Biotech Daily

Tuesday March 8, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: BENITEC UP 17%, ADMEDUS DOWN 11%**

*** INTERNATIONAL STEM CELL READY FOR PHASE I PARKINSON'S TRIAL**

*** MELBOURNE UNI $36m BIO21 EXPANSION FOR CSL HUB**

*** SIRTEX SORAMIC TRIAL RECRUITS 420 PATIENT LIVER CANCER TRIAL**

*** BENITEC BB-HB-331 REDUCES HEP B 98.5% IN MICE**

*** PHARMAUST PLANS 3 PHASE II MONEPANTEL (PPL-1) CANCER TRIALS**

*** IMUGENE HER-VAXX PRODUCT READY FOR GASTRIC CANCER TRIAL**

*** ITL PILOTS MYHEALTHTEST SALES THROUGH ACT PHARMACIES**

*** 3D MEDICAL SIGNS 5-YEAR MACH7 LICENCE WITH PENN STATE**

*** BLUECHIIP SHORTFALL RAISES $125k, TOTAL $815k**

*** APPLE WATCH, FITBIT PASS MEDIBIO, SWINBURNE STRESS TEST**

*** RAPHAEL LAMM, SHOMRON TAKE 7.45% OF ALCHEMIA**

MARKET REPORT

The Australian stock market fell 0.68 percent on Tuesday March 8, 2016 with the ASX200 down 34.8 points to 5,108.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and three were untraded.

Benitec was the best, up two cents or 16.7 percent to 14 cents with 7.1 million shares traded. Compumedics climbed 8.6 percent; Living Cell was up 6.25 percent; Opthea rose 5.3 percent; Actinogen, Biotron and Oncosil were up more than three percent; Ellex and Prana rose more than two percent; Clinuvel, Sirtex, Universal Biosensors and Viralytics were up more than one percent; with Cochlear, Medical Developments and Resmed up by less than one percent.

Admedus led the falls, down five cents or 10.6 percent to 42 cents with 590,316 shares traded. Mesoblast lost 6.5 percent; Cellmid, Genetic Technologies and Osprey fell more than five percent; Prima was down 4.9 percent; Bionomics and Pharmaxis were down more than three percent; Anteo, Impedimed, Polynovo and Starpharma fell more than one percent; with Acrux, CSL and Nanosonics down by less more than one percent.

THE INTERNATIONAL STEM CELL CORP, CYTO THERAPEUTICS

International Stem Cell says it has ethics approval for a 12-patient, phase I trial of its stem cells for moderate to severe Parkinson's disease.

The Carlsbad, California-based International Stem Cell Corp said that through its Australian subsidiary Cyto Therapeutics it had received approval from Melbourne Health for the trial of its ISC-hpNSC, or human partheno-genetic neural cell-derived stem cells and the Royal Melbourne Hospital.

Cyto director Bob Atwill told Biotech Daily that enrolment would begin "as soon as possible".

International Stem Cell chief scientific officer Dr Russell Kern said that enrolment would be "an important milestone".

"Promising preclinical results support our expectation that ISC-hpNSC will bring a long-needed solution for patients suffering from Parkinson's disease," Dr Kern said.

"The ability of our approach to replace and protect dopaminergic neurons and restore neural function offers significant potential benefit to patients," Dr Kern said.

Dr Kern said the company expected preliminary clinical data by the end of 2016.

International Stem Cell said the study was a dose escalation, safety and preliminary efficacy study of ISC-hpNSC, transplanted into the substantia nigra in patients' midbrains.

The company said the open-label, single center, uncontrolled clinical trial would evaluate three dose regimens of 30,000,000 to 70,000,000 neural cells, with patients monitored for 12 months, to evaluate the safety and biologic activity of ISC-hpNSC.

International Stem Cell said that a positron emission tomography (PET) scan would be performed at baseline, as part of the screening assessment and at six and 12 months after surgical intervention, and clinical responses compared to baseline after the administration of ISC-hpNSC, with evaluations using neurological assessments such as Unified Parkinson Disease Rating Scale, Hoehn and Yahr and other scales.

International Stem Cell said that Parkinson's disease was a central nervous system degenerative disorder, mainly affecting the motor system, with no cure and affected more than seven million people worldwide.

