Biotech Daily

Tuesday December 6, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: USCOM UP 9%, ACTINOGEN DOWN 8%**

*** MD ANDERSON, NIH FUND MESOBLAST CANCER TECHNOLOGY TRIAL**

*** ESENSE $3.5m IPO FOR TERPENES, MEDICAL MARIJUANA, RARE PLANTS**

*** DORSAVI SIGNS CONNECT 12-MONTH VISAFE TENNESSEE DISTRIBUTION**

*** DIMERIX RECRUITS PART A OF PHASE II DMX-200 FOR KIDNEY DISEASE**

*** NOVOGEN STARTS CANTRIXIL TRX-E-002-1 OVARIAN CANCER TRIAL**

*** VIBURNUM, WYLLIE FUNDS TAKE 15.5% OF UNIVERSAL BIOSENSORS**

*** DR TRACEY MYNOTT, MYENG REDUCE TO 9% OF ANATARA**

*** JCP TAKES 5% OF VIRALYTICS**

*** FIL TAKES 5% OF MEDIBIO**

MARKET REPORT

The Australian stock market climbed 0.52 percent on Tuesday December 6, 2016 with the ASX200 up 28.3 points to 5,428.7 points. Ten of the Biotech Daily Top 40 stocks were up, 17 fell, 12 traded unchanged and one was untraded.

Uscom was the best, up two cents or 9.1 percent to 24 cents with 145,407 shares traded.

Atcor climbed 4.8 percent; Cellmid was up 3.7 percent; Genetic Signatures and Viralytics rose more than two percent; Admedus, Benitec, Oncosil, Polynovo and Resmed were up more than one percent; with Compumedics and CSL up by less than one percent.

Actinogen ended a month-long run from 3.6 cents and led the falls, down half a cent or 8.1 percent to 5.7 cents with 801,956 shares traded.

Pro Medicus lost 6.4 percent; Impedimed, Prana and Reva fell more than five percent; Living Cell was down 3.3 percent; Clinuvel, Factor Therapeutics, Medical Developments, Nanosonics, Prima and Psivida shed more than two percent; Airxpanders, Cochlear and Pharmaxis were down more than one percent; with Ellex, Mesoblast and Sirtex down by less than one percent.

MESOBLAST

Mesoblast says the MD Anderson Cancer Center and the US National Institutes of Health will fund a trial of two of its technologies for cord blood transplants for cancer.

Mesoblast said that the 25-patient study would investigate its mesenchymal precursor cell-based expansion and ex-vivo fucosylation of haematopoietic stem cells for cord blood transplantation in cancer patients.

The company said that ex-vivo fucosylation was “the addition of the sugar fucose to surface receptors on cells, including [haematopoietic stem cells] and mesenchymal lineage stem cells … [modifying] receptors on these cells by adding carbohydrate or sugar sequences which allows them to be recognized by and bound to their ligands present on endothelial cells lining blood vessels in inflamed tissues and in human bone marrow”.

Mesoblast said that the trial would provide clinical data on whether the combination of the two technologies synergistically facilitated more rapid cord blood haematopoietic stem cell engraftment for bone marrow transplant patients than can be achieved by either technology alone.

The company said the 30,000 allogeneic bone marrow transplants performed each year could be increased substantially, if safe and effective alternative sources of allogeneic haematopoietic stem cells were available, such as cord blood, for patients who could not find a matched donor.

Mesoblast said that cord blood transplants were associated with prolonged engraftment times due to insufficient numbers and inadequate homing capacity of cord blood haematopoietic stem cells, adversely impacting their clinical outcomes.

Mesoblast said that combining its mesenchymal precursor cell-based expansion plus ex-vivo fucosylation of cord blood haematopoietic stem cells aimed to overcome the two key limitations to using cord blood for rapid, early engraftment and bone marrow reconstitution in adult bone marrow transplant patients.

The company said a phase II trial demonstrated that transplantation of haematopoietic stem cells from mesenchymal precursor cell-expanded cord blood resulted in a reduced engraftment time, from a median of 24 days for placebo-treated cells to a median of 15 days for co-cultured cells.

Mesoblast said that a separate phase II study showed that transplantation of fucosylated, but non-expanded, cord blood haematopoietic stem cells (HSCs) also resulted in a reduced median engraftment time of 17 days.

