Biotech Daily

Tuesday January 31, 2012

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: GENERA UP 15%, PSIVIDA DOWN 10%**

*** WEHI BLOOD GENERATION DISCOVERY TREATMENT POTENTIAL**

*** FDA APPROVES MESOBLAST PHASE II DIABETES TRIAL**

*** CHINA APPROVES PROGEN, MEDIGEN PI-88 LIVER CANCER TRIAL**

*** IMMURON, MONASH COLLABORATE ON CLOSTRIDIUM DIFFICILE**

*** SCIGEN APPOINTS ACTAVIS TO DISTRIBUTE INSULIN**

*** US ALLOWS ACRUX 'SPREADING IMPLEMENT' PATENT**

*** BIOTA EARNS $687k INAVIR ROYALTIES FROM DAIICHI SANKYO**

*** CBIO 'HAS MORE THAN TWO QUARTERS CASH'**

*** SUNSHINE HEART HAS LESS THAN TWO QUARTERS CASH**

*** GENESIS HAS LESS THAN ONE QUARTER CASH**

MARKET REPORT

The Australian stock market fell 0.23 percent on Tuesday January 31, 2012 with the S&P ASX 200 down 10.0 points to 4,262.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and nine were untraded.

Genera was the best, up two cents or 15.4 percent to 15 cents with 4,263 shares traded, followed by Living Cell up 11.9 percent to 4.7 cents with 88,000 shares traded and Phosphagenics up 10.8 percent to 20.5 cents with 1.9 million shares traded.

Antisense and Neuren climbed more than four percent; Acrux, Allied Health, Genetic Technologies and Mesoblast were up more than three percent; QRX rose 2.3 percent; with Anteo, CSL and Starpharma up more than one percent.

Psivida led the falls, down 12 cents or 10.3 percent to $1.04, with 75 shares traded, followed by Patrys down 10 percent to 3.6 cents with 455,000 shares traded.

Clinuvel lost 6.7 percent; Benitec fell five percent; Impedimed and Nanosonics fell more than four percent; Phylogica shed 2.5 percent; with Alchemia, Biota, Cochlear and Resmed down more than one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that a study of blood progenitor cells could change the understanding of blood generation, with potential for new blood disorder therapeutics.

The Institute said the research led by Dr Ashley Ng and Dr Maria Kauppi from its cancer and haematology division could have wide-ranging implications for understanding blood diseases such as myeloproliferative disorders, that cause excess production of blood cells, and could be used to develop new ways of controlling how blood and clotting cells are produced.

WEHI said the research team investigated subsets of blood progenitor cells and the signals that cause them to expand and develop into mature blood cells.

“[Blood progenitor cells] are the targets for blood cell hormones, called cytokines, which Prof Don Metcalf and colleagues have shown to be critical for regulating blood cell production,” Dr Ng said.

“In times of stress, such as bleeding, during infection or after chemotherapy, it is really the progenitor cells that respond by replacing lost or damaged blood cells,” Dr Ng said.

Dr Kauppi said the research team was particularly interested in myeloid progenitor cells, which produce megakaryocytes, a type of bone marrow cell that gives rise to blood-clotting platelets.

“We used a suite of cell surface markers specific to these progenitor cells that allowed us to isolate and characterize the cells,” Dr Kauppi said.

The Institute said that the researchers were surprised to find that progenitor cells believed only to be able to produce megakaryocytes were also able to develop into red blood cells.

“We were able to clearly demonstrate that these mouse megakaryocyte progenitor cells had the potential to develop into either megakaryocytes or red blood cells in response to cytokines such as thrombopoietin and erythropoietin, which was quite unexpected,” Dr Ng said.

“In addition, we discovered that other progenitor populations thought to really only make neutrophils and monocytes [other immune cells], were capable of making red blood cell and platelets really well,” Dr Ng said.

“In effect, we will have to redraw the map as to how red cells and platelets are made in the bone marrow,” Dr Ng said.

Dr Kauppi said the researchers found they could regulate whether the progenitor cell became a megakaryocyte or a red blood cell by using different combinations of cytokines.

