Biotech Daily

Tuesday October 11, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: UNIVERSAL BIOSENSORS UP 10%; PRANA DOWN 6%**

*** VIRALYTICS: 'CAVATAK WITH KEYTRUDA SAFE, WELL-TOLERATED'**

*** ANTISENSE HIGHER DOSE ATL1103 NORMALIZES ACROMEGALY SIGF-I**

*** PROF GEOFF FAULKNER, PROF STEVEN LANE WIN $1.25m CSL GRANTS**

*** SIRTEX TRIALS SIR-SPHERES FOR BILE DUCT LIVER CANCER**

*** MMJ RAISES $4m**

*** IMMURON IMM-124E FOR NASH '75% RANDOMIZED'**

*** ANTISENSE SHARE CANCEL, OPTIONS AGM**

*** MATTHEWS, ACORN, DILUTED TO 15% OF REPRODUCTIVE HEALTH**

*** MEDADVISOR APPOINTS SIMON CHAMBERLAIN PRODUCT, STRATEGY**

*** ALL CHANGE AT QRX**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Tuesday October 11, 2016 with the ASX200 up 4.4 points to 5,479.8 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell and eight traded unchanged.

Universal Biosensors was the best, up 3.5 cents or 10.3 percent to 37.5 cents with 270,319 shares traded.

Avita and Uscom climbed more than nine percent; Viralytics improved 8.8 percent; Factor Therapeutics was up 7.9 percent; Orthocell was up 4.8 percent; Clinuvel, Genetic Signatures and Opthea were up more than three percent; Actinogen, Compumedics and Living Cell rose more than two percent; Anteo, Polynovo and Resmed were up more than one percent; with Ellex, Pro Medicus and Starpharma up by less than one percent.

Prana led the falls for the second day in a row, down 0.5 cents or 6.25 percent to 7.5 cents, with 1.4 million shares traded. Cyclopharm lost 5.8 percent; Oncosil fell four percent; Benitec and Bionomics were down more than three percent; Impedimed, Mesoblast and Neuren shed two percent or more; with Cochlear, CSL, Nanosonics, Osprey, Pharmaxis, Psivida and Sirtex down more than one percent.

VIRALYTICS

Viralytics says that two phase Ib trials have shown the Cavatak with Merck's anti-PD-1 checkpoint inhibitor Keytruda, or pembrolizumab, is safe and well-tolerated.

Viralytics said that the data was presented at the European Society for Medical Oncology 2016 Congress in Copenhagen, Denmark.

The company said that its Systemic Treatment Of Resistant Metastatic Disease (Storm) trial was designed to establish safety and determine a dosing schedule for successful tumor targeting for Cavatak as a single agent for advanced solid tumors.

Viralytics said that Cavatak was well tolerated, with no dose-limiting toxicities and biopsies of melanoma, non-small cell lung cancer and metastatic bladder cancer tumor tissue confirmed systemic tumor-targeting by detecting Cavatak.

The company said that six patients in two cohorts in part B of the Storm trial had been completed and the expansion phase of about 80 patients would begin when enrolment of the three patients in the third cohort was completed.

Viralytics said that part B of the dose escalation study of Cavatak in combination with fixed doses of Keytruda, known as Keynote 200, was being undertaken with Merck Inc to evaluate the combination in patients with advanced non-small cell lung cancer or metastatic bladder cancer to establish a recommended dosing regimen for the Cavatak and Keytruda combination, evaluate anti-cancer activity and patient tolerability.

Viralytics said that so far the combination was well-tolerated with no grade 3 or higher treatment-related adverse events.

The company said that the presentation, 'Intravenous coxsackievirus A21 in combination with pembrolizumab in advanced cancer patients: Phase 1b KEYNOTE 200 study' was at: http://www.viralytics.com/our-pipeline/scientific-presentations/.

Viralytics said its 30-patient, phase Ib Cavatak and Pembrolizumab in Advanced Melanoma (Capra) trial was designed to evaluate the safety and tolerability of the established dose of intra-tumoral Cavatak in combination with Keytruda for advanced melanoma where Keytruda would be considered standard-of-care.

The company said that investigators were also assessing evidence of anti-cancer activity, including response rates and bio-markers of anti-tumor immunity.

