Biotech Daily

Thursday January 28, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: OSPREY UP 8%, OPTHEA DOWN 13%**

*** CANCER CRC SHARES $731m MERCK BLOOD DISORDER LICENCE**

*** VICTORIA: RMH, WEHI, PETER MAC LEUKAEMIA TRIAL BACKS VENETOCLAX**

*** ACRUX LAUNCHES LENZETTO FOR MENOPAUSE IN EUROPE**

*** AVEXA RAISES $490k, PLAN FOR TALI; HALTS ATC FOR HIV, COAL MINE**

*** US PATENT FOR PRIMA'S IMP731**

*** ALCHEMIA EGM APPROVES 9.3c RETURN OF CAPITAL**

*** DORSAVI $202k LONDON UNDERGROUND OHS CONTRACT**

*** CYNATA: 'UK REGULATOR APPROVES CYP-001 GVHD TRIAL'**

*** 'FREEMAN ROAD' TAKES 8% OF RESAPP**

MARKET REPORT

The Australian stock market was up 0.6 percent on Thursday January 28, 2016 with the ASX200 up 29.8 points to 4,976.2 points.

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

Osprey was the best, up two cents or 7.7 percent to 28 cents with 40,000 shares traded.

Acrux and Avita climbed five percent or more; Genetic Technologies and Prima rose more than four percent; Antisense and CSL were up more than one percent; with Cochlear, Medical Developments, Pro Medicus and Sirtex up by less than one percent.

Opthea (formerly Circadian) led the falls, down 5.5 cents or 13.4 percent to 35.5 cents with 235,791 shares traded.

Living Cell lost 9.1 percent; Compumedics fell 5.9 percent; Neuren shed 4.35 percent; Actinogen, Admedus and Benitec were down more than three percent; Atcor, Clinuvel, Prana, Resmed, Universal Biosensors and Viralytics shed more than two percent; Anteo, Bionomics, Biotron, Ellex, Nanosonics, Orthocell and Polynovo were down more than one percent; with Mesoblast and Reva down by less than one percent.

COOPERATIVE RESEARCH CENTRE FOR CANCER THERAPEUTICS

The Cancer Therapeutics CRC will share a potentially more than $731 million Merck Sharp and Dohme licence for inhibitors of protein arginine methyltransferase 5 (PRMT5).

The Melbourne-based Cooperative Research Centre for Cancer Therapeutics (CTx) said it was in a collaboration with London's Cancer Research Technology, the development and commercialization arm of Cancer Research UK, with support from the Wellcome Trust, and the drugs to inhibit arginine methyltransferase 5 had potential clinical applications in cancer and non-cancer blood disorders.

CTx chief executive officer Dr Warwick Tong told Biotech Daily that the studies completed so far included in-vitro and in-vivo pre-clinical work.

A Cancer Research Technology media release said it had licenced the rights to Merck Sharp and Dohme, known as Merck Inc in North America, on behalf of CTx with an upfront payment of $US15 million ($A21.3 million) and would be eligible for potential payments of up to $US500 million ($A709.9 million) for achievement of development, regulatory and commercialisation milestones.

The media release said that the agreement provides for royalties on sales and all payments would be shared between the London Cancer Research Technology, Melbourne's CTx and the Wellcome Trust with the majority being returned to CTx and its Australian research partners.

The Cancer Research Technology said the program was the result of initial research by Monash University's Prof Stephen Jane and collaboration between the CTx academic partners.

The media release said that the PRMT5 protein was involved in many cellular processes including the epigenetic control of genes such as p53, a gene that protected the cell against cancer-causing mutations and was faulty in nine of 10 cancers.

The Cancer Research Technology said that high levels of PRMT5 protein were found in mantle cell lymphoma, chronic lymphocytic leukaemia, melanoma, lung and breast cancers and were linked to poor survival.

The media release said that in addition to applications for cancer, PRMT5 inhibitors switched on important genes in the development of blood, which could provide disease-modifying treatment options for patients with blood disorders such as sickle cell disease and beta thalassemia.

Cancer Research Technology said that Merck Sharp and Dohme would be responsible for research and development, including clinical development and for worldwide commercialization of products and would fund a research collaboration with CTx focusing on blood disorders.

Cancer Research Technology's director of business development Dr Phil L'Huillier said his group was "delighted to have brought together the multiple parties involved in the discovery and optimisation of this multi-purpose target."

"The deal provides potentially significant financial returns, which CRT will invest into life-saving cancer research, and most importantly will hopefully bring promising new drugs to cancer patients as well as those suffering from blood disorders where there are no effective treatment options available, Dr L'Huillier said.

