



Biotech Daily

Friday December 18, 2009

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: LABTECH UP 14%; PRIMA DOWN 9%**
- * **MESOBLAST CELLS SHOW DIABETES POTENTIAL IN MICE**
- * **NON-SIGNIFICANT PLE RESULTS TAKE CLINUVEL TO 2nd PHASE III TRIAL**
- * **VIRALYTICS INCREASES DOSE IN HEAD, NECK CANCER TRIALS**
- * **BIOTECH WIN IN FEDERAL \$64m FOR FUND MANAGERS**
- * **BIONOMICS APPOINTS TREVOR THIELE CFO, CO SEC**
- * **TWO-THIRDS OF QRX UNDERWRITTEN RIGHTS ISSUE TAKEN**
- * **WEHI PORES FINDING SHOWS CANCER, DISEASE TARGETS**
- * **AUSBIOTECH TAKES 10 COMPANIES TO SAN FRANCISCO SHOW**

MARKET REPORT

The Australian stock market fell 0.42 percent on Friday December 18, 2009 with the S&P ASX 200 down 19.8 points to 4650.5 points.

Nine of the Biotech Daily Top 40 stocks were up, 20 fell, six traded unchanged and five were untraded.

Labtech was best, up 1.5 cents or 14.3 percent to 12 cents with 119,665 shares traded, followed by Starpharma up 8.5 percent to 64 cents with 1.2 million shares traded.

Antisense, Avexa and Cochlear climbed more than three percent; with CSL, Pharmaxis and Psivida up more than one percent.

Prima led the falls, down 1.5 cents or 8.6 percent to 16 cents with 9.8 million shares traded, followed by Cellmid, Impedimed and Novogen down more than seven percent.

Living Cell lost 5.6 percent; Acrux, Biota, Circadian, Prana, Tissue Therapies and Universal Biosensors down more than three percent; with Alchemia, Bionomics, Bone, Chemgenex, Compumedics, Mesoblast and Sunshine Heart down more than two percent.

MESOBLAST

Mesoblast says its mesenchymal precursor cells increased blood insulin levels and reduced blood glucose levels in mice with diabetes.

Mesoblast said the preclinical trial showed that the adult stem cell platform could be an effective treatment for diabetes.

The company said that a collaborative study with Adelaide's Queen Elizabeth Hospital's Dr Ravi Krishnan showed that a single dose of the cells injected into mice with diabetes resulted in a significant increase in blood insulin levels and sustained reduction in blood glucose levels for the entire three-week period of follow-up.

Mesoblast said the response was "due to restoration in the damaged pancreas of the balance between insulin-producing beta cells, which reduce blood glucose and glucagon-producing alpha cells, which increase blood glucose".

The company quoted the director of the Endocrine and Metabolic Unit at the Royal Adelaide Hospital Prof Michael Horowitz who reviewed the results saying: "These data are very exciting and clearly demonstrate the potential of using these unique adult stem cells in the treatment of patients with type 2 diabetes."

Mesoblast said type 2 diabetes accounted for up to 95 percent of the 230 million diabetics in the western world.

The company said insulin injections were used as a last resort in type 2 diabetics because of the risk of lowering glucose levels too greatly and too rapidly causing hypoglycemia and newer treatments aimed at enhancing the ability of pancreatic beta cells to produce more insulin to better control blood glucose.

Mesoblast said that in the study, diabetes was induced by partial chemical destruction of the pancreas in 35 mice that were then randomized to receive either a single injection into the bloodstream of human mesenchymal precursor cells or control.

Three weeks later, mesenchymal precursor cells-treated diabetic mice had two-fold greater numbers of pancreatic islets than diabetic controls ($p=0.0012$) and a ratio of insulin-producing beta cells to glucagon-producing alpha cells which was 29 percent higher than in diabetic controls ($p=0.005$).

Mesenchymal precursor cells-treated diabetic mice demonstrated a 35 percent maximal reduction in blood glucose levels ($p=0.012$) and a 34 percent increase in blood insulin levels ($p=0.04$) compared with diabetic controls over the three weeks of follow-up, Mesoblast said.

The company said that no subjects had reduction in glucose levels below normal, indicating that mesenchymal precursor cells "may have a safer profile than insulin injections with respect to risk of hypoglycemia".

Prof Horowitz said the results suggested that mesenchymal precursor cells "enhanced endogenous pancreatic beta cell regeneration, resulting in safe and sustained augmentation of insulin secretion and reduction in blood glucose levels".

Mesoblast executive director Prof Silviu Itescu said the company would "move quickly towards the clinic to target what is termed the western world's largest healthcare epidemic".

