Biotech Daily

Wednesday December 13, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: GENETIC SIGNATURES UP 6%; ORTHOCELL DOWN 10%**

*** TELIX, JFE PARTNER FOR TLX-250 FOR CANCER IMAGING IN JAPAN**

*** IMMUTEP RECRUITS 3rd IMP-321, KEYTRUDA MELANOMA COHORT**

*** OVENTUS RAISES $7.6m**

*** ORTHOCELL PLACEMENT RAISES $1.5m, SHARE PLAN**

*** CANN SHARE PLAN FOR UP TO $10m, TO TAKE TOTAL TO $78m**

*** BRAIN PLACEMENT FOR $10m, SHARE PLAN FOR $1.25m**

*** PHARMAUST: 'MONEPANTEL SAFETY, EFFICACY FOR DOG LYMPHOMA'**

*** SECOND STUDY BACKS EPAT PAINCHEK**

*** NANOSONICS: 'MORE UK GUIDELINES BACK PROBE CLEANING'**

*** CLARITY SARTATE FOR KIDS MENINGIOMA TRIAL ETHICS APPROVAL**

*** RESAPP PREPARES FOR SMARTCOUGH-C-2 TRIAL**

*** SUDA: 'DATA BACKS ANAGRELIDE PLATELET REDUCTION FOR TUMORS'**

*** BRIAN MCNAMEE REPLACES CSL CHAIR JOHN SHINE, ABBAS HUSSAIN**

*** CLINICAL GENOMICS APPOINTS J&J'S ROY DAVIS DIRECTOR, ADVISOR**

MARKET REPORT

The Australian stock market edged up 0.14 percent on Wednesday December 13, 2017 with the ASX200 up 8.6 points to 6,021.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, 13 traded unchanged and one was untraded.

Genetic Signatures was the best, up two cents or 6.25 percent to 34 cents with 15,005 shares traded. Admedus climbed 5.1 percent; LBT and Telix improved more than four percent; Neuren was up 3.1 percent; Mesoblast and Starpharma rose more than two percent; Bionomics, Cyclopharm, Polynovo and Universal Biosensors were up more than one percent; with CSL, Nanosonics, Sirtex and Volpara up by less than one percent.

Orthocell led the falls, down four cents or 10.4 percent to 34.5 cents with 537,375 shares traded. Avita and Viralytics fell more than four percent; Clinuvel and Pro Medicus lost more than three percent; Actinogen, Benitec and Prana shed more than two percent; Cochlear, Ellex, Impedimed, Medical Developments and Optiscan were down one percent or more; with Resmed down 0.9 percent.

TELIX PHARMACEUTICALS

Telix says it has a manufacturing partnership with Tokyo's JFE Engineering Corp to produce TLX-250 for cancer imaging for the Japanese market

Telix said that JFE had expertize in the installation of cyclotron infrastructure and radio-pharmaceutical manufacturing and had recently installed a Cyclone 18 megaelectronvolt (MeV) cyclotron from Belgium's Ion Beam Applications SA at its Yokohama facility and was preparing for beam activation and zirconium-89 production in early 2018, the first commercial production in Japan.

The company said that the importation of radioactive isotopes into Japan was "typically very challenging" and the prospect of domestic production of new medical isotopes generated significant clinical interest in novel imaging and therapeutic radio-pharmaceuticals.

Telix chief executive officer Dr Christian Behrenbruch said his company had "an extensive commitment" to zirconium-89 isotopes in its diagnostic imaging portfolio, particularly for TLX-250 imaging with zirconium-89-girentuximab as its lead program.

The company previously said that the zirconium-TX250 positron emission tomography agent for imaging clear cell renal cell carcinoma was its lead program and was in a phase III trial (BD: Nov 15, 2017).

"Japan generally represents potentially the second largest market for our imaging products after the United States and this agreement with JFE paves the way to making our products available to Japanese cancer patients," Dr Behrenbruch said.