Dr Tong said the licence was "a great result for Australian science and the CRC Program as a whole and further demonstrates what can be achieved when science and commercialization capabilities unite".

Wellcome Trust head of business development Dr Richard Seabrook said the Trust was "excited to see that the support from our Seeding Drug Discovery Award is playing a key role in moving the project forward" and hoped the collaboration would lead to treatments for haemoglobin disorders such as sickle cell and beta thalassemia.

VICTORIA GOVERNMENT

The Victoria Government says a 116-patient phase I trial has shown that venetoclax can kill cancer cells in patients with advanced chronic lymphocytic leukaemia.

The State Government said that the Melbourne dose-escalation trial showed that patients could achieve complete remission with about 80 percent of patients having "promising responses to the drug, with 20 percent of those involved going into complete remission".

A Victoria Government media release said that "many patients … maintained this response more than a year after their treatment began, with some patients remaining in remission more than four years on".

The Government said that the trial was conducted at the Royal Melbourne Hospital and the Peter MacCallum Cancer Centre, in partnership with the Walter and Eliza Hall Institute, all of which are Victorian Comprehensive Cancer Centre alliance partners.

The study, entitled 'Targeting BCL2 with Venetoclax in Relapsed Chronic Lymphocytic Leukemia', was published in the New England Journal of Medicine and an abstract is at: http://www.nejm.org/doi/full/10.1056/NEJMoa1513257?query=featured_home.

The abstract said that 56 patients received treatment in one of eight dose groups that ranged from 150 to 1200 mg per day and in an expansion cohort, 60 additional patients were treated with a weekly stepwise ramp-up in doses as high as 400 mg per day.

The study said that of the 116 patients who received venetoclax, 92 (79%) had a response with complete remissions in 20 percent of the patients, including five percent who had no minimal residual disease on flow cytometry.

The abstract said that 15-month progression-free survival estimate for the 400-mg dose groups was 69 percent and concluded that "selective targeting of BCL2 with venetoclax had a manageable safety profile and induced substantial responses in patients with relapsed [chronic lymphocytic leukemia or small lymphocytic lymphoma], including those with poor prognostic features".

The abstract said that the study was funded by Abbvie and Genentech.

The Victoria Government said the Parkville-based Victorian Comprehensive Cancer Centre would open in mid-2016 and be the new home for the Peter MacCallum Cancer Centre, with 160 in-patient beds, 110 same-day beds, eight operating theatres, two procedure rooms and eight radiation therapy bunkers and would provide cancer research and clinical facilities for Melbourne Health and more than 1,200 cancer researchers.

ACRUX

Acrux says that its Lenzetto estradiol spray for menopause symptoms, marketed as Evamist in the US, has been launched in Poland and the Czech Republic.

Acrux said that Lenzetto was licenced exclusively in Europe to Gedeon Richter and would be rolled out in multiple additional European countries over the coming months.

Evamist, then known as Ellavie, was approved by the US Food and Drug Administration in 2007 and marketed in the US from 2008, but the Australian Therapeutic Goods Administration demanded further trials for local approval, which Acrux considered not financially worthwhile at that time (BD: Nov 12, 2009).

Evamist was distributed by KV Pharmaceuticals in the US and was one of the few products earning revenue when KV faced quality and manufacturing issues, as it was manufactured at a separate, third party pharmaceutical company (BD: Feb 2, 2009).

Acrux chief executive officer Michael Kotsanis told Biotech Daily that the Dublin, Ireland-based Perrigo became the US distributor for Evamist in November 2014, re-launching the product in March 2015, with Acrux receiving tiered royalties.

Acrux climbed four cents or 5.9 percent to 72 cents.

AVEXA

Avexa says it has raised $490,000 at four cents a share, will offer a share plan for its Tali acquisition and will cease funding apricitabine and Alabama coal mining.

In 2014, Avexa said it expected revenue from its Alabama coal mine in 2014 to fund a 300-patient, phase III trial of apricitabine (ATC) for HIV approved by both the US Food and Drug Administration and the European Medicines Agency (BD: Jun 25, 2014).

Chairman Iain Kirkwood said at that time that Avexa had invested $9 million in loans and equity for the coal mine and held 30 percent, with Avexa major shareholder, Singapore's Jonathan Lim, holding a further 30 percent and US interests holding the balance.

The company faced internal problems following the closure of its phase III ATC program, the resignation of the chief executive officer Dr Julian Chick and a request for a board spill (BD: May 10, 2010).

Today, the company said it had reviewed "the company's drug development projects and the investment in the US coal venture and have suspended all associated expenditures".