The company said that preclinical results from an MD Anderson Cancer Center study led by Dr Elizabeth Shpall showed that when mesenchymal precursor cell (MPC) based expansion and ex-vivo fucosylation technologies were combined, there was a “very rapid engraftment time of approximately seven days”.

“Our data suggest that combining Mesoblast’s MPC-based HSC expansion and ex-vivo fucosylation technologies may be the optimal clinical strategy for rapid engraftment of cord blood transplants, potentially making cord blood transplantation a real option for many desperate patients who cannot find a suitable alternative,” Dr Shpall said.

Mesoblast said that the trial, entitled ‘Cord Blood Ex-vivo MPC Expansion Plus Fucosylation to Enhance Homing and Engraftment’ would be led by Dr Shpall and Dr Amanda Olson and if positive, Mesoblast's ex-vivo fucosylation technology might be incorporated into the company's phase III program of mesenchymal precursor cell-expanded haematopoietic stem cells.

The company said that many patients with advanced blood cancers required a stem cell transplant to repopulate bone marrow HSCs after chemotherapy treatment, but it could be difficult to find a matched donor, especially for patients of a racial or ethnic minority.

Mesoblast fell half a cent or 0.4 percent to $1.19.

ESENSE-LAB

Esense says it hopes to raise up to $3.5 million in an initial public offer at 20 cents a share to develop terpenes to reconstruct essential oils including cannabis and saffron.
Esense chairman and Otsana Capital director Dr Brendan de Kauwe told Biotech Daily that the prospectus was lodged today but was not publicly available.
The prospectus said that the Perth, Western Australia-based Otsana Capital was the lead manager to the offer.
Dr de Kauwe said that inquiries should be directed to Otsana at: http://www.otsana.com/.
The Esense prospectus said the offer would close on December 21, 2016 and the company hoped to list on the ASX under code 'ESE' on January 13, 2017.
Dr de Kauwe said that terpenes were the molecules that provided health and benefit to plants and by reconstructing them, through reverse engineering, allowed the company to create any essential oil from the target plant without using the plant.
Dr de Kauwe said this was important for slow-growing and rare plants such sandalwood and ginseng.
Dr de Kauwe said that the aim was to reconstruct pharmaceutical grade products in a laboratory with consistency and replicability.
The Israel-based Esense said that the board and management team included chief executive officer Haim Cohen, with directors Quentin Megson, Eran Gilboa, Galit Assaf and Ilan Saad, with chief technical officer Dr Yaron Penn, chief scientific adviser Prof Zvi Vogel and head scientist Dr Mira Carmeli-Weissberg.

DORSAVI

Dorsavi says it has a 12-month Visafe distribution agreement with Connect Healthcare with a minimum committed value of $140,000.
Dorsavi said that the Memphis, Tennessee-based Connect would act as a sales agent for the Visafe wearable sensor workplace health and safety system.
The company said that Connect was "active in the occupational health and safety space with an emphasis on marrying analytics and strategy to deliver innovative, proactive and personal ways to educate employees and partner with them in their quest to support a healthier workforce".
Connect founding partner Christine Ferris said that Visafe was "attractive to all levels of entry into the workers' compensation process".
"From insurance carriers and brokers to employers, Dorsavi provides proven solutions that benefit employee productivity," Ms Ferris said.
"As the only FDA-approved wearable sensor in the US, Dorsavi offers results and solutions that can't be matched by any other wearable technology in the market," Ms Ferris said.
Ms Ferris said that Dorsavi was "a best-in-class fit with our model … and we've already seen the impact it has on hospital clients from a clinical setting, to labour-intensive employers who want to offset their rapidly rising claims," Ms Ferris said.
Dorsavi said that earlier this year it signed the Portland, Washington-based Workright NW as a Visafe distributor and the company had signed more than $250,000 in sales to date (BD: Jul 6, 2016).
Dorsavi chief executive officer Dr Andrew Ronchi said that the company was "building a distribution model on a state-by-state basis in the US and we are partnering with organizations who understand the market and see the significant opportunity for Visafe".
Dorsavi was up one cent or two percent to 51 cents.

DIMERIX

Dimerix says it has dosed all 27 patients in the dose-escalation, first part of its phase II trial of DMX-200 for chronic kidney disease.

Dimerix said the first part intended to recruit up to 30 patients to explore the safety and potential reduction of proteinuria in patients with chronic kidney disease.

The company said that treatment was expected to be completed by mid-2017 and the data would inform the optimal dose for the second part of the study, in which up to 30 more patients would be recruited.

