Biotech Daily

Thursday September 11, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: LIVING CELL UP 5%, AVEXA DOWN 11%**

*** VIRALYTICS 'ENCOURAGED' BY TWO CAVATAK STUDIES**

*** EASTLAND EXPECTS POSITIVE MALARIA TRIAL RESULTS**

*** HEARTWARE FILES HEART PUMP CE MARK APPLICATION**

*** PROGEN EXECUTIVES AGREE TO 6 MONTHS NOTICE CLAUSE**

MARKET REPORT

The Australian stock market fell a further 1.8 percent on Thursday September 11, 2008 with the All Ordinaries down 89.9 points to 4,871.5 points.

Five of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and eight were untraded.

Living Cell was best, climbing one cent or 5.26 percent to 20 cents on small volumes, followed by Alchemia up one cent or 3.23 percent to 32 cents, Circadian up 2.41 percent, Biota up 1.99 percent and Prana up 1.06 percent.

Avexa led the falls, down three cents or 10.91 percent to 24.5 cents with 1.8 million shares traded, followed by Antisense down 8.82 percent to 6.2 cents and Clinuvel down 7.55 percent to 24.5 cents.

Acrux and Genetic Technologies lost more than six percent; Bionomics, Chemgenex and Novogen fell than five percent; Cochlear was down 3.76 percent; Arana, Cytopia, Optiscan, Pharmaxis and Ventracor shed more than two percent; with Mesoblast, Peplin, Progen, Starpharma and Viralytics down more than one percent.

VIRALYTICS

Viralytics has presented two posters on Cavatak at a Hunter Medical Research Institute conference on translational cancer research in Newcastle, New South Wales.

The first poster, entitled 'Immune response to an Oncolytic Human Picornavirus, Coxsackievirus A21 (Cavatak) in Patients with Late Stage Melanoma' was authored by Prof Shafren and researchers from the University of Queensland, Queensland's Princess Alexandra Hospital and the University of Newcastle in New South Wales.

Presented by Viralytics chief scientist and director Prof Darren Shafren addressed serum immune responses produced by late stage melanoma patients following two intra-tumoral injections of Cavatak. The data was generated from Viralytics phase I dose escalation trial of Cavatak in late stage melanoma patients.

Under results and conclusions, the authors said Cavatak induced generation of neutralizing levels of serum specific anti-viral antibodies in five of six patients by about day 10 post-first injection, the production of which appeared not to be dose related.

Preliminary data indicated that one of three patients in Cohort I and all patients in Cohort II displayed some elevation in serum levels of Th1-related response cytokines.

Intra-tumoral delivery of Cavatak induced some reduction in the volume of the injected tumor of two of six patients at 24 days post-Cavatak administration.

As these reductions in the volume of the injected tumors coincided with the appearance of high levels of serum neutralizing anti-Cavatak antibody, the potential inhibitory activity of systemic anti-viral antibody in the localized tumor environment may be questioned.

"Interestingly, both the patients … that displayed higher serum levels of the Th1-related cytokines … also displayed volume reductions in the injected tumor at 24 days post Cavatak administration," the authors said.

"Such cytokine responses may have been generated via host immune cells directly challenging Cavatak infected tumor cells and/or tumor cells alone."

The poster said the primary aim of the study was to assess the efficacy and safety of two escalating intra-tumoral doses of Cavatak in nine patients with stage IV melanoma.

A secondary objective was to evaluate the host immune response to two intra-tumoral injections administered 48 hours apart, in terms of examining serum for levels of anti-Cavatak specific neutralizing antibody and a panel of immuno-regulatory cytokines.

The second poster entitled 'Coxsackievirus a21 oncolytic virotherapy as a novel treatment for malignant glioma' was authored by Prof Shafren and researchers from the University of Toronto and the University of Newcastle.

They said that cultures of established glioma cells expressed similar levels of DAF on the cell surface, however the levels of ICAM-1 on these cells were highly variable.

GBM6 which is a minimally passaged cell line, expressed the highest amount of ICAM-1 in contrast to the other long-term passaged cells.

