repair and regeneration, which was registered with the TGA and had been used in more than 250 patients.
Orthocell listed on the ASX on August 12, 2014 having raised $40 million in an initial public offer at 40 cents a share (BD: Aug 11, 12, 2014).
Orthocell fell three cents or 8.3 percent to 33 cents.

ATCOR MEDICAL

Atcor says it has won a tender to provide 10 of its non-invasive, central aortic blood pressure and arterial stiffness diagnostic Sphygmocor for a multi-centre trial in France.
Atcor said that the study was being coordinated by the Universitaire de Bordeaux and would determine the relationship between arterial stiffness, as measured by pulse wave velocity and the progression of Alzheimer's disease.
The company said that pulse wave velocity was a measure of how fast pressure waves moved through blood vessels and would also measure cardiovascular events such as strokes and heart attacks, and examine if high levels of pulse wave velocity, known to increase cardiovascular risk, also influenced the progression of Alzheimer's disease.
Atcor chief executive officer Duncan Ross said the contract extended Sphygmocor's clinical trial use to brain illnesses.
"While knowledge of what causes death and tissue loss in Alzheimer's is not definitive, the accumulation of plaques is directly related to large artery stiffness," Mr Ross said.
"This can be accurately measured by carotid-femoral pulse wave velocity and pulse wave reflection," Mr Ross said.
Atcor was up 0.1 cents or 1.1 percent to 9.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has received a non-compliance letter from the Nasdaq requiring it to ensure its share price is above $US1.00 within 180 days.

Genetic Technologies said that the Nasdaq had informed it, that its share price had been below the $US1.00 minimum for the 30 consecutive business days to August 28, 2014.

The company said that the Nasdaq letter said it had 180 calendar days to February 25, 2015 to regain compliance, with the minimum bid price at or above $US1.00 for 10 consecutive business days.

Genetic Technologies said that the deficiency notice did not immediately affect its Nasdaq listing and the letter only applied to the Nasdaq and not the shares trading on the Australian Securities Exchange.

Genetic Technologies fell 0.2 cents or eight percent to 2.3 cents.