Biotech Daily

Thursday November 6, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ELLEX UP 10.5%, CLINUVEL DOWN 6%**

*** PRIMA CVAC 2nd REMISSION OVERALL SURVIVAL**

*** ORTHOCELL CLAIMS TO GROW HUMAN TENDONS**

*** MIELE EXPANDS NANOSONICS TROPHON EUROPEAN DISTRIBUTION**

*** EUROPEAN PATENTS FOR ACTINOGEN, CORTICRINE 11 BETA-HSD1**

*** IP AUSTRALIA ACCEPTS CYNATA CYMERUS MANUFACTURING PATENT**

*** CIRCADIAN COMPLETES $3.4m RIGHTS ISSUE**

*** ANTISENSE PLAN RAISES $267k OF HOPED FOR $1.5m, $2m TOTAL**

*** CORRECTION: IMUGENE**

*** RESONANCE, UWA WIN 2014 WA INNOVATOR GONG FOR HEPAFAT-SCAN**

*** PROF DAVID CRAIK WINS $80k GSK AWARD FOR CYCLOTIDES**

MARKET REPORT

The Australian stock market fell 0.21 percent on Thursday November 6, 2014 with the S&P ASX 200 down 11.8 points to 5,506.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and four were untraded.

Ellex was up three cents or 10.5 percent to 31.5 cents with 60,035 shares traded, followed by Genetic Technologies up 10 percent to 2.2 cents with 98,000 shares traded.

Antisense and Nanosonics climbed more than seven percent; Atcor was up five percent; Oncosil was up 4.8 percent; Circadian and Optiscan climbed more than three percent; Prana rose 2.5 percent; Benitec and Pharmaxis were up more than one percent; with CSL, Resmed and Starpharma up by less than one percent.

Clinuvel led the falls, retreating 30 cents or six percent to $4.70 with 78,120 shares traded.

Bionomics and Impedimed lost more than five percent; Patrys fell 4.55 percent; Avita, Tissue Therapies and Viralytics were down three percent or more; IDT shed 2.6 percent; Acrux, Alchemia, Mesoblast, Neuren and Phosphagenics were down one percent or more; with Cochlear and Sirtex down by less than one percent.

PRIMA BIOMED

Prima says it that CVac demonstrated “a clinically meaningful improvement in overall survival compared to standard of care in second remission ovarian cancer patients”.

Prima said that the further data from the 63-patient CAN-003 phase II trial of CVac added to the “a clinically meaningful improvement in progression-free survival in second emission ovarian cancer patients” reported earlier this year (BD: May 15, 2014).

In 2013, top-line analysis of the CAN-003 trial failed to show significant progression-free survival, which led to a change of endpoint for the phase II/III CAN-004 trial to overall survival (BD: Sep 19, 2013).

In May, Prima said that overall survival data from the CAN-003 trial would mature for analysis by the end of 2014.

Today, the company said that among the 20 second remission patients in the trial the median overall survival for standard-of-care patients was 25.53 months, which was consistent with current literature.

Prima said that for patients treated with CVac, a median had not been reached after 36 months ($p = 0.07$).

“This implies at least a 10 month median survival advantage for second remission patients treated with CVac,” the company said.

Prima said that second remission patients treated with CVac were living significantly longer and were “83 percent less likely to die compared with standard-of-care patients” and followed the very positive progression-free survival data for second remission patients in May 2014.

In May, Prima said that in 20 second remission patients the median progression-free survival for CVac was estimated to be greater than 12.91 months, compared to median progression-free survival of 4.94 months for the control group ($p = 0.04$), but progression-free survival was not improved for patients in first remission.

Today, the company said that for first remission patients, the interim data demonstrated a slightly positive trend in CVac patients with no median reached yet in the CVac or standard-of-care group, confirming the decision to focus further clinical development on second remission patients.

