Biotech Daily

Tuesday June 19, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market slipped 0.03 percent on Tuesday June 19, 2018 with the ASX200 down 2.0 points to 6,102.1 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and one was untraded. All three Big Caps were up.

Impedimed was the best on no news for the second day in a row, up 7.5 cents or 16.7 percent to 52.5 cents with 1.5 million shares traded. Optiscan climbed 8.45 percent; Airxpanders and Prescient improved more than four percent; Benitec was up 3.85 percent; CSL, LBT, Nanosonics, Oncosil and Opthea rose two percent or more; Cochlear and Ellex were up more than one percent; with Resmed and Sirtex up by less than one percent.

Immutep led the falls, down half a cent or 14.7 percent to 2.9 cents with 40 million shares traded, followed by ITL down 10.6 percent to 21 cents with 36,237 shares traded. Factor Therapeutics lost 6.5 percent; Actinogen fell four percent; Bionomics, Medical Developments, Mesoblast, Polynovo and Uscom were down three percent or more; Clinuvel, Cynata and Universal Biosensors shed two percent or more; Compumedics and Pro Medicus were down more than one percent; with Neuren, Starpharma and Volpara down by less than one percent.

MICROBIOTICA, UNIVERSITY OF ADELAIDE

The Cambridge UK-based Microbiotica says it will work with the University of Adelaide to develop a defined bacterial product for ulcerative colitis.

Microbiotica said that it was collaborating with the University's Dr Sam Costello who led a faecal microbiota transplantation study which showed the ability to induce remission in ulcerative colitis without significant side-effects.

The company said the data was "compelling evidence for a novel therapeutic approach based on resetting gut microbiota" and it would analyze clinical samples from the Adelaide study to identify the specific bacteria which successfully treated the condition.

Microbiotica said it had developed a platform for "culture-based precision metagenomics", enabling large-scale strain-level characterization of microbiome profiles linked to patient phenotype.

The company said the financial details of the collaboration were not disclosed.

Microbiotica chief scientific officer Dr Trevor Lawley said that "very few placebo-controlled clinical studies have been completed which show that altering a patient's microbiome through faecal microbiota transplantation can cause remission in ulcerative colitis".

"Dr Costello is a pioneer in this area and this collaboration is strategically important to our ulcerative colitis program," Dr Lawley said.

"We are adopting a clinic-first discovery approach and taking this high-quality research to the next stage to generate a therapeutic candidate which we will progress as an orally-administered defined bacterial therapy for ulcerative colitis," Dr Lawley said.

Dr Costello said that ulcerative colitis was a disease with significant unmet therapeutic need "and while faecal microbiota transplantation is already showing promise in inducing remission, a defined bacterial product would be a big step forwards".

Microbiotica is a private company.

KAZIA THERAPEUTICS (FORMERLY NOVOGEN)

Kazia says interim results from its phase I trial of Cantrixil for ovarian cancer show few dose-limiting toxicities, with stable disease in three of five evaluable patients.

In 2016, the then Novogen said it had enrolled the first of up to 60 patients in its phase I, trial to assess the appropriate Cantrixil intra-peritoneal infusion dose (BD: Dec 6, 2016).

Today, the company said the dose escalation part of the trial to determine the maximum tolerated dose had enrolled 10 patients, of an up to 42-patient trial.

Kazia chief executive officer Dr James Garner told Biotech Daily that of the 10 enrolled, two withdrew before treatment due to disease progression, with three more withdrawing prior to the first evaluation point of two cycles, or six weeks, of Cantrixil as a monotherapy.

Dr Garner said that of the five evaluable patients, two had disease progression, three had stable disease, defined as tumors increasing by less than 20 percent or shrinkage of less than 30 percent, with one stable patient later showing a partial response.

Dr Garner said that following the two cycles of Cantrixil as a monotherapy, part A of the trial included up to six cycles, or 18 weeks, of increasing doses of Cantrixil with the patient's individual chemotherapy regime.

Dr Garner said that three patients had completed the full 24-week dosing, with part A of the trial expected to conclude by October 2018, when part B would begin to investigate Cantrixil at its maximum tolerated dose with chemotherapy.

In its media released to the ASX, Kazia said the data monitoring committee recommended additional patients should be enrolled "to more fully understand the safety profile and to determine definitively the maximum tolerated dose".

Kazia fell 1.5 cents or 2.4 percent to 60 cents.

