Biotech Daily

Thursday March 17, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BIOTRON UP 33%, OSPREY DOWN 13%**

*** VICTORIA PLEDGES $1.2b FOR SUNRISE, REGIONAL INDUSTRIES**

*** CSIRO, ARMI IMPROVE BONE MARROW STEM CELL HARVESTING**

*** WEHI: 'T-CELL RELEASE DISCOVERY COULD IMPROVE TREATMENTS'**

*** TISSUE THERAPIES HOPES TO RAISE $15m**

*** NETHERLANDS REIMBURSES SIRTEX SIR-SPHERES TREATMENT**

*** BIOTRON: 'BIT225 COMBINATION BETTER THAN INTERFERON, RIBAVIRIN'**

*** MESOBLAST LICENCES STEM CELL TECHNOLOGY FOR DIABETES**

*** ISRAEL'S ADAMA LICENCES STARPHARMA PRIOSTAR 2,4-D HERBICIDE**

*** NOVOGEN RECEIVES $2.8m FEDERAL R&D TAX REFUND**

*** PRO MEDICUS TO BUY-BACK 10m SHARES**

*** BLUECHIIP LOSES DIRECTOR MATT MORGAN**

MARKET REPORT

The Australian stock market was up 0.96 percent on Thursday March 17, 2016 with the ASX200 up 49.2 points to 5,168.2 points. Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and three were untraded. All three Big Caps fell.

Biotron was the best, up 2.1 cents or 33.3 percent to 8.4 cents with 17.0 million shares traded, followed by Mesoblast up 15.7 percent to $2.80 with 2.15 million shares traded. Cellmid climbed 11.1 percent; Oncosil rose 6.9 percent; Avita was up five percent; Living Cell improved four percent; Pro Medicus was up 3.8 percent; Anteo, Opthea and Prima rose more than two percent; Actinogen, Compumedics, Ellex, Nanosonics, Orthocell, Starpharma and Viralytics were up more than one percent; with Sirtex up 0.3 percent.

Osprey led the falls, down four cents or 12.9 percent to 27 cents with 44,000 shares traded. Admedus lost 6.7 percent; Prana was down 5.4 percent; Antisense and Universal Biosensors fell more than four percent; Resmed was down 3.75 percent; Pharmaxis shed two percent; Acrux, Medical Developments and Reva were down more than one percent; with Clinuvel, Cochlear, CSL and Psivida down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says it has $1,208 million for projects in innovative and regional industries to propose projects that will create infrastructure and jobs in the State.

In an embargoed industry media briefing on March 15; 2016 Victoria Industry Minister Lily D'Ambrosio said that the State Government had created three funds the $200 million Future Industries Fund, the $508 million Premier's Jobs and Investment Fund and the $500 million Regional Jobs and Infrastructure Fund.

Ms D'Ambrosio told Biotech Daily that the funds were not dedicated to specific projects but the funds would be available "for major projects to help the sector".

Ms D'Ambrosio said that the funds were not directed at projects".

"Organizations and businesses need to apply," Ms D'Ambrosio said.

Officers of the Department of Economic Development, Jobs, Transport and Resources gave the Government's investment in Bio-21 for a CSL hub as an example of a project that benefitted the sector.

Interested companies and organizations can contact the Department of Economic Development's medical technologies and pharmaceuticals director Andrew Wear by email: andrew.wear@ecodev.vic.gov.au.

A Victoria Government media release said that the sectors targeted were medical technologies and pharmaceuticals, new energy technologies, food and fibre, transport, defence technologies, construction technologies, international education and professional services.

The Government said that under the Future Industries Fund, grants of up to $100,000 were available for scoping, planning and feasibility studies, with up to $1 million to implement approved projects.

Among the aims for the nine named innovative industries were to:

Implement collaborative initiatives in areas of world leading capability;

Support networking opportunities to increase connections across the sector;

Grow and promote Victoria's capabilities in clinical trial and service provision;

Drive innovation in pharmaceuticals manufacturing;

Encourage research and development and continuous improvement in manufacturing;

Support Victorians to enter the medical technology and pharmaceuticals manufacturing workforce;

Assist companies to access local research and development infrastructure and expertise;

Better use of digital technologies and capabilities to foster growth;

Build workforce capacity to grow the sector;

Promote the sector with a high quality brand;

Support targeted international investment and trade activities;

Make it easier for businesses and researchers to access capital;

Improve commercialization of research;

Encourage and attract entrepreneurs through the $60 million start-up initiative Launchvic;

Work with the Commonwealth to optimize tax and regulatory settings;

Better leverage Commonwealth support and initiatives; and

Improve domestic market access to support local jobs.