The company said that the motor symptoms of Parkinson's disease resulted from the death of dopamine-generating cells in the substantia nigra in the midbrain and early in the course of the disease the most obvious symptoms were movement-related, followed by thinking and behavioral problems, with dementia commonly occurring in the advanced stages of the disease, and depression the most common psychiatric symptom.

The company said that medications typically used in the treatment, L-DOPA and dopamine agonists, improved the early symptoms of the disease, but as the disease progressed and dopaminergic neurons continued to be lost, the drugs eventually became ineffective while producing a complication marked by involuntary writhing movements.

International Stem Cell said that ISC-hpNSC consisted of a highly pure population of neural stem cells derived from human parthenogenetic stem cells.

The company said that pre-clinical studies in rodents and non-human primates had shown improvement in Parkinson's disease symptoms and increase in brain dopamine levels following the intracranial administration of ISC-hpNSC.

International Stem Cell said that ISC-hpNSC provided neurotrophic support and cell replacement to the dying dopaminergic neurons of the recipient brain.

The company said that ISC-hpNSC was safe, well tolerated and did not cause adverse events such as dyskinesia, systemic toxicity or tumors in preclinical models.

International Stem Cell said that ISC-hpNSC might have therapeutic applications for neurological diseases affecting the brain, the spinal cord and the eye.

CSL, UNIVERSITY OF MELBOURNE, BIO21 INSTITUTE

The University of Melbourne says the Bio21 Institute in Parkville will be expanded to house CSL's global research and translational medicine hub.

In a joint media release, the University of Melbourne, the Bio21 Molecular Science and Biotechnology Institute and CSL said that Prime Minister Malcolm Turnbull made the announcement after touring the Bio21 Institute, yesterday.

The media release said that CSL had been a Bio21 partner since 2007 and the University would spend $36.4 million on a 5,000 square metre expansion for the expansion of platforms that underpin personalized medicine and the development of new diagnostics.

The media release said Bio21 would be home to the CSL global hub for research and translational medicine, and CSL was expected to double the number of research scientists to about 150, with work to begin this year and expected to be completed in 2017.

University of Melbourne Vice-Chancellor Prof Glyn Davis said the expansion was "an important industry-university partnership that will enable greater knowledge and technology transfer, drive innovation and ensure Australian research is translated into positive health outcomes around the world".

CSL chief scientific officer and research and development director Dr Andrew Cuthbertson said that "the increased presence at Bio21 will allow CSL to increase its collaborations with university researchers, plus other research institutes and hospitals … [and] provide an expanded base for new national and international collaborations".

CSL fell 72 cents or 0.7 percent to $102.43 with 1.2 million shares traded.

SIRTEX MEDICAL

Sirtex says Germany's University of Magdeburg has completed recruitment of 420 patients in the trial of sorafenib with SIR-spheres for inoperable primary liver cancer.

Sirtex chief executive officer Gilman Wong said that the 'Sorafenib and Micro-therapy Guided by Primovist-Enhanced MRI in Patients with Inoperable Liver Cancer' (Soramic) trial was "the fourth clinical study to complete patient recruitment across our five major clinical studies program and represents the largest SIR-Spheres Y-90 resin microspheres combination study ever undertaken in [hepatocellular carcinoma]".

Sirtex said that the primary endpoint of the study was overall survival with secondary endpoints of quality of life and safety.

The company said that the results were expected in 2018.

The University of Magdeburg's clinic for radiology and nuclear medicine director and co-principal investigator Prof Jens Ricke said that for the past 10 years "sorafenib has been the sole standard of care" for treating patients with advanced hepatocellular carcinoma (HCC), or any HCC that had spread beyond the liver.

"We hope that the results of this large [randomized controlled trial] will demonstrate that the combination of sorafenib and SIR-Spheres microspheres may provide a new treatment standard for patients with HCC who are not eligible for surgical resection or ablation," Prof Ricke said.

Sirtex said that the study combines "the most promising novel diagnostic and therapeutic approaches in HCC treatment", the diagnosis with hepatocyte specific contrast agent Primovist, microtherapy with yttrium 90 radioembolisation SIR-Spheres, or radiofrequency ablation and systemic treatment with the tyrosine kinase inhibitor sorafenib.