Prima chair Lucy Turnbull said the data was “a strong confirmation that CVac could considerably extend the progression-free period and the overall length of life in second remission patients with ovarian cancer”.

“CVac has an excellent safety and tolerability profile that also supports a potentially high quality of life given its very limited side effects,” Ms Turnbull said.

Prima chief executive officer Marc Voigt said the data was “extremely encouraging and further supports the positive overall survival trend we presented earlier this year for second remission patients”.

“Whilst we had anticipated the [overall survival] data for second remission patients to be mature enough for final analysis by the end of this calendar year, given the better than expected results with the median for CVac patients still not yet reached, we will continue to monitor the second remission CAN-003 patients and look forward to updating the market on their progress,” Mr Voigt said.

Prima said that the interim overall survival data for second remission patients would be included in a presentation, entitled ‘Trial evaluating overall survival in epithelial ovarian cancer (EOC) patients in second remission with an autologous dendritic cell therapy targeting mucin 1’ at the Society for Immunotherapy of Cancer meeting, in National Harbor Maryland, on November 8, 2014 by Prima chief technical officer Dr Sharron Gargosky.

Prima climbed 0.7 cents or 17.5 percent to 4.7 cents, before closing unchanged at four cents with 55.5 million shares traded.

ORTHOCELL

Orthocell says it has grown human tendons in a laboratory for the first time.
Orthocell said that the experiments to grow functional human tendons in a bioreactor were presented at the Australian Society of Elbow and Shoulder Surgeons conference in Melbourne by chief scientific officer Prof Ming Hao Zheng.
The company did not provide any detail about growing the human tendons, the size, structure or utility of the material grown, but said that the “scientific breakthrough” resulted from a collaboration with the University of Western Australia, Curtin University, Griffith University and the University of Auckland and was supported by an Australian Research Council linkage grant.
Prof Zheng said that “the secret to growing a human tendon graft outside the body is to culture viable tendon cells and create the exact amount of stimulation to these cells, so that they feel at home and produce the necessary components to form tendon tissue”.
“In the future this could represent a product to replace severely damaged tendons, complementing our existing Ortho-ATI tendon repair product,” Prof Zheng said.
Orthocell said that the data presented by Prof Zheng demonstrated how the Ortho-autologous tenocyte implantation (ATI) product works.
Prof Zheng said that “we have shown that we can grow and maintain potent and viable tendon cells in culture using the same patented cell growth technology behind Ortho-ATI”.
“The Ortho-ATI technology is not simply relieving pain and improving function, it is facilitating the growth of new tendon tissue and this focused study demonstrates that achievement,” Prof Zheng said.
Orthocell was up three cents or 8.8 percent to 37 cents with 1.1 million shares traded.

NANOSONICS

Nanosonics says that German distribution partner Miele Professional has expanded European sales to the Netherlands, Belgium, Luxembourg, Austria and Italy through.
Nanosonics said that it had been working closely with Miele on the introduction of the Trophon EPR ultrasound probe cleaning system in Germany.
The company said that Miele recognized the benefits of Trophon EPR, was encouraged by early market feedback and proposed an expansion to the existing agreement to include the five new countries where Miele held “a leadership position in disinfection and sterilization”.
Nanosonics chief executive officer Michael Kavanagh said that “the requirements for stricter controls and more efficacious solutions for ultrasound probe decontamination are growing in Europe”.
“This expanded agreement enables us to enter five new markets where Miele is a leader in medical disinfection and sterilization,” Mr Kavanagh said.
“Market development activities will begin shortly in these markets commencing with training of the Miele sales and service force in each of the countries,” Mr Kavanagh said.
“Miele will also showcase Trophon EPR at Medica, the world’s largest medical trade fair in Dusseldorf in November,” Mr Kavanagh said.
Miele Professional International division director Andreas Barduna said that the company’s experience with Trophon EPR in Germany “has been positive and we are excited to be able to introduce the technology into these new countries”.
Nanosonics said that a pivotal clinical trial in Germany showed a threefold higher risk of cross contamination using the current standard practice in much of Europe of quaternary ammonium wipes compared to Trophon EPR (BD: sep 17, 2014).
Nanosonics was up seven cents or 7.45 percent to $1.01 with 1.3 million shares traded.