Program guidelines are available at: www.business.vic.gov.au.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION
AUSTRALIAN REGENERATIVE MEDICINE INSTITUTE

The CSIRO says that with the Australian Regenerative Medicine Institute it has developed a less invasive method for harvesting stem cells, reducing side effects.

In a media release the CSIRO said that for bone marrow transplantation, stem cells were harvested from healthy donors and used to treat patients with cancers including leukaemia, with the process taking a long time and requiring injections of a growth factor to boost stem cell numbers, which often led to side effects.

CSIRO said that the method reduced the time to obtain adequate numbers of stem cells, without the need for a growth factor.

The Organization said that combining the newly-discovered small molecule antagonist N-(benzenesulfonyl)-L-prolyl-L-O-(1-pyrrolidinylcarbonyl)tyrosine), or BOP, with the molecule AMD3100 mobilized stem cells in bone marrow into the blood stream.

CSIRO researcher Dr Susie Nilsson said her team was able to demonstrate that combining the two molecules directly impacted stem cells so they could be seen in the blood stream within an hour of a single dosage.

The joint research, entitled 'Therapeutic targeting and rapid mobilization of endosteal HSC using a small molecule integrin antagonist' was published in Nature Communications and an abstract is available at:
http://www.nature.com/ncomms/2016/160315/ncomms11007/full/ncomms11007.html.

"Current treatment requires the donor to have growth factor injections for several days leading up to the procedure," Dr Nilsson said.

"Using the new method eliminates the need for this, meaning a procedure that once took days can be reduced to around an hour," Dr Nilsson said.

"Until now AMD3100 has only been effective in increasing stem cell numbers when combined with the growth factor," Dr Nilsson said.

"But the growth factor can cause unpleasant side effects like bone pain and spleen enlargement for some donors," Dr Nilsson said.

"Other donors simply don't respond well, and their stem cell count never gets high enough for a successful transplant," Dr Nilsson said.

The CSIRO said that the scientists found that combining the two small molecules not only eliminated the need for the growth factor, but when the harvested cells were transplanted they could replenish the entire bone marrow system and there are no known side effects.

The Monash University-based Australian Regenerative Medicine Institute director Prof Peter Currie said that a major benefit of the discovery was that harvesting stem cells would become more efficient and effective, considerably reducing the stress for donors, which in turn benefited patients.

"We're looking forward to seeing patients benefit from this discovery," Prof Currie said.

"So far successful pre-clinical studies have demonstrated the effectiveness of the treatment," Prof Currie said.

"The next step is a phase I clinical trial assessing the combination of BOP molecule with the growth factor, prior to the eventual successful combination of the two small molecules BOP and AMD3100," Prof Currie said.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers “have redefined how killer immune cells are mobilised in the body’s response to infections or cancer cells”.

WEHI said that the discovery of how two pathways co-operated to release the immune system’s cytotoxic, or killer, T-cells, could be used to improve the treatment of chronic infections or cancer.

The research article, entitled ‘A molecular threshold for effector CD8+ T- cell differentiation controlled by transcription factors Blimp-1 and T-bet’ was published in Nature Immunology.

An abstract is at: http://www.nature.com/ni/journal/vaop/ncurrent/full/ni.3410.html.

WEHI said that killer T-cells detected, attacked and killed abnormal cells in the body, such as cells infected with viruses or that had undergone cancerous changes.

The Institute said that Dr Axel Kallies, Dr Annie Xin and Dr Frederick Masson investigated how killer T-cells were generated during immune responses.

WEHI said that the formation of killer T-cells was guided by signals, called cytokines, released by other immune cells.

“These signals are transmitted to two separate regulator proteins within the T-cell, called Blimp-1 and T-bet,” Dr Kallies said.

“For several years it has been known that these molecules both contribute to the formation of killer T-cells, but we haven’t understood how they work together,” Dr Kallies said.

“We showed that the combination of both signals triggers the formation of killer cells that can fight a viral infection. If one of these signals is lost, the immune response is dampened but still functional,” Dr Kallies said.

“This creates a buffered system that helps the organism to fight different types of infections or cancerous cells,” Dr Kallies said.

“It’s a great example of how our body has checks and balances in place to ensure the immune system is switched on at the right time, such as during an infection, but can be toned down at other times to avoid a damaging attack on healthy cells,” Dr Kallies said.

WEHI said that CD8 killer-T cells were central to recent breakthroughs in cancer immunotherapy, “an extremely successful new approach to cancer treatment” that harnessed the immune system to rid the body of cancer cells.