"JFE's tremendous experience and operational capability is a real asset to our commercial plans in Japan," Dr Behrenbruch said.

Telix said that the exclusive agreement initially focused on technology transfer and feasibility assessment for producing TLX-250 for the Japanese market and the parties intended to work together to conduct pilot studies at several Japanese nuclear medicine centres, as well as engage with Japan's Pharmaceuticals and Medical Devices Agency to obtain advice on extending Telix's clinical development activity in the US and Europe to include Japan.

Telix was up 2.5 cents or 4.3 percent to 61 cents.

IMMUTEP (FORMERLY PRIMA BIOMED)

Immutep the third cohort of its 22-patient, 'Two active immune-therapeutics in melanoma' (Tacti-mel) trial is fully recruited.

Immutep said that the sixth and last patient in the cohort received their first treatment earlier this week, bringing the total number of patients recruited to the trial to 18.

The company previously said the trial combined IMP321 with Keytruda and should be fully enrolled by mid-2018 (BD: Oct 27, 2017).

Last year, the then Prima said that interim data from the first cohort indicated IMP321 at the 1mg dose level was safe and well-tolerated (BD: Dec 22, 2016).

In April, Prima said that safety was confirmed in the second cohort dosed with 6mg of IMP321 and the third cohort would be dosed at 30mg of IMP321 (BD: Apr 19, 2017).

Today, the company said that eligible patients had unresectable or metastatic melanoma who either had a sub-optimal response or had disease progression with pembrolizumab, or Keytruda, monotherapy as a first-line of treatment and would be dosed with eftilagimod alpha, or IMP321, in combination with pembrolizumab.

Immutep said that to date, no dose limiting toxicity had been observed in any patient at any dose level, with data from the three cohorts expected by July 2018.

Immutep was unchanged at 2.4 cents with 1.7 million shares traded.

OVENTUS MEDICAL

Oventus says it raised $7.6 million in “a heavily oversubscribed” placement arranged by Bell Potter at 55 cents a share.
Oventus said the placement would strengthen its balance sheet and enable the roll-out of its O2Vent products for obstructive sleep apnoea.
Oventus fell three cents or 4.3 percent to 67 cents.

ORTHOCELL

Orthocell says it has raised $1.5 million in a placement at 34 cents a share and will offer a share plan.
Orthocell said the placement included $250,000 raised from directors, subject to shareholder approval, and management.
The company said it would offer a share plan at the same price for eligible shareholders at the record date of December 12, with the plan opening on December 18 and closing on December 29, 2017.
Orthocell said the proceeds would be used to accelerate the Celgro commercialization and progress US regulatory approvals and key studies, advance the development of Ortho-ATI and other research and development pipeline products
Orthocell fell four cents or 10.4 percent to 34.5 cents.

CANN GROUP

Cann says it expects to raise up to $10 million in an underwritten share plan at $2.50 a share, following last month’s $58.7 million placement (BD: Nov 30, 2017).
In November, Cann said it expected to raise $50 million in the placement and a further $10 million in the share plan.
Today, the company said that shareholders eligible at the record date of November 29 would be able to apply for parcels of shares up to $15,000.
The company said the offer would open on December 14 2017 and close on January 19, 2018.
Cann said the share plan was fully underwritten by Canaccord Genuity (Australia) with. PAC Partners and Canaccord Genuity joint lead managers to the plan.
The company said that along with the placement and share plan raising $68.7 million it would allot new shares to the Vancouver, British Columbia-based partner Aurora Cannabis to take it to a 22.9 percent holding.
Cann was unchanged at $2.56 with 653,319 shares traded.