The company said that the Soramic study continued to recruit for another study cohort with curative intent, comparing radiofrequency ablation with sorafenib to radiofrequency ablation with placebo.

Sirtex was up 39 cents or 1.3 percent to $30.01 with 953,490 shares traded.

BENITEC BIOPHARMA

Benitec says that its BB-HB-331 therapy targeting the hepatitis B virus, shows “robust and durable suppression” of the virus in mice, following a single administration.

Benitec said that the DNA-directed RNA interference (ddRNAi) drug comprised an adeno-associated virus-8 capsid and recombinant DNA engineered to express three short hairpin RNA (shRNA) that targeted and inhibited viral RNA expressed from three well conserved regions across multiple hepatitis B genotypes.

The company said that the study assessed the activity of BB-HB-331 in the Phoenixbio mouse model, in which mouse liver cells were replaced with human hepatocytes making the animals susceptible to hepatitis B infection.

Benitec said that once infected with hepatitis B, mice were treated with a one-time systemic injection of BB-HB-331.

The company said that weekly assessment of serum antigen levels, hepatitis B viral proteins and extracellular hepatitis B DNA were conducted for the duration of the 56-day study.

Benitec said that the key findings were that a single treatment reduced serum hepatitis B DNA by 1.83 logs, equivalent to 98.5 percent elimination of circulating hepatitis B virus; reduced intracellular liver hepatitis B DNA by 94.9 percent; suppressed serum antigens, HBsAg and HBeAg, by 97.6 percent and 92.6 percent, respectively, and decreased levels of hepatitis B viral RNA and covalently closed circular DNA.

The company said that in-vivo experiment validated the BB-HB-331 in-vitro findings observed in human hepatocytes isolated from the mouse model (BD: Dec 7, 2015).

Benitec chief scientific officer Dr David Suhy said the results “demonstrate the utility of an approach that combines RNAi with gene therapy to treat [hepatitis B]”.

“In addition to these encouraging results, we note that the [hepatitis B] serum DNA and antigen levels continued to drop through the predetermined conclusion of the study, and may not have reached their lowest levels,” Dr Suhy said.

Benitec was up two cents or 16.7 percent to 14 cents with 7.1 million shares traded.

PHARMAUST

Pharmaust says it is having discussions with a UK-based clinical oncologist for a phase II trial of monepantel, formerly known as PPL-1, for oesophageal cancer.

Pharmaust said that similar studies would be undertaken with patients with two other types of cancer at centres in Australia and the US, respectively.

Last year, Pharmaust said its phase I/II trial of PPL-1 for cancer showed the drug was safe, despite palatability issues, with the seventh and final patient showing “meaningful suppression of key cancer marker p70S6K” (BD: Jul 23, Oct 21, 2015).

Today, the company said that the purpose of the three phase II studies was to provide short-term feedback on the efficacy of monepantel to identify which leading cancer or cancers it should pursue for development and product registration purposes.

Pharmaust said it would use positron emission tomography analysis of tumors to determine the effects of monepantel.

The company said that the provision of the capsule-reformulated compound in the next eight to 10 weeks from the Nottingham UK Juniper Pharma Services would trigger the initiation of patients, subject to the Medicines and Healthcare Products Regulatory Agency approval.

Pharmaust said that the first trial would be a single-arm trial in patients that have failed standard of care.

Pharmaust fell half a cent or 4.2 percent to 11.5 cents.

IMUGENE

Imugene says it has completed manufacturing a clinical batch of its HER-Vaxx immunotherapy for a phase Ib/II gastric cancer trial planned to begin by September 2016.
Imugene said that a re-formulation of HER-Vaxx showed a 10-fold increase in cancer fighting antibody production and several batches of both the peptide antigen and the final vaccine drug substance had been manufactured by Austrian manufacturer Pichem GmbH.
The company said that batch-to-batch variation and stability studies had been completed and following optimization, manufacturing of the final clinical batch had been completed and optimizing the formulation led to a saving of more than $500,000 from the budget.
Imugene acting chief executive officer Leslie Chong said the manufactured batch was “a critical milestone … in our preparation for commencing our clinical trial in patients with gastric cancer”.
Imugene was unchanged at one cent with 9.3 million shares traded.