Dr Kallies said he hoped his research showing how killer T-cells were formed would lay the groundwork for future advances in cancer immunotherapy.

“There have been amazing improvements in immunotherapy recently that can be traced directly back to basic immunology research conducted over the last decade,” Dr Kallies said.

“Our team is now looking at how we can apply our discoveries to approaches aimed at improving cancer therapies,” Dr Kallies said.

TISSUE THERAPIES

Tissue Therapies expects to raise $15 million through a two-tranche placement and a rights issue at 3.5 cents a share.

Biotech Daily understands that $9.65 million is expected to be raised in the placement, with a further $5.3 million to be raised in a rights issue that is expected to be fully underwritten by stock brokers Taylor Collison.

Tissue Therapies requested a capital raising trading halt yesterday and Biotech Daily has been able to confirm media reports and internet share market speculation on the fund raising (BD: Mar 16, 2016).

Tissue Therapies last traded at 4.7 cents.

SIRTEX MEDICAL

Sirtex says that the Netherlands Healthcare Institute Zorginstituut Nederland will reimburse the use of SIR-Spheres for colorectal liver metastases.

Sirtex said that the decision was based “on clinical evidence of the efficacy and safety of SIR-Spheres Y-90 resin microspheres” for treating patients with colorectal liver metastases who had failed or were intolerant to prior chemotherapy.

The company did not cite the level of reimbursement, but sales figures in its half year report to December 31, 2015 implied a cost of $19,657 per dose (BD: Feb 24, 2016).

Sirtex chief executive officer Gilman Wong said the company was “delighted the Netherlands Healthcare Institute has recognised the established safety and efficacy of SIR-Spheres microspheres in this patient population, which will lead to more patients seeking treatment at leading specialist centres across the Netherlands”.

Mr Wong said the company was engaging with government bodies throughout the Europe Middle East and Africa region which “could lead to an expansion in the reimbursement offered for SIR-Spheres microspheres over time”.

Sirtex said that a patient registry would analyze data on the first 500 patients with colorectal liver metastases who receive Sir-Spheres under the reimbursement program.

The company said that colorectal cancer was the third most common cancer in the Netherlands, with an annual incidence of about 14,000 cases and 5,200 deaths a year.

Sirtex was up 10 cents or 0.33 percent to $30.29 with 470,179 shares traded.

BIOTRON

Biotron says its 30-subject phase II study of BIT225 showed that genotype 1 patients were more likely to clear virus than the former standard-of-care alone.

Biotron said that the Thailand multi-centre, placebo-controlled, randomized trial was designed to assess the safety and antiviral activity of three month’s dosing of BIT225 in patients infected with hepatitis C and provided information on a new capsule form of BIT225, “critical for determining dosage in further studies with the drug”.

The company said that the trial achieved its safety and efficacy primary endpoints, as well as its secondary endpoints, including assessment of the antiviral activity and pharmacokinetics of the new capsule formulation and BIT225 was safe and well-tolerated with none of the patients withdrawing due to BIT225-related adverse events.

The company said that patients treated with BIT225 and interferon with ribavirin were “significantly more likely to clear virus within 24 weeks of commencing treatment than those treated with [interferon with ribavirin] alone”.

The company said that 12 weeks after stopping BIT225 treatment, 82 percent of patients treated with BIT225 with interferon and ribavirin were clear of virus, compared to 60 percent of those treated with interferon and ribavirin alone.

Biotron managing-director Dr Michelle Miller said that the “safety profile of BIT225 in these … patients was excellent, and the drug had a clear beneficial antiviral effect over and above the standard-of-care”.

Biotech Daily is aware that the current treatment for hepatitis C includes 12-week courses of oral medication, without interferon and ribavirin.

Dr Miller said the data supported “a potential role for BIT225 to be used in combination with new … drugs” toshorten patient treatment times and improve outcomes Biotron was continuing to explore licencing opportunities for BIT225.

Dr Miller said the trial data could support a phase II trial in patients infected with HIV-1, against which the drug is also active expected to begin in mid-2016.

Biotron was up 2.1 cents or 33.3 percent to 8.4 cents with 17.0 million shares traded.

MESOBLAST

Mesoblast says it has licenced technology which can modify mesenchymal lineage adult stem cells to enhance their homing properties to sites of excessive inflammation.

Mesoblast said that the ex-vivo fucosylation mesenchymal lineage adult stem cells developed at Harvard Medical School induced durable reversal of type 1 diabetes in mice.

A Mesoblast spokesperson told Biotech Daily that the technology was licenced from Harvard Medical School's Prof Robert Sackstein.