IMMUTEP

Immutep says it has reached the midpoint in patient enrolment for its phase IIb active immunotherapy with paclitaxel (Aipac) trial of IMP321 for metastatic breast cancer.
Immutep said 113 of the planned 226 patients had been enrolled in the trial at clinical trial sites in Belgium, France, Germany, Hungary, the Netherlands, Poland and the UK.
Last month, Immutep chief executive officer Mark Voigt said the Aipac trial was in combination with paclitaxel, marketed by Bristol-Myers Squibb as Taxol, with progression-free survival results expected in mid-2019 (BD: May 3, 2018).
Today, Immutep chief scientific officer Dr Frederic Triebel said the company was “very excited to have reached this important milestone”.
Immutep fell half a cent or 14.7 percent to 2.9 cents with 39.96 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says that adding the standard CA-125 test to its ovarian cancer algorithm showed accuracy of 95 percent, with 88 percent sensitivity and 93 percent specificity.
Bard1 said it had conducted a study to evaluate and compare the accuracy of the original Bard1 algorithm alone, the cancer antigen-125 (CA125) algorithm alone, and the combined Bard1-CA125 algorithm to detect ovarian cancer in 200 ovarian cancer patients and 200 control patients.
The company said the combined algorithm had “excellent diagnostic accuracy” with an average “area under the curve”, or AUC, of 0.95, or 95 percent accuracy.
In March, Bard1 said the previous ovarian cancer algorithm showed 89 percent sensitivity (accurate positives) and 82 percent specificity (accurate negatives) in detecting ovarian cancer (BD: Mar 6, 2018).
Today, the company said the combined Bard1-CA125 algorithm had excellent diagnostic accuracy with an average area under the curve of 0.98 in training sets, and an average area under the curve of 0.95, with 88 percent sensitivity and 93 percent specificity in test sets.
Bard1 said that the addition of the CA125 test to its ovarian cancer test increased sensitivity for detection of ovarian cancer by six percent and specificity by 14 percent over the previously reported results for the Bard1 algorithm alone.
The company said that on completion of the assay development project to transfer the research Bard1 assay to the Procartalplex technology, it intended to conduct clinical studies to evaluate the test for the screening and diagnosis of ovarian cancer.
Bard1 chief scientific officer Dr Irmgard Irminger-Finger said that “CA125 values correlate with tumor burden and more accurately detect late-stage cancer, whereas Bard1 auto-antibodies reflect the early immune response to tumor formation and are present from early to late-stage cancer, hence the Bard1-CA125 combination is presumed to more accurately detect early and late stages”.
“This study confirmed that addition of CA125 to the Bard1 ovarian test improved its sensitivity across all stages and reduced false positives,” Dr Irminger-Finger said.
“Our goal is to develop Bard1-ovarian as an accurate and reliable screening test for early detection of ovarian cancer when it can be potentially cured and help save women’s lives,” Dr Irminger-Finger said.
Bard1 was unchanged at 1.5 cents with 41.7 million shares traded.

REVA MEDICAL

Reva says it has Conformité Européenne (CE) mark approval for all Fantom Encore coronary scaffolds, including its 3.0mm and 3.5mm diameter stents.
Earlier this year, Reva said it had CE mark approval for the 2.5mm diameter Fantom Encore with its 95-micron strut profile and today it said the CE mark had been expanded to include the 3.0mm and 3.5mm diameter scaffolds (BD: Feb 26, 2018).
In 2017, Reva said it had CE mark for its original Fantom scaffold (BD: Apr 4, 2017).
Reva chief executive officer Dr Reggie Groves said that the approval was “an important milestone in our commercial growth plan for our coronary scaffolds”.
“In addition to pursuing distribution partnerships and increasing our clinical evidence to support marketing activities, we have extended our technological lead in this area,” Dr Groves said. “We are on-track to launch the Fantom Encore product line later this year.”
Reva was unchanged at 23 cents.

MEDIBIO

Medibio says it has Australian Therapeutic Goods Administration approval for its cardiac rhythm depression diagnostic aide and mental health monitoring platform.
Last month, Medibio said it had Conformité Européenne (CE) mark approval for its Logic mental illness diagnostic platform (BD: May 3, 2018).
Medibio was unchanged at 15.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has an agreement with Melbourne’s Swisstec Health Analytics to establish a joint venture for blockchain technology.
Genetic Technologies said it would work with Swisstec finalise the joint venture proposal to use the blockchain technology to provide medical services, personalized health management and facilitate data management and artificial intelligence-based services.
The company said the joint venture would provide pathways to predictive genomic screening, radiology diagnostics, clinical consultations and medical procedures, initially focussed on Southeast Asia, where it would have access to more than 12,000 hospitals.
Genetic Technologies said it and Swisstec would be equal owners of the joint venture, with two directors from each company, and Genetic Technologies would have a 20 percent stake in Swisstec with the final agreement expected by mid-July 2018.
Genetic Technologies was up 0.05 cents or 5.9 percent to 0.9 cents with 5.5 million shares traded.

DORSAVI

Dorsavi says the US Patent and Trademark Office has granted a patent covering its wearable sensor knee diagnostic technology.
Dorsavi said that the patent, titled ‘Method and apparatus for monitoring deviation of a limb’ would provide intellectual property protection until 2034.
The company said the patent claims covered the sensors and algorithms that it used to estimate the deviation or tilting of the tibia, indicating whether the knee and lower limb were well or poorly aligned, and the algorithms could help determine whether a patient was at further risk of injury.
Dorsavi said it had seven patent families granted, including 13 patents in eight countries.
Dorsavi was up half a cent or 3.85 percent to 13.5 cents with 88,513 shares traded.