BRAIN RESOURCE

Brain says it has commitments to raise $10 million in a placement at six cents a share and would offer a share plan capped at $1.25 million for existing investors (BD: Oct 25, 2017).
Brain said that eligible shareholders at the record date of December 12, could apply for shares in parcels of up to $15,000 each with the plan opening on December 15, 2017 and closing on January 5, 2018 and the plan was underwritten to $750,000.
The company said the proceeds would be used for growth in the US.
Brain said that the placement shares would come with one free option for three new shares exercisable at eight cents within 12 months of issue, but the options would not be available in the share plan.
Brain fell 2.5 cents or 21.7 percent to nine cents.

PHARMAUST

Pharmaust says its phase II trial of monepantel for dog lymphoma has met its primary endpoints of safety and efficacy.

Pharmaust said that six of seven dogs diagnosed with B-cell lymphoma and treated with monepantel had stable disease, with one dog developing progressive disease and there was a median reduction in tumor size of four percent.

The company said the trial objective was to assess the efficacy of monepantel as a first-line therapy in dogs diagnosed with B-cell lymphoma that had not received chemotherapy.

Pharmaust said that the dogs were treated for two weeks with daily doses of monepantel as a first-line therapy before commencing conventional chemotherapy.

The company said that B-cell lymphoma was chosen as the target indication as it was the most commonly treated cancer in dogs.

Pharmaust principal investigator Dr Angela Frimberger said the company was "pleased … that after two weeks of daily treatment with [monepantel] alone, six … of seven dogs achieved stabilization of their cancers, reductions in tumor sizes and no significant side-effects".

Dr Frimberger said that B-cell lymphoma was "an extremely progressive cancer" and without effective treatment dogs typically showed progressive disease after two weeks.

"Given the excellent safety margin we are seeing we expect the optimum clinical dose of the drug, once reformulated, will be substantially higher than the dose we have been using," Dr Frimberger said.

Pharmaust chief executive officer Dr Richard Hopkins said the company was "really pleased with the outcome to this pilot study which, according to our advisory team, strongly supports further clinical evaluation of monepantel".

"Monepantel will be the first mTOR inhibitor tested as a cancer therapy in dogs and has potential to address a major unmet need for new drugs in the pet cancer market," Dr Hopkins said.

Pharmaust said it expected to begin its monepantel trial program in early 2018.

Pharmaust was up 0.2 cents or 4.3 percent to 4.9 cents with 2.4 million shares traded.

EPAT TECHNOLOGIES

Epat says a second study has confirmed "excellent performance" of its Painchek mobile telephone application compared to the standard Abbey pain scale.

Epat said the study reviewed assessed 400 paired assessments in 34 aged care facility residents and showed that the Painchek facial recognition system had "excellent validity and reliability properties".

The company said the detailed study results would be published in the journal Dementia and Geriatric Cognitive Disorders early in 2018.

Epat chief executive officer Philip Daffas told Biotech Daily that he could not release specific data until publication, but said that there was "very high correlation" between the Painchek system and the Abbey pain scale.

Epat said the results confirmed previous clinical findings published in the Journal of Alzheimer's Disease (BD: Aug 16, 2017).

The company said the results showed that Painchek was able to distinguish the presence of pain under various clinical testing conditions reflective of rest and movement such as sitting and walking.

Mr Daffas said the study "reconfirms the Painchek [application] as a reliable and accurate pain assessment tool for people who are unable to verbalize their pain effectively".

Epat climbed 0.6 cents or 11.8 percent to 5.7 cents with 7.1 million shares traded.

