Biotech Daily

Tuesday April 8, 2014

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: UNIVERSAL BIO UP 14%, REVA DOWN 17%**

*** WEHI: 'THROMBOPOIETIN ACTS ON PLATELET PROGENITORS'**

*** VIRALYTICS CAVATAK ACTIVE AT NON-INJECTED SITES, PD-1 POTENTIAL**

*** RESONANCE REQUESTS CAPITAL RAISING TRADING HALT**

*** AVITA DEVELOPS NON-REFRIGERATED RECELL TREATMENT**

*** REGENEUS TO HARVEST HUMAN FAT FOR ALLOGENEIC STEM CELLS**

*** MESOBLAST PLEADS 'NASDAQ FALL, SHORTS' TO ASX 16% FALL QUERY**

*** VIRAX PATHWAY ACQUISITION, 490m SHARES EGM**

MARKET REPORT

The Australian stock market slipped 0.06 percent on Tuesday April 8, 2014 with the S&P ASX 200 down 3.1 points to 5,410.6 points.

Six of the Biotech Daily Top 40 stocks were up, 21 fell, 10 traded unchanged and three were untraded.

Universal Biosensors was the best, up four cents or 13.8 percent to 33 cents with 198,250 shares traded.

Mesoblast climbed 7.6 percent; Pharmaxis was up 5.5 percent; Uscom was up 3.6 percent; Acrux rose 2.3 percent; with Benitec and Resmed up by less than one percent.

Reva led the falls, down three cents or 16.7 percent to 15 cents with 98,182 shares traded, followed by Compumedics down 13.6 percent to 9.5 cents with 108,387 shares traded and Genetic Technologies down 10.7 percent to five cents with 115,000 shares traded.

Cellmid lost 7.1 percent; Antisense and Psivida were down more than six percent; Bionomics and Patrys fell more than five percent; Viralytics fell 4.8 percent; Alchemia and Tissue Therapies were down more than three percent; Clinuvel, Impedimed, Prana and Starpharma shed two percent or more; GI Dynamics, IDT, Nanosonics, Neuren, QRX and Sirtex lost more than one percent; with Cochlear and CSL down less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its scientists have identified how bone marrow cells become over-stimulated and produce too many platelets.

The Institute said that platelets were essential to stop bleeding and were produced by small fragments breaking from their parent cells, mega-karyocytes.

The Institute said that in blood diseases such as essential thrombocythemia, too many platelets could clog blood vessels, causing clots, cardiac arrest or strokes.

WEHI said that researchers Prof Warren Alexander, Prof Don Metcalf, Prof Douglas Hilton Dr Ashley Ng, Dr Maria Kauppi and colleagues led the research, entitled 'Mpl expression on mega-karyocytes and platelets is dispensible for thrombopoiesis but essential to prevent myeloproliferation' and was published in the Proceedings of the National Academy of Sciences.

An abstract is at: http://www.pnas.org/content/early/2014/04/02/1404354111.abstract.

Dr Ng said the hormone thrombopoietin was responsible for signalling bone marrow cells to produce platelets but until now researchers did not know precisely which cells responded to its signals.

The Institute said that by studying the receptor for thrombopoietin, called the myeloproliferative leukemia virus oncogene or Mpl, on blood cells in the bone marrow, the team pinpointed which cells were involved in making platelets following thrombopoietin stimulation.

"Thrombopoietin did not directly stimulate the platelet's parent cells, the megakaryocytes, to make more platelets," Dr Ng said.

"Thrombopoietin signals actually acted on stem cells and progenitor cells, several generations back," Dr Ng said.

To reach this conclusion, the researchers genetically removed the myeloproliferative leukemia virus oncogene (Mpl) receptors from megakaryocytes and platelets.

Dr Ng said the result was very surprising.

"The progenitor and stem cells in the bone marrow began massively expanding and effectively turned the bone marrow into a mega-karyocyte making machine," Dr Ng said.