Avexa said that the ATC early access program did not attract any orders "despite being available since January 2015 and extensive work by our partner Link with HIV activist groups internationally".

The company said that the global oil price fall flowed through to natural gas prices in the US which competed directly with large industrial consumers and it had been "extremely difficult to attract a sufficient volume of orders to make the North Pratt coal mine viable".

Avexa said it would concentrate on the Monash University-developed Tali technology for diagnosing intellectual disabilities and proposed to change the company name to Tali Healthcare, with a resolution to be put to shareholders no later than the 2016 annual general meeting (BD: Oct 12, Nov 26, 2015).

The company said that the share plan would have a record date of January 26, 2016 and allow investors to acquire shares in parcels of up to $15,000 at a discount to the market price and without incurring brokerage or other charges.

Avexa was unchanged at five cents.

PRIMA BIOMED

Prima says it has been granted a US patent relating to its IMP731 antibody, originally developed by Immutep, acquired by Prima in 2014 (BD: Oct 2, 2014).

Prima said that patent, entitled 'Cytotoxic anti-LAG-3 monoclonal antibody and its use in the treatment or prevention of organ transplant rejection and autoimmune disease' and the granted claims provided protection to November 2031 for specific sequences of the antibody and its use in depleting LAG-3 T-cells by complement dependent cytotoxicity and antibody-dependent cell cytotoxicity.

The company said that the rights for the development of the IMP731 antibody were granted in December 2010 to Glaxosmithkline which had begun first-in-human clinical trials of a proprietary antibody, GSK2831781, derived from IMP731.

Prima was up 0.2 cents or 4.4 percent to 4.7 cents with 2.6 million shares traded.

ALCHEMIA

Alchemia says an extraordinary general meeting has approved the return of 9.3 cents a share (BD: Dec 17, 2015).

Alchemia said that about $30.2 million would be returned to shareholders at the record date of February 3 and payment would be made on February 24, 2016.

Alchemia fell 0.1 cents or 1.01 percent to 9.8 cents with 1.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says the UK regulator has confirmed that its Cymerus mesenchymal stem cell product CYP-001 is suitable for use in a phase I trial for graft versus host disease
Cynata said that following a scientific advice meeting the Medicines and Healthcare Products Regulatory Agency (MHRA) advised that its existing program of pre-clinical studies was expected to be sufficient to support the approval of the proposed clinical trial and no additional preclinical studies were required, and agreed with the general design of the proposed clinical trial.
The company said it intended to conduct the trial at centres in the European Union, including the UK, and Australia and the trial was on-track to begin by July 2016.
Cynata was up seven cents or 23.3 percent to 37 cents.

DORSAVI

Dorsavi says that Transport for London, which operates the London Underground, has signed a more than GBP100,000 ($A202,202) contract to reduce workplace injuries.
Dorsavi said that it would use its Visafe wearable monitor technology to identify manual handling tasks contributing to increased risk of musculoskeletal injury.
The company said the contract was its third and largest with Transport for London which was seeking objective data to inform its program to reduce manual handling injury risk.
Dorsavi said the UK lost 9.5 million working days to musculoskeletal injury in 2014-'15, with manual handling the main work activity causing back disorders and there were more than 500,000 cases of work-related musculoskeletal injury in the same period.
The company said that employers were "highly focussed on providing preventative and proactive initiatives to prevent work related musculoskeletal injuries" which made up to 44 percent of all work related illnesses.
Dorsavi said that the Visafe workplace assessment with Transport for London would place sensors on workers to determine movement, posture and associated muscle strain on workers' lower back and shoulders and the program would consider the musculoskeletal impact of vibration experienced by train drivers.
Dorsavi was untraded at 36 cents.

RESAPP HEALTH

Freeman Road Pty Ltd, for The Avenue account, says it has increased its substantial holding in Resapp from 30,000,000 shares (5.34%) to 44,000,000 shares (7.59%).
The substantial shareholder notice, signed by director Tee Yen Ng of St George's Terrace, Perth, Western Australia, said Freeman Road sold 1,000,000 shares for $152,500 or 15.25 cents a share and converted 15,000,000 options to shares for $390,000 or 2.6 cents a share.
Previously Biotech Daily has reported that the Australian White Pages has a Freeman Road located in Maroubra, Sydney, while the Linkedin page for Trevor Marchant said that he was the owner of Freeman Road Pty Ltd (BD: Jul 24, 2015).
Biotech Daily attempted to contact Mr Marchant and Freeman Road at that time, but without success.
Resapp fell 0.5 cents or 4.0 percent to 12 cents with 2.2 million shares traded.