NANOSONICS

Nanosonics says two British professional organizations have issued guidance requiring the appropriate disinfection or sterilisation of ultrasound probes.
Nanosonics said the British Medical Ultrasound Society and the UK Society and College of Radiographers issued the guidance in 'Guidelines for Professional Ultrasound Practice Revision 2, December 2017'.
The company quoted the guidelines saying: "All ultrasound transducer probes should be cleaned immediately after a scan to remove all organic matter and body fluids".
Nanosonics said ultrasound probes should undergo appropriate disinfection or sterilisation and all critical probes contacting sterile tissues or blood should be preferably sterilized, but if sterilization was not possible, they should be minimally high-level disinfected and used with a sterile sheath.
The company said that semi-critical probes including semi-invasive probes contacting mucous membranes and non–invasive probes contacting non-intact or broken skin should be high-level disinfected either manually or with automated systems and high-level disinfection is still required when using a sheath as sheaths can have micro-perforations or can break.
Nanosonics said the guidance drew on best practice infection prevention guidance for ultrasound probes previously published by the National Health Services of Wales and Scotland as well as more recent guidance from the Health Service Executive of Ireland and the joint guidance from the Australasian College for Infection Prevention and Control and Australasian Society for Ultrasound in Medicine.
Nanosonics chief executive officer Michael Kavanagh said that the British Medical Ultrasound Society guidance was "a welcome addition to a fast-growing number of international guidance documents being released which recognize the importance of high-level disinfection of all semi critical ultrasound probes to minimize the risk of cross-contamination and improve patient safety".
Nanosonics was up one cent or 0.4 percent to $2.60 with 964,112 shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has ethics approval for its six-patient pilot clinical trial of Sartate for paediatric meningioma due to start by July 2018 at Sydney's Royal North Shore Hospital.
Clarity said the single-centre, open-label, non-randomized, phase I/IIa diagnostic and therapy trial would administer its peptide receptor radionuclide therapy using its copper-67 labelled Mecosar-Tyr3-octreotate (67Cu-Sartate) to participants with meningioma.
Clarity executive chairman Dr Alan Taylor said the ethics approval was "an important milestone for Clarity as it marks our first human [diagnostic and therapy] trial using the perfect pairing of copper-64 and copper-67".
"The data collected from the study will be invaluable for progressing a number of copper-67 products into therapeutic trials," Dr Taylor said.
Clarity said that meningioma was a tumor that formed on membranes that covered the brain and spinal cord just inside the skull and meningiomas were the most common type of tumor that originated in the central nervous system.
The company said that Sartate targeted somatostatin receptor type 2 (SSTR2), which was expressed in a number of cancers, including meningioma, neuroendocrine tumours and a number of paediatric cancers.
Clarity said the trial would help pave the way for the use of 67Cu-Sartate in this patient group as well as for aggressive children's cancers, such as neuroblastoma.
Clarity is a public unlisted company.

RESAPP HEALTH

Resapp says the Baylor College of Medicine and Texas Children's Hospital has given institutional review board approval for the Smartcough-C-2 study.

Resapp said that the Smartcough-C-2 study was a follow-on from its Smartcough-C study "which was not a representative evaluation of Resappdx due to a range of issues during execution and clinical adjudication".

In August, Resapp fell 82.3 percent on news that its 1,245-patient Smartcough-C trial failed to meet its endpoints for the diagnosis of respiratory disease (BD: Aug 9, 2017).

Resapp said at that time that "contrary to instructions and training, a high number of patients were treated before clinical research staff recorded their cough sounds [and] a high number of recordings were also found to contain a second person's cough sounds or an unacceptable amount of background noise and interference".

The first Smartcough-C trial was conducted at the Texas Children's, Boston's Massachusetts General Hospital and the Cleveland Clinic and Resapp chief executive officer Dr Tony Keating told Biotech Daily the same three hospitals would conduct the Smartcough-C-2, prospective, multi-site, double blind study.

Resapp said the study would evaluate the efficacy of the Resappdx software application in the diagnosis of childhood respiratory diseases from cough sounds and enrol patients aged 29 days to 12 years presenting with signs or symptoms of respiratory disease.

Resapp said the primary endpoints for the study were positive and negative agreement with clinical diagnoses for pneumonia, lower respiratory tract disease, viral lower respiratory tract infection, bronchiolitis, asthma/reactive airways disease, upper respiratory tract disease and croup.

Dr Keating said "there were significant learnings from our previous Smartcough-C study and we are pleased with the improvements that we, alongside our clinical advisory board and the principal investigators at the study sites, have made".