Viralytics said that early data from the first eight evaluable patients showed reductions in a number of injected and non-injected visceral and non-visceral lesions, with some patients showing evidence of post-injection systemic exposure to Cavatak, and the combination well-tolerated with no grade 3 or higher treatment-related adverse events.

The poster, entitled 'Phase Ib study of intratumoral oncolytic coxsackievirus A21 (CVA21) and pembrolizumab in subjects with advanced melanoma is available at the Viralytics: http://www.viralytics.com/our-pipeline/scientific-presentations/.

Viralytics managing-director Dr Malcolm McColl said the company was pleased with enrolment and the potential benefits from the Cavatak and Keytruda combination.

Viralytics also reported "positive clinical data" from its phase Ib Melanoma Intra-Tumoral Cavatak and Ipilimumab (Mitci) combination clinical trial.

The company said the combination of Cavatak and the anti-CTLA-4 checkpoint inhibitor ipilimumab, or Yervoy, had shown a patient disease control rate of 82.4 percent and an objective response rate of 53 percent, that is 14 of 17 evaluable patients and nine of 17 patients, respectively.

Viralytics said that two-thirds of the 17 patients had been previously treated with at least one line of systemic therapy and in a subset of patients previously treated with checkpoint inhibitor therapies, overall tumor responses and stable disease were observed in seven of the eight patients.

Viralytics was up eight cents or 8.8 percent to 99 cents.

ANTISENSE THERAPEUTICS

Antisense says that 13 weeks of higher dose ATL1103 normalized insulin-like growth factor I in two of three acromegaly patients, with the third normalized at 26 weeks.

Antisense said that the open-label study of the safety, tolerability, pharmacokinetics and efficacy in acromegaly patients dosed the three patients with ATL1103 at 300mg twice weekly in two patients, capped at a weekly dose of 6.0mg/kg in the third patient.

The company said that the primary efficacy endpoint was the reduction of serum insulin-like growth factor I (sIGF-I) levels.

Antisense said that acromegaly patients had significantly higher levels of sIGF-I than healthy individuals and normalization was accepted by authorities as the therapeutic goal for treatment.

The company said that the three patients were dosed for 13 weeks, with one patient receiving an extended dosing period of an additional 12 weeks, at the request of the principal investigator.

Antisense said that all three patients were followed-up for two months with an interim analysis confirming that the drug appeared effective and safe at the doses tested with normalisation of IGF-I in one patient and therapeutically relevant reductions in two patients (BD: Jul 27, 2016).

The company said that the maximal suppression of IGF-I in the third patient was 44 percent from baseline at week 26, compared to 33 percent at week-13, which was higher than the mean reduction reported in the interim analysis of 26.7 percent at week-13 and 18.6 percent at week-14.

Antisense said that the suppression of IGF-I was consistent with ATL1103 dose modelling predictions that greater effects were achievable with longer ATL1103 dosing regimens.

The company said that the dosing frequency was reduced in the third patient to 300mg once weekly during the extending dosing due to mild grade 1 thrombocytopenia, or low platelet counts, which stabilized at the reduced dosing frequency and returned to normal levels during the follow-up period.

Antisense said that IGF-I levels normalized during the extended dosing period despite this reduction in dosing frequency and there were no new significant adverse safety findings beyond those reported in the July interim analysis.

The company said that ATL1103 appeared to be well-tolerated at the higher doses, no patient withdrew from the study and there were no serious adverse events.

Antisense chief executive officer Mark Diamond said that “while it was a small study, it is most pleasing to report on the very encouraging efficacy and safety profile of ATL1103 demonstrated in this higher dose trial”.

“All three patients received a therapeutic benefit from the drug and two of the three patients achieved the goal of sIGF-I normalization including the patient administered with ATL1103 for an extended dosing period of six months, whose disease had not been controlled on their prior acromegaly medications,” Mr Diamond said.

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Antisense said that in the previous 26-patient phase II trial, the highest dose was 200mg twice weekly with no cap on the dose-to-weight basis, so lighter patients received up to 6.9mg/kg/week, with a secondary analysis showing that ATL1103 reduced sIGF-I in a dose dependent manner (BD: Sep 3, 2014; May 15, Nov 4, 2015).