The pre-clinical study, entitled 'HCELL Expression on Murine MSC Licenses Pancreatotropism and Confers Durable Reversal of Autoimmune Diabetes in NOD Mice' was published in the journal Stem Cells and an abstract is available at: http://www.ncbi.nlm.nih.gov/pubmed/25641589.

Mesoblast said that the results showed that the cell targeting technology increased by three-fold the numbers of mesenchymal lineage cells reaching the inflamed pancreas in autoimmune diabetic mice following intravenous infusion, compared with unmodified mesenchymal lineage cells.

The company said that this resulted in a markedly increased number of mice who reverted to having normal blood glucose and in a durable reversal of type 1 diabetes.

The study's lead investigator, Harvard Medical School's Prof Sackstein said that the hypothesis was that inflammation that destroyed pancreatic islet cells could be controlled by selectively targeting the pancreas with anti-inflammatory mesenchymal lineage cells.

"The realization was that this new clinical approach essentially cured mice of type 1 diabetes," Prof Sackstein said.

Last year, results of Mesoblast's 61-patient phase II trial of mesenchymal precursor cells (MPCs) for type 2 diabetes which began in 2012, were re-published in Diabetes Care, saying that a single intravenous infusion of MPCs showed the cells were safe, tolerable, and improved glycaemic control as evidenced by reduction in haemoglobin A1c (HbA1c) in type 2 diabetes patients (BD: Jan 31, 2012; Dec 4, 2013; Jul 23, 2015).

Today, Mesoblast said that by enhanced targeting of the cells to the inflamed pancreas, the ex-vivo fucosylation technology had "the potential to further augment the glucose lowering properties of MPC-300-IV, and to extend its use to patients with type 1 diabetes".

The company said that type 1 diabetes had significant morbidity and mortality despite the use of insulin and other glucose-lowering agents.

Mesoblast said that the prevalence of type 1 diabetes continued to increase in people under the age of 20 years, making innovative new treatments a major strategic focus for the pharmaceutical industry.

Mesoblast said that ex-vivo fucosylation, or the addition of fucose to cell surface receptors on stem cells.

The company said that the process modified the receptors by adding carbohydrate or sugar sequences which allowed them to be recognized by, and bound to, their ligands present on endothelial cells lining blood vessels in inflamed tissues.

Mesoblast said the licenced technology was supported by US granted patents including patents: 7,875,585, entitled 'Hematopoietic cell E-selectin / L-selectin ligand glycosylated CD44 polypeptide'; patent 8,084,236 entitled 'Compositions and methods for modifying cell surface glycans'; patent 8,728,810 entitled 'Methods for modifying cell surface glycans'; and patent 8,852,935 'Compositions and methods for modifying cell surface glycans', with expiry dates to 2027, and with the potential for further patent term adjustments and/or extensions.

Mesoblast was up 38 cents or 15.7 percent to $2.80 with 2.15 million shares traded.

STARPHARMA

Starpharma says that Israel's Adama Agricultural Solutions has licenced its Priostar dendrimer technology for an enhanced, proprietary 2,4-D herbicide for the US market.
Starpharma said that dichlorophenoxyacetic acid (2,4-D) was "one of the top three herbicides sold world-wide" with global sales in 2014 estimated at $US680 million and the US market worth about $US115 million.
The company did not specify how much it would receive from Adama for the licence, but said it would receive royalties on sales of the Priostar-improved 2,4-D products and the agreement included a mechanism to expand the licence to additional territories.
Starpharma said that Adama had undertaken development of a new, unique 2,4-D product containing the Priostar dendrimer technology, which was expected to provide better flexibility and weed control benefits to the grower, as well as improved safety.
The company said that the development would "allow for on-target application, thus benefiting the environment by reducing the amounts of product required".
Starpharma was up one cent or 1.6 percent to 64.5 cents.

NOVOGEN

Novogen says it has received $2,865,708 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Novogen said the rebate related to research and development expenditure for the year to June 30, 2015
The company said the funds would be used to support its Cantrixil (TRXE-002-1) to a phase I trial in 2016.
Novogen was unchanged at 11 cents.

PRO MEDICUS

Pro Medicus says it will buy-back up to 10 percent of its 101,700,406 shares on issue, beginning on April 1, 2016 and continuing to March 31, 2017.
Pro Medicus was up 12 cents or 3.8 percent to $3.28.

BLUECHIIP

Bluechiip says that non-executive director Matt Morgan has resigned effective immediately.
Bluechiip appointed Mr Morgan as a director in 2014 (BD: Feb 3, 2014).
Bluechiip fell 0.7 cents or 25.9 percent to two cents with three million shares traded.