"Our findings support a theory whereby mega-karyocytes and platelets control platelet numbers by mopping-up excess amounts of thrombopoietin in the bone marrow," Dr Ng said.

"In fact, we show this mopping-up action is absolutely essential in preventing blood disease where too many mega-karyocytes and platelets are produced," Dr Ng said.

"The findings may have implications for human disease," Dr Ng said.

"We know people with myeloproliferative disorders, such as essential thrombocythemia, produce too many mega-karyocytes and platelets," Dr Ng said.

"Interestingly, previous studies have shown mega-karyocytes and platelets in people with essential thrombocythemia have fewer Mpl receptors, which fits our model for excessive platelet production," Dr Ng said.

"By using genetic signatures, we were able to compare the blood progenitor cells responsible for overproducing mega-karyocytes in our model, to progenitor cells in people with essential thrombocythemia," Dr Ng said.

"We were able to show that progenitor cells in our model and in patients with essential thrombocythemia, had a signature of excessive thrombopoietin stimulation," Dr Ng said.

"We think this study now provides a comprehensive model of how thrombopoietin controls platelet production, and perhaps gives some insight into the biology and mechanism behind specific myeloproliferative disorders," Dr Ng said.

VIRALYTICS

Viralytics says intra-tumoral Cavatak shows activity at non-injected sites and pre-clinical potential with anti-programmed cell death-1 monoclonal antibodies.

Viralytics said data from its phase II trial of intra-tumorally injected Cavatak for late-stage melanoma (Calm trial) showed anti-tumor activity at non-injected sites.

The company said that partial or complete resolution of non-injected tumors was evidence to support a dual mechanism of action for Cavatak with targeted direct cancer killing activity and generation of patient anti-cancer immune responses

Viralytics said that the Utah-based Huntsman Cancer Institute oncologist and lead study investigator Dr Robert Andtbacka presented the additional clinical trial and pre-clinical data on the effect of Cavatak, or coxsackievirus A21, at the American Association of Cancer Research conference in San Diego, California, April 5 - 9, 2014.

The company said that investigators reported partial or complete reduction of non-injected tumors in multiple patients who had been on treatment at least eight weeks.

Viralytics said that the findings provided “promising evidence of oncolytic immunotherapy” with anti-cancer activity observed in tumor cells at the site of injection as well as in tumors at distant body locations.

“Reductions in non-injected tumors are a key measure of success for intra-lesional therapies such as Cavatak, as it suggests generation of an anti-cancer immune response in addition to Cavatak’s targeted cancer cell killing at the site of injection,” Dr Andtbacka said.

“These interim results are very encouraging, and I look forward to providing a more in-depth clinical update at [the American Society of Clinical Oncology] in June,” Dr Andtbacka said.

Viralytics said that Cavatak was well-tolerated by patients with no reports of serious adverse events1 or grade 3 or 4 adverse events related to the Cavatak treatment.

The company said that programmed cell death-1 was an inhibitory receptor expressed by T-cells and Dr Andtbacka presented results from a preclinical study assessing the combination of Cavatak with a new class of cancer therapy, anti-programmed cell death-1 (PD-1) monoclonal antibodies.

Viralytics said that Cavatak with PD-1 monoclonal antibodies demonstrated significantly greater in-vivo anti-cancer activity compared to the anti-PD-1 monoclonal antibodies or Cavatak treatment alone.

“The preclinical results of Cavatak in combination with an anti-PD-1 antibody look promising,” Dr Andtbacka said.

“These findings, along with the immunotherapeutic activity seen in the Calm trial, support a potentially significant application of Cavatak in combination with anti-PD-1 antibodies that warrants clinical investigation,” Dr Andtbacka said.

Viralytics chief executive officer Dr Malcolm McColl said the data demonstrating anti-cancer activity of Cavatak in patients with serious metastatic disease was “positive news for Viralytics”.

Viralytics fell 1.5 cents or 4.8 percent to 29.5 cents with 1.2 million shares traded.

RESONANCE

Resonance has requested a trading halt “pending a material announcement regarding to a capital raising”.