Antisense was up 0.8 cents or 20 percent to 4.8 cents.

SIRTEX MEDICAL

Sirtex says it will start a 180-patient, randomized, controlled study of SIR-Spheres in patients with unresectable intra-hepatic cholangio-carcinoma, or bile duct cancer.
Sirtex said that cholangio-carcinoma was the second most common primary liver cancer and the study, known as Sircca was a prospective, multi-centre, randomised, controlled study of SIR-Spheres yttrium-90 resin microspheres preceding cisplatin-gemcitabine chemotherapy versus chemotherapy alone as a first-line treatment of patients with unresectable intra-hepatic cholangio-carcinoma, or ICCA.
The company said that cholangio-carcinoma started in the bile duct and there was an annual incidence of about 5,000 patients in the US.
Sirtex said the trial would be conducted in 30 centres in Australia and Europe, with the first patient expected to be recruited by the end of 2016 and the last patient in late 2018.
Sirtex chief executive officer Gilman Wong said the Sircca study "reflects the continued investment into our SIR-Spheres microspheres business to generate further clinical evidence to support new regulatory applications and product reimbursement".
"ICCA is a particularly attractive opportunity for Sirtex, where the use of our product has already shown promise and treatment options are very limited for these patients, while survival rates remain poor," MR Wong said.
Sirtex said that the European Society of Medical Oncology recently highlighted the use of yttrium-90 microspheres for the treatment of cholangio-carcinoma following the publication of clinical practice guidelines on biliary cancers as a supplement to the Annals of Oncology, with lead author, the University of Manchester's Prof Juan Valle saying that selective internal radiation therapy, or radio-embolization "may be considered in patients with inoperable ICCA, usually after first-line chemotherapy".
Sirtex chief medical officer Dr David Cade, said the company was "delighted to see SIR-Spheres … cited as an important post-chemotherapy option for patients with locally advanced or metastatic ICCA, given no current standard of care exists beyond first-line treatment with cisplatin and gemcitabine chemotherapy in these patients".
"We believe that these are the first international clinical guidelines to include [selective internal radiation therapy] as a treatment option for patients with ICCA," Dr Cade said.
"We anticipate the ESMO guideline will be an important catalyst to drive awareness on the use of SIR-Spheres microspheres in ICCA across Europe, and accordingly we would expect to receive a benefit in our ability to recruit patients onto the Sircca study," Dr Cade said.
"This study will be the largest ever interventional oncology study undertaken in this rare, but important disease, where prospective randomized data are lacking," Dr Cade said.
Sirtex fell 52 cents or 1.7 percent to $29.97 with 888,805 shares traded.

MMJ PHYTOTECH

MMJ says it has raised $4 million in an over-subscribed placement at 20.5 cents a share to institutional and sophisticated investors at $0.205 per share.
MMJ said that it accepted over-subscriptions of $2 million and the funds raised would provide additional working capital, as it focused on the spin out of its core cannabis subsidiaries, United Greeneries Holdings Ltd and Satipharm AG to the Toronto Stock Exchange listed Top Strike Resources (BD: Sep 28, 2016).
The company said that the better than expected result from the placement could mean that it would be able to reduce the cash component of the transaction and take a greater equity stake in Top Strike.
MMJ was unchanged at 23 cents.

IMMURON

Immuron says that its 120-patient, phase II trial of IMM-124E for non-alcoholic steato-hepatitis has recruited and randomized 90 patients or 75 percent of the cohort.
Immuron said that there had been no serious adverse events related to the study drug.
The company said it expected to finalize the randomization of all 120 patients at its 28 active clinical sites in the US, Australia and Israel by the end of 2016.
Immuron head of medical Dr Dan Peres said the 75 percent recruitment was a “significant milestone [and] the result of our efforts to significantly accelerate our recruitment rate including amending our clinical trial protocol which has allowed our sites to recruit more efficiently”.
The company said it announced the launch of the double-blind, placebo-controlled study of IMM-124E for non-alcoholic steato-hepatitis in December 2014, with the first patient randomized in February 2016 (BD: Nov 27, 2014; Feb 3, 2015).
Immuron was untraded at 26.5 cents.