ACTINOGEN

Actinogen says that European applications have been allowed for two patents relating to the composition and use of 11 beta-hydroxysteroid dehydrogenase type 1 inhibitor.
Actinogen said that the 11 beta-hydroxysteroid dehydrogenase type 1 (11 beta-HSD1) inhibitor was in clinical development for dementia by Corticrine, which the company had acquired pending shareholder approvals (BD: Aug 27, 2014).
In August, Actinogen said that Corticrine was a spin-out from the University of Edinburgh and had licenced worldwide development and commercialization rights to UE2343 for Alzheimer's disease.
Today, the company said that the two patents were entitled '(4-phenyl-piperidin-1-yl)-[5-(1h-pyrazol-4-yl)- thiophen-3-yl]-methanone compounds and their use" and '3,3-disubstituted-(8-aza-bicyclo[3.2.1]oct-8-yl)- [5-(1h-pyrazol-4-yl)-thiophen-3-yl]-methanone and related compounds and their use'
Actinogen said that the patents related to pharmaceutical compositions of 11 beta-HSD1 inhibitor and the use of these compounds to inhibit 11 beta-HSD1 to treat disorders that were ameliorated by the inhibition of the enzyme.
The company said that the claims in the patents covered the method to treat diseases including metabolic syndrome, which includes type 2 diabetes and obesity and associated disorders including insulin resistance, hypertension, lipid disorders and cardiovascular disorders such as ischaemic coronary heart disease, central nervous system disorders such as mild cognitive impairment and early dementia, including Alzheimer's disease.
Actinogen said that it had been notified that a similar patent had been allowed in Israel, entitled '(4-phenyl-piperidin-1-yl)-[5-(1h-pyrazol-4-yl)-thiophen-3-yl]-methanone compounds and their use'
The company said that the patents added to Corticrine's intellectual property portfolio around UE2343, with patents protected until 2028 and beyond.
Actinogen said it was preparing for a phase I multiple-ascending dose study expected to begin early in 2015.
Actinogen fell 0.4 cents or 9.1 percent to four cents.

CYNATA THERAPEUTICS

Cynata says that the Australian Patent Office, IP Australia, has accepted "a key patent application" for its Cymerus stem cell technology.
Cynata said that the application, entitled 'Generation of clonal mesenchymal progenitors and mesenchymal stem cell lines under serum-free conditions' was owned by the Wisconsin Alumni Research Foundation and among the intellectual property licenced exclusively by the Foundation to Cynata.
The company said that the inventors were Dr Maxim Vodyanyk and Prof Igor Slukvin, founders, advisors and significant shareholders of Cynata.
Cynata chief executive officer Dr Ross Macdonald said that the patent application covered "a core element of our proprietary stem cell manufacturing technology".
"We continue to strengthen Cynata's already comprehensive patent estate relating to the scalable manufacture of consistent, high quality mesenchymal stem cell therapeutic products targeting a range of major diseases worldwide," Dr Macdonald said.
Cynata said that it expected the Australian patent would be granted in January 2015.
Cynata was up two cents or 5.9 percent to 36 cents.

CIRCADIAN TECHNOLOGIES

Circadian says its two-for-five underwritten non-renounceable rights issue at 17.5 cents a share has raised $3.4 million.
Circadian said that the rights issue offered up to 19,453,313 new shares and it received acceptances for 9,186,955 shares, or 44 percent of shares on offer.
The company said that the rights issue was underwritten by Bell Potter Securities and the shortfall would be placed with a number of institutional and sophisticated investors.
Circadian said that one option would be attached for every two shares subscribed under the rights issue, exercisable at 27 cents by November 25, 2018.
The company said that the first tranche of the $14 million placement had been completed and the second tranche was subject to approval at the annual general meeting on November 18, 2014.
Bell Potter Securities was the lead manager for the placement and rights issue.
Circadian was up half a cent or three percent to 17 cents.