Trading will resume on April 10, 2014 or on an earlier announcement.

Resonance last traded at 6.3 cents.

AVITA MEDICAL

Avita says it has developed a new version of Recell spray-on skin that no longer requires refrigeration.

Avita said the new version improved the commercial and practical benefits to clinicians and had been cleared for use in Europe and the UK.

The company said that it was submitting an application for review to Australia's Therapeutic Goods Administration, where the current product must be refrigerated.

Avita said that the regulatory approval and commercial launch of the non-refrigerated Recell was part of its commercialization strategy, which included improvements in ease of use to enhance its clinical value.

Avita interim chief executive officer Tim Rooney said the elimination of the inconvenience of the temperature-controlled product would be valuable in generating Recell sales.

"Until now, Recell has required refrigeration, which often meant it was not immediately on hand in the operating theatre," Mr Rooney said. "The fact that this product can be stored on the shelf until use is a valuable element in providing a more convenient and attractive product, particularly in situations where time is of crucial importance."

Avita said that Recell was used "to disaggregate [granulate] cells from a patient's skin sample and to collect those cells into suspension for reintroduction to the patient".

The company said that the cell suspension could be used for various applications, including treatment of acute burns, scars, vitiligo and chronic wounds.

Avita said that the enzyme formulation, which was responsible in part for the cell disaggregation process, was subjected to comprehensive ageing and performance testing by an Australian laboratory before it was granted regulatory approval for sale in the United Kingdom and Europe.

Avita was unchanged at 12 cents.

REGENEUS

Regeneus says it has ethics approval to collect stem cells from human donors for use in production of its Progenza allogeneic off-the-shelf stem cell product for osteoarthritis.

Regeneus said that the private Bellberry health research ethics committee approval meant it could begin manufacturing the cells for its first-in-man clinical trial to assess initial safety and preliminary efficacy in human volunteers with knee osteoarthritis.

Regeneus clinical development director Dr Richard Lillischkis said the company was collecting adipose, or fat, tissue from human donors and "extracting and expanding the stem cells to produce large numbers of vials of frozen stem cells for use in clinical trials".

The company said that access to an off-the-shelf product would mean stem cell therapy was less invasive for patients than autologous treatments and provide a convenient treatment option for specialists.

Regeneus said that treating doctors would remove a vial of cells from the freezer, thaw the cells and inject them in to a patient's joints.

The company said that the new allogeneic product would need to pass safety and efficacy trials to achieve market access.

Regeneus said it had targeted the Japanese market for its allogeneic product to take advantage of laws that provided an accelerated approval process for allogeneic human cell therapies without the need for expensive phase III clinical trials.

The company said it marketed its autologous product Hiqcell that has been used to treat more than 1,000 human arthritic joints in clinical trials and commercial settings, as well as the allogeneic Cryoshot for canine and equine osteoarthritis.

Regeneus was up half a cent or 1.1 percent to 44.5 cents.

MESOBLAST

Mesoblast has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price fell from $5.47 on March 31 to $4.57, a 16.45 percent decrease, on April 7, 2014 and noted an increase in trading volumes.
Mesoblast said the decrease in price was "primarily as a result of a fall in the Nasdaq Biotechnology Index of 4.01 percent on Friday April 4, 2014, together with an increase in short positions".
Mesoblast climbed 35 cents or 7.6 percent to $4.96 with 1.3 million shares traded.

VIRAX HOLDINGS

Virax shareholders will vote on resolutions relating to the acquisition of Pathway Oncology Pty Ltd for its GGTI-2418 and GGTI-2417 anti-cancer assets (BD: Mar 17, 2014).
The resolutions to the meeting include the issue of 240,000,000 shares for the assets in three tranches and the placement of 250,000,000 shares to raise $3,000,000,
The meeting will be held at the Heritage Board Room, Melbourne Hotel, 942 Hay Street, Perth, Western Australia, on May 9, 2014 at 10am (AWST).
Virax fell 0.1 cents or 9.1 percent to one cent.