"We believe there is clear proof of principle to use our patented cells for diabetes and we will work towards translating these results to humans as quickly as possible," Prof Itescu said.

Mesoblast fell 3.5 cents or 2.5 percent to \$1.365.

CLINUVEL PHARMACEUTICALS

Clinuvel says that despite non-significant symptom reduction in its 36 patient phase III trial of afamelanotide for polymorphic light eruption it is planning a second larger trial.

Clinuvel said the preliminary results from its multicenter randomized double-blind placebo controlled study of three courses of 20mg afamelanotide implants showed “a trend toward reduction of characteristic dermal symptoms”.

The company said polymorphic light eruption (PLE) was a recurrent seasonal ultra-violet light-related skin disorder seen mostly in fair-skinned patients, in the northern hemisphere. Analysis of the physician’s Global Severity Index during the 120 days and 150 days of seasonal treatment demonstrated a reduction in severity of symptoms in patients receiving afamelanotide compared to placebo (p=0.448 and p=0.077).

Clinuvel said that in all sun-exposed areas of the skin tested, compared to starting values, an increase in melanin density was found at 120 days (p=0.009) and 150 days (p=0.007) “indicating a strong elevation in melanin density in phototype I and II patients during spring and summer”.

A senior dermatologist told Biotech Daily that, in general, exposure to sunlight increases melanin density.

Clinuvel said that overall, the safety profile of afamelanotide administered during the trial was good and “positive reports from leading academic dermatologists in the trial form the basis for further testing of afamelanotide 16mg as final commercial product”.

Clinuvel said a phase III trial would compare two doses of the drug from March to October 2010 with up to-50 Caucasian patients with severe and recurrent polymorphic light eruption in five European academic centres.

The company said that the data from this study and other trials currently in progress would support the final registration dossier of afamelanotide in erythropoietic protoporphyria and solar urticaria in Europe and Australia.

Clinuvel’s chief scientific officer Dr Hank Agersborg said the results “fit well in the pharmacological context of afamelanotide’s development program as a novel therapy in light and [ultra-violet light]-related skin disorders”.

“Based on my recent interaction and long experience with US and EU regulators, all preclinical and clinical data seen give me the confidence that Clinuvel is edging towards successful regulatory review,” Dr Agersborg said.

Clinuvel was unchanged at 27.5 cents with 1.3 million shares traded.

VIRALYTICS

Viralytics says all three patients in the first group of its phase I head and neck cancer trial have completed treatment.

Viralytics said each patient received a single intra-tumoral injection of Cavatak and following review of the clinical data by an independent safety committee, Viralytics has been given approval for the second stage of the trial with patients receiving three intra-tumoral injections of Cavatak.

The company said a third group of patients would be recruited to receive six intra-tumoral injections of Cavatak.

Viralytics said the phase I study was primarily designed to assess the safety and efficacy of Cavatak with an increasing number of treatments.

The company said data from the study on patient tolerance and Cavatak’s anti-tumor activity was designed to provide information for preparation of a phase II study and, overall, Cavatak continued to be well-tolerated by late stage cancer patients.

Viralytics was unchanged at 3.8 cents.

FEDERAL GOVERNMENT

Nearly half of the 11 fund managers granted \$64 million in the Innovation Investment Follow-on Fund (IIFF) program are primarily biotechnology focused.

The \$64 million allocation is part of the \$83 million program announced in March and a Department of Innovation Industry Research and Science official told Biotech Daily that the remaining \$19 million was yet to be allocated (BD: Mar 18, 2009).

The Minister for Innovation Senator Kim Carr said the IIFF funding would assist 35 early stage companies to continue developing and commercializing their technologies.

Fund managers include GBS Venture Partners, Starfish Ventures, Start-Up Australia Ventures, Coates Myer (CM Capital) and Amwin Management which is related to Champventures.

The Government media release did not disclose the amounts provided to the fund managers nor the amounts intended to be invested in the target companies.

Start-Up Ventures Australia has previously disclosed its \$8.45 million IIFF allocation as a \$7 million investment in Bionomics and \$1.45 million in private Queensland company, Mimetica (BD: Sep 3, 2009).

GBS Ventures partner Andrew Baker told Biotech Daily his company had been allocated \$10 million to be spent on seven companies.

"I announced the IIFF program in March as part of the Rudd Government's comprehensive response to the global recession," Senator Carr said.

"It was a timely and temporary measure to assist early stage companies with high potential through the crisis," Senator Carr said.

"The global recession, the worst in 75 years, made accessing high risk capital extremely difficult," Senator Carr said.

"The IIFF provides the leg-up that some of our best and brightest start-ups need to continue. If we lose them, we will never get them back," he said.

"The companies that benefit from this fund employ more than 450 people in high-skill, high-wage jobs," Senator Carr said.