ITL

ITL says that Myhealthtest has expanded its sales distribution network by piloting distribution of its HbA1c diabetes test in pharmacies in the Australian Capital Territory.
ITL said that so far, sales of the test had been solely through Myhealthtest’s online shop.
The company said that customers could access the direct-to-consumer pathology test in chemist shops and the purchase price would cover all testing costs.
ITL said that the availability in pharmacies would take Myhealthtest direct to its target market and potentially provide a foothold for sales of further tests in the pipeline.
Australian Capital Territory pharmacist and diabetes educator Elise Apolloni said it was “great that the consumer can make a decision of when to have their HbA1c levels tested and use the kit at a time convenient from them, whether that be in the pharmacy as part of a consultation, with their [general practitioner] or at home”.
“Ultimately, it is about empowering the consumer to be a champion for their own health, and with the ability to test HbA1c with a kit from home, hopefully a person living with diabetes will feel motivated by the results,” Ms Apolloni said.
Myhealthtest general-manager Nick Cerneaz said that “giving people with diabetes improved access to our HbA1c diabetes test combined with the benefits of advice and expertise on diabetes management from the pharmacist will also lead to improved health outcomes for the many people in Australia living with this difficult condition”.
ITL was unchanged at 21 cents.

3D MEDICAL

3D Medical says it has signed a five year licence for Mach7 imaging with Pennsylvania State University Milton S Hershey Medical Centre.
3D said that the Mach7 enterprise imaging platform would provide the backbone architecture and workflow management for all digital imaging and communications in medicine (Dicom) medical image data generated from the Centre’s radiology and cardiology departments, as well as all non-Dicom clinical media and the migration of all legacy data onto the Mach7 enterprise imaging platform.
The company said the Centre generated more than 500,000 medical imaging studies each year and the adoption of Mach7 enabled the consolidation of multiple disparate legacy data systems which would deliver significant cost savings, clinical efficiencies and increased productivity.
3D Medical was up 0.2 cents or 3.5 percent to 5.9 cents with 1.1 million shares traded.

BLUECHIIP

Bluechiip says it has raised a further $125,000 through the placement of 4,385,965 share purchase plan shortfall shares at 2.85 cents a share.
In February, Bluechiip said the share plan raised $240,000 and in December its placement raised $450,000 at four cents, taking the total to $815,000 (BD: Dec 17, 2015; Feb 25, 2016).
Bluechiip was unchanged at three cents.

MEDIBIO

Medibio says an evaluation of wrist-based wearable devices with its cardiac test for mental illness shows they can be used as alternatives to electrocardiogram monitors.
In February, Medibio said that Swinburne University's Software Innovation Lab would evaluate the devices for its heart rate-based mental health test by examining the data quality and suitability of devices, including the Apple Watch, Fitbit Surge, Samsung Gear S2 and the Jawbone UP3, for potential integration and connectivity to its mental health platform, including corporate stress products (BD: Feb 9, 2016).
Today, Medibio said that the Laboratory had confirmed "that both the Apple Watch and Fitbit Surge meet all performance requirements, allowing them to be used successfully as an alternative to ECG monitors in [its] corporate stress product … and paves the way for the release of a consumer stress [internet application].
Medibio was up half a cent or 2.5 cents to 20.5 cents.

ALCHEMIA

The Melbourne-based Shomron Pty Ltd says it has become a substantial shareholder in Alchemia with 24,222,212 shares or 7.45 percent of the company.
In a substantial shareholder notice signed by Raphael Lamm said the shares were bought on March 7, 2016 for $193,773 or 0.8 cents a share.
Last week, in a notice signed by David Lamm, Kentgrove Capital said it had acquired 64,619,996 Alchemia shares or 19.9 percent of the company and yesterday David Lamm was appointed a director of Alchemia (BD: Mar 4, 7, 2016).
Raphael Lamm told Biotech Daily that David Lamm is his brother.
Alchemia was up 0.2 cents or 25 percent to one cent with 24.1 million shares traded.