Four out of the six glioma cell lines examined were sensitive to Cavatak treatment.

The two cell lines that were not responsive to Cavatak treatment expressed minimal levels of ICAM-1 (approximately 200-2000 receptors per cell), suggesting that there may be a threshold level of receptor expression for successful Cavatak viral oncolysis.

"Of the five normal brain tissue specimens examined for ICAM-1 expression by immuno-histochemistry, all were negative for ICAM-1 expression. In contrast, glioblastoma multiforme specimens were all strongly positive for ICAM-1 expression following IHC staining," the poster said.

Viralytics said the results were "encouraging" and investigation with minimally cultured glioma cells may be required.

The posters are at www.viralytics.com under Scientific Publications.

Viralytics fell 0.1 cents or 1.85 percent to 5.3 cents.

HEARTWARE

Heartware has filed an application for European approval for its left ventricular assist system that would allow its commercial launch throughout the European Union.
Heartware said its submission for Conformitée Européenne (CE) mark approval was "based on data from the first 25 patients to have been implanted with the Heartware left ventricular assist device in the company's international clinical trial".
"Of the 25 patients, 23 patients (92 percent) successfully met the primary endpoint of the clinical trial, namely survival to 180 days or heart transplantation," Heartware said.
Heartware chief executive officer Doug Godshall said the company was encouraged by the results from its international trial "and by the enthusiasm being expressed by surgeons and cardiologists".
Mr Godshall said Heartware hoped to be approved for CE mark "before the end of the year and to commence sales in the European Union soon thereafter".
Heartware said it would continue to enroll patients into the international trial and to date a total of 43 patients had been implanted with the device in Europe and Australia.
Heartware said it would cease enrolment when 50 patients had been implanted across the five participating centers.
Heartware said it was currently running a bridge-to-transplant clinical trial in the US under conditional investigational device exemption approval.
"The trial will enroll 150 patients across a maximum of 28 centers," Heartware said.
Heartware was unchanged at 60 cents.

EASTLAND MEDICAL SYSTEMS

Eastland Medical Systems says an independent report and trial results of the Artimist sublingual malaria treatment will produce "positive findings and advantages".
Eastland said the report was strictly confidential until published but the report "confirms the previous announced positive findings and advantages".
Eastland chief executive officer Dermott Patterson said the company had been "awaiting the independent report as we move to commence the field trials of treatment of infected children and the report gives us extreme confidence in that outcome".
Mr Patterson said the field trial was targeted for November 2008, subject to authorization of the relevant authorities.
He said the company would not have to to conduct phase II studies.
"As HC Berlin Pharma AG is now in the final stages of listing its shares on the Frankfurt Stock Exchange and await the confirmation of that date, these two factors will permit the company to move forward with its corporate plan and commercial growth over the coming months," Mr Patterson said.
Eastland said phase I single dose clinical studies for Artimist were completed in Malaysia in November 2007 with positive results indicating the treatment is safe to use.
Phase I multi-dose clinical study for Artimist were undertaken in South Africa in February 2008 with positive results indicating the formulation was well tolerated and showed no adverse effects in any of the trial subjects.
Phase II toxicity studies do not have to be completed as the drug is already approved, the company said.
Eastland was unchanged at 12.5 cents.

PROGEN

Progen says executive termination clauses have been amended removing impediments to potential merger and acquisition activity.

Progen said the changes involved the removal of the payment of a 12 month termination benefit to the executives should another company or entity acquire control of Progen.

The previous clauses said that if an acquiring company or entity terminated employment within 12 months of acquisition then the executives would be entitled to 12 months base salary.

Separately, the executives had different termination terms with Progen.

The executives who have agreed to this amendment are chief executive officer Justus Homburg, chief operating officer and company secretary Linton Burns and the vice-president of business development Sarah Meibusch.

Progen said the three executives employment contracts are capable of termination with six months notice, or payment of salary, in lieu of notice.

The amendments have immediate effect.

Progen fell one cent or 1.52 percent to 65 cents.