"An important objective of the program is to fund investee companies quickly," Senator Carr said.

"Already \$15.58 million has been provided, ranging from \$200,000 to \$7 million to companies involved in the information and communications technology, manufacturing and bioscience sectors.

"Making money available for investment through the IIFF program has boosted confidence and shaken loose additional private sector capital," Senator Carr said.

BIONOMICS

Bionomics has appointed Trevor Thiele as chief financial officer and company secretary replacing Stephen Birrell.

Bionomics said Mr Thiele had 25 years experience as a chief financial officer along with commercial, financial management and treasury roles with listed and private companies in a range of industries.

Mr Thiele holds a Bachelor of Arts in Accounting from the University of South Australia and is a member of the Institute of Chartered Accountants in Australia.

Bionomics said Mr Birrell joined Bionomics in October 2005 and made "a significant contribution to the management of Bionomics during this period".

Bionomics fell one cent or 2.7 percent to 36.5 cents.

QRXPHARMA

QRX says it received valid acceptances for 11,189,584 shares at 80 cents a share or 65.8 percent of the total number offered in its rights Issue.

The company said the 5,810,416 shortfall shares would be placed with underwriter RBS Morgans Corporate.

QRX was unchanged at 81.5 cents.

WALTER AND ELIZA HALL INSTITUTE

The Walter and Eliza Hall Institute says its scientists have identified a key step in the biological process of programmed cell death or apoptosis.

The Institute said apoptosis was important as it removed unwanted and sometimes dangerous cells, protecting people against cancer development, but could lead to the development of degenerative diseases when healthy cells are errantly destroyed.

In a media release the Institute said research by Dr Ruth Kluck from its Molecular Genetics of Cancer Division was "crucial to the development of drugs that can turn on apoptosis, thereby more effectively killing cancer cells".

"It could also be used in developing compounds that turn off the apoptosis that leads to degenerative disorders," the Institute said.

WEHI said Dr Kluck was investigating the role in apoptosis of two proteins, Bak and Bax, and understanding their role could identify targets against which drugs to regulate cell death could be designed.

"The pivotal step towards cell death is the formation of a pore in the mitochondria; mitochondria make and supply energy to the cells," Dr Kluck said.

"Pore formation is the point of no return in apoptotic cell death as it allows cytochrome c, which is the protein that initiates cell death, to escape from the mitochondria," Dr Kluck said.

"Only two proteins are known to form the pore, Bak and Bax," she said.

WEHI said that in 2008 Dr Kluck and her colleagues published their finding that to form the pore, Bak first changes shape and then combines with another Bak protein to form a doublet.

"We have now identified the second step in how Bak forms that pore," Dr Kluck said.

"Once the doublet is formed it can combine with other Bak doublets by what's called a second interface. This second interface seems to allow doublets to assemble into the larger complexes that form the pore," Dr Kluck said.

Dr Kluck co-wrote 'Bak Activation for Apoptosis Involves Oligomerization of Dimers via Their Alpha-6 Helices' published in Molecular Cell on November 25, 2009. A summary is at <http://www.cell.com/molecular-cell/abstract/S1097-2765%2809%2900821-1>.

Dr Kluck said the team would continue to study how the large complexes of Bak and Bax force a hole in the mitochondrial membrane, how to start this process more effectively in cancer cells, and how to prevent it in brain and other healthy cells.

"A major black box in understanding apoptosis is how Bak and Bax work," Dr Kluck said.

"Because these proteins change shape and lodge in a membrane they are hard to study. Any understanding we gain about how Bak and Bax form a pore, how they change shape and how they bind to each other, will help us understand how cancer cells can be targeted to die," Dr Kluck said.

AUSBIOTECH

Ausbiotech will co-host Australian Biotech on Show, an investor event to be held at the JP Morgans annual healthcare conference in San Francisco on January 11, 2009.

Ausbiotech said the event would be held in partnership with Austrade, Blueprint Life Sciences, GBS Ventures and RBS Morgans at the Sir Francis Drake Hotel.

The industry organization said 10 late-stage Australian biotechnology companies would be at the conference along with 30 to 40 life science investment companies and business development executives from major pharmaceutical and biotechnology companies.

The companies that have confirmed they will present at the conference are Alchemia, Biota, Chemgenex, Mesoblast, Phosphagenics, Prima, QRX and Universal Biosensors.

Ausbiotech said the JP Morgans annual healthcare conference was “the premier investor conference of its kind”.

Ausbiotech chief operating officer Glenn Cross said the event was “an unparalleled chance to showcase the exciting developments occurring in Australian biotech companies that are worth investing in and the benefits of investing in our comparatively small but impressive industry”.