“Now that we have properly identified the major cells and determined how they respond to cytokine signals involved in red blood cell and platelet production, the stage is set for understanding how these progenitors are affected in health and disease,” Dr Kauppi said.

“We can also better understand, for instance, how genetic changes may lead to the development of certain blood diseases,” Dr Kauppi said.

Dr Ng said the findings would also help researchers discover new ways in which the progenitor cells can be controlled.

“This research is the first step in the future development of treatments for patients with blood diseases,” Dr Ng said.

“This may occur either by limiting blood cell production when too many are being made, as with myeloproliferative disorders, or stimulating blood production when the blood system is compromised, such as during cancer treatment or infection.” Dr Ng said.

The paper, entitled ‘Characterization of thrombopoietin (TPO)-responsive progenitor cells in adult mouse bone marrow with in vivo megakaryocyte and erythroid potential’ was published by the Proceedings of the National Academy of Sciences and an abstract is available at: http://www.pnas.org/content/early/2012/01/24/1121385109.abstract.

MESOBLAST

Mesoblast says the US Food and Drug Administration has approved a 60-patient phase II trial of its mesenchymal precursor cells for type 2 diabetes.

Mesoblast said that the randomized, placebo-controlled phase II trial would compare the effects of a single intravenous injection of one of three escalating doses of off-the-shelf or allogeneic mesenchymal precursor cells (MPCs) compared with placebo in type 2 diabetes patients with elevated blood glucose levels.

The company said the primary endpoint of the study would be to show safety of all three doses over three months of follow-up.

Mesoblast said that secondary endpoints included effects of each dose on blood glucose control, changes in inflammatory markers and hormones that may be abnormal in patients with type 2 diabetes and effects on C-reactive protein, an established predictor of cardiac arrest and death in patients with type 2 diabetes.

The company said that the MPC product for type 2 diabetes was the first of its suite of biologic therapies to be delivered via an intravenous injection and the dose ranges would be based on results from its preclinical studies in 17 cynomolgous macaque monkeys with obesity-related type 2 diabetes (BD: Nov 10, 2011).

Mesoblast said that the most effective doses were 1 or 2 million MPCs/kg which resulted in significant and sustained reductions in fasting blood glucose levels over three months compared to baseline, with no reductions in blood glucose levels were seen in controls.

The company said that 45 patients with poorly controlled type 2 diabetes, would be randomized to receive one of three escalating doses of 0.3, 1 or 2 million MPCs/kg, with 15 patients in the placebo arm, evaluated for three months for the primary endpoints associated with treatment safety and tolerability.

Secondary endpoints of the study include assessment of glycaemic control, assessment of C-reactive protein levels and other inflammatory markers, and possible effects on end-organ function such as kidneys and heart.

Mesoblast was up 20 cents or 3.2 percent to $6.45.

PROGEN PHARMACEUTICALS

Progen says that China has approved a phase III trial application by licencee, Taiwan's Medigen Biotechnology Corp for PI-88 for hepatocellular carcinoma.

Progen halted its phase III trial of the drug in 2008, citing an absence of partners and slow patient recruitment (BD: Mar 11, Jul 23, 2008).

Today, Progen said that China's State Food and Drug Administration approved Medigen's investigative new drug application for PI-88, which was also approved in Taiwan and Korea, allowing Medigen to open sites and commence patient enrolment in China.

The company said that China had the highest prevalence of hepatocellular carcinoma in the world, followed by Japan and Korea.

Progen said the randomized, placebo-controlled, multinational trial, was designed to confirm the efficacy and safety of PI-88 in the adjuvant treatment of heptocellular carcinoma after surgical resection.

The company said that disease-free survival was the primary efficacy endpoint and patients were being recruited at 18 sites in Taiwan and Korea.

Progen said it was entitled to milestone payments based on the achievement of various stages of clinical development and royalties on sales following marketing approval.

Progen said it was also contracted to supply the clinical trial material to Medigen through its contract manufacturing subsidiary, Pharmasynth.