Resapp was up 0.1 cents or 1.4 percent to 7.2 cents with 1.1 million shares traded.

SUDA PHARMACEUTICALS

Suda says that studies presented at the American Society of Haematology meeting support the use of its anagrelide for the treatment of solid tumors.

Suda said the meeting in Atlanta, Georgia was held December 9 to12, 2017 with three abstracts presented recognizing the role of play in the regulation of tumor growth and metastasis into the vascular space in a session entitled 'New Innovations in Platelet Regulation of Tumour Growth and Metastasis'.

The company said the session included data from key opinion leaders who presented on the underlying mechanisms by which the platelet-tumor interaction was mediated and how the reduction of platelets could help mediate tumor growth and metastasis.

Suda said it recently acquired anagrelide, which was "a potent anti-thrombotic agent used to reduce elevated levels of platelets" and had the potential to be developed as an anti-cancer agent.

Suda chief executive officer Stephen Carter said the data provided "further support for our rationale to acquire and develop an oro-mucosal spray of anagrelide as a novel anti-cancer therapy".

"There is strong evidence to suggest that platelets play an extremely important role in tumor growth [and] anagrelide is a potent and selective inhibitor of platelets that is currently limited in its use by its route of administration," Mr Carter said.

Suda was unchanged at 1.5 cents.

CSL

CSL says it has appointed former chief executive officer Dr Brian McNamee as its chairman-elect and Abbas Hussain as a director, effective from February 14, 2018.
CSL said that chairman Prof John Shine announced his intention to retire at the conclusion of the annual general meeting in October 2018 following 11 years on the board and six years as chair.
The company said that Dr McNamee was its chief executive officer and managing-director for 23 years before retiring in 2013 and led the former Commonwealth serum Laboratories from Australian Government ownership, through privatization and listing on the ASX to becoming an industry leader.
CSL said that since retiring from the company, Dr McNamee had advised private equity group Kohlberg Kravis Roberts on its pharmaceutical and healthcare investments and acquisitions, and pursued private start-up and company-making activities.
Dr McNamee holds a Bachelor of Medicine and Bachelor of Surgery from the University of Melbourne.
The company said that the London-based Mr Hussain was most recently Glaxosmithkline head of pharmaceutical, managing the pharmaceuticals and vaccine business in 150 countries including the US, Europe, Japan and emerging markets.
CSL said that Mr Hussain previously was Eli Lilly Europe's head and from 2009 to 2017 was a Director of Viiv Healthcare, a Pfizer Glaxosmithkline partnership.
The company said that Mr Hussain previously was a director of South Africa's Aspen Healthcare and the Duke National University of Singapore Medical School.
The company said that Mr Hussain was currently a director of Immunocore, a T-cell receptor company developing biological drugs to treat cancer, infectious diseases and autoimmune diseases.
CSL said that Mr Hussain held a Bachelor of Science in medicinal chemistry and pharmacology from Loughborough University in the UK.
CSL was up 92 cents or 0.65 percent to $141.53 with 552,990 shares traded.

CLINICAL GENOMICS

Clinical Genomics says it has appointed Roy Davis as a director and senior advisor, effective from January 1, 2018.
Clinical Genomics said that Mr Davis had more than 30 years' experience in business development, strategic planning and creating joint ventures in the US, Europe and Japan.
The company said that Mr Davis was with Johnson & Johnson for 27 years rising to group president, group chairman and franchise chairman as well as head of its Development Corp.
Clinical Genomics said that Mr Davis was Ortho Diagnostics managing-director and general-manger and was the founding president of Johnson & Johnson's Veridex which had a breakthrough technology for circulating tumor cells.
The company said that Mr Davis was currently an advisor to Huron Global Management Consulting and its Innosight subsidiary.
Clinical Genomics said that Mr Davis held a Bachelor of Science from the The State University of New York at Albany, and a Master of Science from New York's Rensselaer Polytechnic Institute.
Clinical Genomics is a private company.