CORRECTION: SUDA PHARMACEUTICALS

Last night's edition quoted Suda saying that Canada has "accepted" a patent application for SUD-003 for erectile dysfunction and SUD-004 for pulmonary arterial hypertension.
Suda also said that the Canadian Intellectual Property Office had "granted" the company's first application for its sildenafil-based products, titled 'Oral Spray Formulations and Methods for Administration of Sildenafil' with similar patents granted in the US, Japan, Russia, Australia, New Zealand and Singapore, and applications pending in other jurisdictions, providing protection until December 2032.
Biotech Daily mistakenly reported the patent as an application rather than a completed patent grant and apologizes unreservedly for the error.
The Monday sub-editor apparently "had a big weekend" and missed the headline, which going forward she will have to get over and move forward in a differently challenging narrative.
Suda fell 0.2 cents or 20 percent to 0.8 cent with six million shares traded.

RHINOMED

Rhinomed says the Woonsocket, Rhode Island-based CVS pharmacy retailer will stock the mute anti-snoring nasal dilators in more than 1100 shops.
Rhinomed said Mute was sold in more than 9,000 shops in the US, of which previously 100 were CVS pharmacies.
The company said it had received purchase orders for more than 18,000 units, which were expected to be available at CVS between August and September 2018, with revenue not expected until the end of 2018.
Rhinomed was unchanged at 12 cents.

MMJ PHYTOTECH

MMJ says that Health Canada has issued Harvest One Cannabis subsidiary United Greeneries a narcotics dealer's licence.
MMJ previously said it owned 34 percent of Harvest One (BD: Apr 6, 2018).
Today, the company said the licence allowed United Greeneries to import narcotics into Canada, including its marijuana-based Gelpell microgel CBD or cannabidiol capsules which were produced in Switzerland and sold as a nutritional supplement in the European Union and as a prescription drug in Australia.
MMJ said the licence allowed Harvest One to export its medical cannabis products to other markets with favorable medical cannabis regulations, including Germany.
MMJ was up 1.5 cents or 4.8 percent to 33 cents.

UNIVERSAL BIOSENSORS

The Sydney-based Jencay Capital says it has increased its substantial holding in Universal Biosensors from 8,877,774 shares (5.04%) to 10,824,146 shares (6.14%).
The substantial shareholder notice signed by director Brett Rock said that between May 2 and June 15, 2018 Jencay acquired 1,946,372 shares for $471,833, or 24.2 cents a share.
Universal Biosensors fell half a cent or 2.2 percent to 22.5 cents.

MESOBLAST

Mesoblast says that Joseph Swedish has been appointed as a director, replacing former Teva executive Dr Ben-Zion Weiner, effective from today.
Mesoblast said that Mr Swedish had more than two decades of experience as the chief executive officer of US healthcare organizations and most recently was Anthem Inc's executive chairman.
The company said that prior to Anthem, Mr Swedish was the chief executive officer of integrated healthcare delivery systems including Trinity Health and Colorado's Centura Health.
Mesoblast said that Mr Swedish was currently a director of IBM Corp, CDW Corp and Proteus Digital Health.
The company said that Mr Swedish held a Bachelor of Science from the University of North Carolina and a Master of Health Administration from the Durham, North Carolina-based Duke University.
In 2012, Mesoblast appointed Teva Pharmaceutical Industries executive Dr Weiner as a non-executive director, saying the former Teva head of research and development had been appointed as the special adviser to the then Teva chief executive officer Dr Jeremy Levin (BD: May 10, 2012).
In 2016, Teva returned Mesoblast's phase III cardiac program and last year reduced its holding to below the five percent substantial level (BD: June 14, 2016; Oct 25, 2017).
In 2011, the then Cepahlon, which was later acquired by Teva, held 19.99 percent of Mesoblast (BD: Dec 18, 2010, Feb 14, 2011).
The company said it thanked Dr Weiner "for his valuable contributions to Mesoblast over the past five years, especially in relation to our research and development pipeline".
Mesoblast said that Ignite Partners was its adviser for the appointment.
Mesoblast fell 4.5 cents or three percent to $1.47 with 1.2 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has appointed Jann Skinner as a non-executive director, effective from today.
Telix said that Ms Skinner had experience in audit and accounting and in the insurance industry.
The company said that Ms Skinner was a partner at Pricewaterhousecoopers for 17 years before retiring in 2004 and was currently an independent non-executive director of QBE Insurance Group.
Telix said that Ms Skinner was a director of the Create Foundation and HSBC Bank Australia.
The company said that Ms Skinner held a Bachelor of Commerce from the University of New South Wales.
Telix was unchanged at 65 cents.