Dimerix said that five patients had completed dosing and one had withdrawn, leaving 21 participants in the study.

The company said that DMX-200 was being developed as an adjunct therapy, adding the chemokine receptor CCR2 blocker propagermanium to participants on the stable angiotensin II type I receptor blocker irbesartan, a drug registered in the US for hypertension and treatment of diabetic nephropathy in certain patients.

Dimerix said that proteinuria, or blood in the urine, was common in chronic kidney disease patients, was a strong independent risk factor for disease progression and that reducing proteinuria reduced the risk of disease progression and progressive loss of renal function leading to renal failure and the development and progression of cardiovascular disease.

Dimerix chief executive officer Kathy Harrison said that interim data showed “a good safety profile and encouraging signs of reduction of proteinuria”.

“This trend has continued, hence the company is confident that the current patient cohort will provide the data needed to support planning for part part B of the study which will focus on the efficacy outcomes for the treatment,” Ms Harrison said.

Dimerix was unchanged at 0.8 cents.

NOVOGEN

Novogen says it has enrolled the first of up to 60 patients in its first-in-human, phase I, dose-escalation study of Cantrixil, or TRX-E-002-1, for ovarian cancer.

Novogen said that the 18-month study was designed to understand the safety and tolerability of Cantrixil in ovarian cancer patients and would run at six hospitals in the US and Australia.

The company said that the trial would assess the appropriate dose of Cantrixil when administered through weekly direct infusions into the intraperitoneal cavity of patients with ovarian cancer who failed at least two prior lines of chemotherapy.

Novogen said that the study was not designed to assess efficacy, but patients would be monitored for radiological evidence of disease response and exploratory biomarkers would be assessed.

The company said that after an initial period of treatment with Cantrixil alone, clinicians would be permitted to add other approved therapies, which would provide useful information regarding the ability of Cantrixil to be used in combination with standard-of-care chemotherapy.

Novogen clinical and regulatory affairs director Dr Kimberley Lilischkis said that the start of the trial was “a further step in Novogen’s transition to a clinical-stage drug development company”.

Novogen said that ovarian cancer was the most common cause of cancer death from gynaecologic tumors in the US, with more than 200,000 women worldwide estimated to develop ovarian cancer every year and about 100,000 dying from the disease.

Novogen was up 0.4 cents or 4.4 percent to 9.4 cents.

UNIVERSAL BIOSENSORS

Viburnum Funds says it has increased its holding in Universal Biosensors from 23,852,665 Chess depositary interests (13.58%) to 27,256,676 CDIs (15.51%).
The Perth, Western Australia-based Viburnum notice said that between June 27 and December 5, 2016 the funds acquired 3,404,013 shares for $1,063,274 or 31.2 cents a share
Universal Biosensors was unchanged at 33.5 cents.

ANATARA LIFESCIENCES

Anatara chief science officer and Myeng Pty Ltd director Dr Tracey Mynott says she has reduced her holding from 5,002,635 shares (14.55%) to 4,391,337 shares (8.89%).
In a substantial shareholder notice, Dr Mynott said the 611,298 shares were sold on November 30 and December 1, 2016 for $654,314 or $1.07 a share.
In 2014, Dr Mynott said that the 5,002,635 shares were acquired between July 15, 2010 and April 30, 2013 for $500, or 0.01 cents a share and most were issued in lieu of payment for her work as well as the intellectual property she created relating to the use of the pineapple stem-based bromelain technology (BD: Oct 16, 21, 2014).
Anatara fell nine cents or 7.6 percent to $1.09.

VIRALYTICS

JCP Investment Partners says it has become a substantial shareholder in Viralytics with 12,181,035 shares or 5.07 percent.
The Melbourne-based JCP said that the shares were acquired between August 2 and December 2, 2016 with the single largest purchase 2,815,000 shares for $3,102,461 or $1.10 a share.
JCP said that the shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees, JP Morgan Nominees and UBS Nominees.
Viralytics was up three cents or 2.5 percent to $1.21.

MEDIBIO

The Hong Kong-based FIL Limited says it has become a substantial shareholder in Medibio with 6,816,492 shares (5.17%).
FIL said it bought the shares between October 28 and December 1, 2016 at prices ranging from 40 cents and 49 cents.
Medibio fell one cent or 2.6 percent to 38 cents.