ANTISENSE

Antisense will ask investors to cancel Strongbridge Biopharma’s 8.5 percent holding, approve an option issue to shareholders and offer an unmarketable parcel facility.
Antisense said that it received $1,000,000 from Strongbridge on the cancellation of its ATL1103 licence and Strongbridge had agreed to the cancelation of 15,025,075 shares for no monetary consideration.
The company said that the proposed bonus and new option issues recognized that ATL1103 partnering plans had not progressed as expected and the existing listed loyalty options were due to expire in January 2017.
Antisense said that it intended to issue free bonus options to all ordinary shareholders on a pro-rata basis on terms to be determined following the annual general meeting.
The meeting will vote to allow directors Mark Diamond, Robert Moses and Dr Graham Mitchell to participate in the option issue and the re-election of directors Mr Moses, Dr Gary Pace and William Goolsbee.
The meeting will be held at Giorgios Restaurant, 1235 High Street, Armadale, Victoria on November 10, 2016 at 11am (AEDT).

CSL

CSL says that Prof Geoff Faulkner and Prof Steven Lane have each won $1.25 million, five-year, Centenary Fellowships for research in leukaemia and Alzheimer’s disease.
CSL said that Prof Faulkner and Prof Lane were the inaugural fellows in the $25 million program to support Australian biomedical researchers.
The company said that the University of Queensland’s Prof Faulkner would investigate the storage of long-term memory in brain DNA and would test his theory in brains affected by Alzheimer’s disease.
CSL said that the Queensland Berghofer Medical Research Institute’s Prof Lane was researching the leukaemia treatments to reduce relapse rates in older patients.
The company said that 85 percent of children with leukaemia could be cured, but for patients over 60 years, only 10 percent survived beyond one year.
CSL said that Prof had developed a method to profile the genetics of leukaemia types and model them, allowing him to map the effectiveness of chemotherapy treatments against the genomes of individual cancers.
CSL fell $1.22 or 1.1 percent to $105.48 with 717,766 shares traded.

REPRODUCTIVE HEALTH SCIENCE

Dr Colin Matthews, Jonathan Mathews and Acorn Trust say they has increased in Reproductive Health from 8,964,556 shares to 10,757,468 shares but have been diluted from 17.47 percent to 14.84 percent.

The Adelaide-based Jonathan Matthews said that as trustees for the Acorn Trust they participated in the recent rights issue acquiring 1,792,912 shares at 7.5 cents share.

Last week, Reproductive Health said its one-for-five, fully underwritten rights issue raised $487,928 with a $502,150 shortfall to be allocated to Taylor Collison (BD: Oct 6, 2016).

Reproductive Health was untraded at 7.8 cents.

MEDADVISOR

Medadvisor says that it has appointed Simon Chamberlain as general-manager of product and strategy.

Medadvisor said that Mr Chamberlain was previously Medibank Private's customer and distribution general-manager and had held executive roles at companies including Qantas digital hotel booking start up Hooroo, as well as marketing services consultancy Experian and online consumer intelligence provider Hitwise.

The company said that Mr Chamberlain had experience "building businesses from start-up through to global scale in standalone businesses as well as within larger corporate environments".

Medadvisor said that Mr Chamberlain's role would be "to support and help accelerate the growth of Medadvisor's business, to help build awareness amongst key stakeholder groups and to open up new channels of user acquisition".

Medadvisor was up half a cent or 14.3 percent to four cents with 1.7 million shares traded.

QRX PHARMA

Qrx says it has appointed John Rainbow and Tim Heesh as directors replacing Bruce Hancox and Dr Richard Treagus, effective from today, October 11, 2016.

QRX said that Mr Rainbow had been a legal practitioner for more than 25 years in New South Wales and had contributed at a senior board level and as in-house legal counsel.

The company said that Mr Heesh was a member of the Chartered Accountants in Australia and New Zealand and the Australian Restructuring, Insolvency and Turnaround Association.

QRX said that following the failure to have its dual opioid Moxduo approved by the US Food and Drug Administration and a period of voluntary administration, the company creditors voted for a deed of company arrangement, returning the management and control to directors (BD: Aug 14, 2014; May 25, Dec 9, 2015).

QRX was in a suspension and last traded at 2.8 cents.