ANTISENSE THERAPEUTICS

Antisense says it has received applications for $269,990 of a hoped for $1.5 million in its partly-underwritten share purchase plan at 11.5 cents a share.
Antisense said that the plan was underwritten to $1,000,000 and the shortfall had been placed with the underwriter, Patersons Securities.
In September, Antisense said it had raised $1 million in a placement and hoped to raise a further $1.5 million in the share plan (BD: Sep 25, 2014).
Antisense said that the funds would be used to progress partnering plans for ATL1103 for acromegaly, US Food and Drug Administration interactions on a potential phase IIb study for ATL1102 for multiple sclerosis and the planned higher dose clinical trial of ATL1103 in acromegalic patients.
Antisense was up 0.75 cents or 7.5 percent to 10.75 cents.

IMUGENE

Imugene says the record date in its share purchase plan materials was October 31 and should have been November 3, 2014.
Yesterday Imugene said that it had commitments for a placement of $2.25 million at one cent a share, to be followed by a share plan.
No Biotech Daily sub-editors were hurt in making this correction.
Imugene was up 0.2 cents or 18.2 percent to 1.3 cents with 2.2 million shares traded.

RESONANCE HEALTH

Resonance says that with the University of Western Australia it has won the Western Australia Innovator of the Year for its Hepafat-Scan liver fat concentration diagnostic.
Resonance said that the magnetic resonance imaging-based non-invasive Hepafat-Scan diagnostic was its most recent product to come to market and provided “an accurate measurement of the concentration of fat in a patient’s liver, addressing the growing prevalence of fatty liver disease”.
The company said that the Hepafat-Scan recently gained regulatory clearance to be marketed in the US, Australia and Europe.
Resonance was up 0.8 cents or 22.2 percent to 4.4 cents with 1.2 million shares traded.

GLAXOSMITHKLINE

Glaxosmithkline says that the University of Queensland's Institute for Molecular Bioscience's Prof David Craik has won the $80,000 GSK Award for Research Excellence.
In a media release, Glaxosmithkline said that Prof Craik was a biological chemist at the Institute and discovered the largest known family of circular proteins, called cyclotides, which he was using to develop drug design approaches to treat pain and disease and crop insecticides.
Glaxosmithkline said that Prof Craik's research was inspired by a Norwegian doctor's discovery of an African tea for childbirth.
"The tea shortened labor, but at the time they didn't know why the plant-based medicine worked," Prof Craik said.
"It was the unusual circular structure of the molecules," Prof Craik said.
"We knew peptides had great potential, but were previously unable to be taken orally as the digestive system would break them down," Prof Craik said.
"Our circular peptides are joined from head to tail, which makes them much stronger," Prof Craik said.
"I did extensive fieldwork in Africa and elsewhere searching for plants with similar circular peptides to understand their structure," Prof Craik said.
Glaxosmithkline said that Prof Craik developed the chemistry for making designer cyclotides, which could be used to develop new drugs with improved oral availability with few side effects.
"My team has been working on using cone snail venom as a pain relief drug 100 times more potent than morphine," Prof Craik said.
"We are also producing peptide-based drug leads for chronic diseases in edible plant seeds, which we hope will give developing countries access to produce vital medicines at relatively low cost," Prof Craik said.
Glaxosmithkline vice president and general manager Geoff McDonald said the award "represents outstanding Australian research and we are proud to be able to support Prof Craik and his team to continue their pioneering research".
"Prof Craik's cyclotides could potentially underpin new treatments for cancer, chronic pain and multiple sclerosis in the future and revolutionalize drug delivery methods," Mr McDonald said.