Progen was untraded at 17 cents.

IMMURON

Immuron says it has a collaboration agreement with Monash University to develop products to prevent and/or treat Clostridium difficile infections.
Immuron said the therapeutic would be based on its hyper-immune bovine colostrum platform technology, used in its commercially available diarrhoea treatment Travelan.
The company said that Clostridium difficile infections were a major medical problem, especially in hospitals and long-term care facilities because the bacteria produce toxins that cause inflammation of the colon, causing severe diarrhoea and, in serious cases, death.
Immuron said that about 28,000 people died each year from these infections in the US.
The company said that Monash University had a Federal Government through an Australian Research Council Linkage grant.
Immuron said it and Monash University would together own the technology to be generated and Immuron had the exclusive global commercialization rights.
The company said Clostridium difficile infections resulted in an estimated annual economic burden of more than $US10 billion globally.
Immuron said that current therapies were based on antibiotics that were not fully effective and encouraged the emergence of antibiotic-resistant strains.
Immuron was up 0.1 cents or 2.4 percent to 4.2 cents.

SCIGEN

Scigen says it has a memorandum of understanding with Actavis Group PTC to sell recombinant human insulin in the Asia-Pacific, Middle East and Africa.
The Iceland-founded, Switzerland-based Actavis paid QRX a $US6 million upfront fee for a US licence for its Moxduo Immediate Release pain relief drug (BD: Jan 22, 2012).
Scigen said that the Swiss-based Ferring SA would distribute insulin in some Middle East and Africa markets following a renegotiated licence agreement.
Scigen said that Actavis would pay up to EUR1,400,000 ($A1,736,890) including EUR1,000,000 at signing of the final agreements.
The company said that both parties expected that sales would begin “on the turn of 2012 and 2013” and profits would be shared on an equal basis.
Scigen said that formal documentation was expected “in the following weeks”.
Scigen was untraded at 6.8 cents.

ACRUX

Acrux says the US Patent and Trademark Office has allowed patent application number 11/678,673 entitled ‘Spreading Implement’, with an anticipated expiry date of July 2029.
Acrux said that similar patent applications were pending in other pharmaceutical markets around the world.
The company said that the patent protected the applicator that was an integral part of the Axiron product and was used to apply the testosterone solution to the skin.
Acrux said the patent was part of a series of patents that protected the Axiron product, including the pending application describing the underarm administration of testosterone, which is at an advanced stage of review in the US.
Acrux was up 13 cents or 3.95 percent to $3.42.

BIOTA

Biota says that Daiichi Sankyo has confirmed that gross sales of Inavir were YEN1.7 Billion ($A20.95 million) with indicative royalties of $687,000 for the three months to December 31, 2011.

In October 2011, Biota reported there were no sales of Inavir in the three months to September 30, 2011 but sales of Inavir for the three months to June 30, 2011 were YEN400 million ($4.7 million) providing a royalty of $160,000 (BD: Jul 29, Oct 31, 2011).

Biota fell one cent or 1.2 percent to 82 cents.

CBIO

CBio says its net operating cash burn for the three months to December 31, 2011 was $4,762,000 with cash at the end of the quarter of $7,269,000.

CBio acting managing-director Helen Cameron told Biotech Daily that the Appendix 4C Quarterly Report disclosed that the cash burn included a $2 million repayment of a convertible loan and “termination payments to directors …[of] $1.092 million”.

CBio fell 0.9 cents or 8.6 percent to 9.6 cents.

SUNSHINE HEART

Sunshine Heart says its net operating cash burn for the three months to December 31, 2011 was $3,941,000, with cash at the end of the quarter of $6,419,000.

Sunshine Heart provided no further information.

Sunshine Heart was untraded at four cents.

GENESIS RESEARCH & DEVELOPMENT

Genesis says its net operating cash burn for the three months to December 31, 2011 was $72,000 with cash at the end of the quarter of $64,000.

Earlier this month, Genesis said it was the process of providing a back door listing for the Sydney based Mariposa (BD: Jan 22, 2012).

Genesis was untraded at three cents.