Biotech Daily

Tuesday June 18, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 28%, USCOM DOWN 21%**

*** FDA BACKS FURTHER HEARTWARE DESTINATION THERAPY COHORT**

*** USCOM COMPLETES PULSECOR ACQUISITION**

*** CLINUVEL US PHASE III SCENESSE EPP RESULTS 'DELAYED BY CRO'**

*** GI DYNAMICS ADDS FIVE MORE EURO ENDOBARRIER CENTRES**

*** PHARMAXIS POOLED DATA SHOWS 34% EXACERBATION REDUCTION**

MARKET REPORT

The Australian stock market fell 0.24 percent on Tuesday June 18, 2013 with the S&P ASX 200 down 11.5 points to 4,814.4 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and four were untraded.

Impedimed was the best, up 2.2 cents or 28.2 percent to 10 cents with 426,349 shares traded, followed by Avita up 20 percent to 12 cents with 939,375 shares traded, Ellex up 12.5 percent to 22.5 cents with 41,958 shares traded and Viralytics up 12 percent to 28 cents with 56,123 shares traded.

GI Dynamics climbed 8.1 percent; Clinuvel and Psivida were up more than seven percent; Pharmaxis rose 6.9 percent; Neuren was up 5.1 percent; Heartware was up 3.4 percent; Living Cell and Sirtex rose more than two percent; Bionomics and Optiscan were up more than one percent; with Resmed up 0.4 percent.

Uscom led the falls, down 4.5 cents or 21.4 percent to 16.5 cents with 190,000 shares traded, followed by Compumedics down 16 percent to 6.3 cents, with 50,000 shares traded.

Allied Health lost 8.5 percent; Osprey was down 6.25 percent; Nanosonics fell 4.2 percent; Alchemia, Cellmid, Medical Developments, Patrys, Reva and Universal Biosensors were down more than three percent; Prana shed two percent; Prima and Starpharma were down more than one percent; with Acrux, Cochlear, CSL and Mesoblast down by less than one percent.

HEARTWARE INTERNATIONAL

Heartware says the US Food and Drug Administration has allowed enrolment of an additional patient cohort for its 'Endurance' pivotal destination therapy clinical study.
Heartware said that the FDA granted conditional approval to an investigational device exemption supplement to allow the additional patient cohort in the randomized, controlled, unblinded, multi-center clinical trial to evaluate the use of the Heartware ventricular assist system as a destination therapy in advanced heart failure patients.
The company said that the non-inferiority study completed enrollment of 450 patients with end-stage heart failure who had not responded to standard medical management and who were ineligible for cardiac transplantation, with patients randomized to either the Heartware system or any alternative FDA-approved left ventricular assist device in a two to one ratio.
The company said that primary endpoint of the trial was stroke-free survival at two years, defined as alive on the originally implanted device, transplanted or explanted due to patient recovery, with secondary endpoints including adverse events such as bleeding and infection, as well as functional status, hospitalization, assessment of neuro-cognitive function and patient quality of life.
Heartware said that the final implant was conducted in May 2012, which will result in the final patient reaching the two-year follow-up point in May 2014.
The company said that the FDA gave conditional approval to a protocol, designed to confirm observations from the Endurance trial, that sites adhering to more regular monitoring and management of patient blood pressure had a notably lower incidence of neurological events.
Heartware said that the supplemental cohort would enroll up to an additional 240 Heartware ventricular assist device patients, as well as up to an additional 120 control patients, who would be followed for 12 months after implant.
The company said the data from the new cohort was expected to be incorporated into a pre-market approval application for the Heartware system for destination therapy.
Heartware said patient enrollment could begin at the 50 Endurance trial centres, following FDA prescribed changes to the protocol and institutional review board approvals.
The company said that in November 2012 the FDA granted approval of its system for the bridge-to-transplant indication and concurrent with the approval, the company began a post-approval study to assess device performance in a real-world setting.
Heartware said that its post-approval study was a registry of 600 patients who received a Heartware ventricular assist device and an additional 600 control patients, with enrolment expected to be completed by the end of 2013.
Heartware was up nine cents or 3.4 percent to $2.74.

USCOM

Uscom says it has completed the purchase of all the assets of Pulsecor for five million at a transaction price of 50 cents a share.
Uscom said the acquired assets included the BP+ supra-systolic central blood pressure device, the Cardioreporter pulse pressure wave analysis software, 34 blood pressure measurement and analysis patents and four trademarks.
The company said that Pulsecor's BP+ product had US Food and Drug Administration 510k clearance, Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approval and was on sale internationally and inventor Prof Nigel Sharrock had joined its medical advisory board.
Uscom fell 4.5 cents or 21.4 percent to 16.5 cents.

PHARMAXIS

Pharmaxis says pooled data of its two phase III trials shows Bronchitol cystic fibrosis patients had 34 percent fewer exacerbations over 26 weeks, compared to controls.

Pharmaxis said that the new analyses from the pooled data was presented at the European Cystic Fibrosis Society conference in Lisbon, Portugal and was awarded 'best poster' status.

The company said that in the pooled studies, as previously announced, adult patients treated with Bronchitol, demonstrated a statistically significant ($p < 0.001$) improvement in lung function and a 24 percent non-significant reduction in the incidence of exacerbations requiring intra-venous antibiotics, compared to those that received best standard of care alone.

Pharmaxis said that the new analyses showed that adult patients who responded after six weeks of Bronchitol with 'any improvement in lung function', experienced 34 percent fewer exacerbations over the 26 week period, compared to receiving best standard of care alone.

The company said that health economic data collected during the trials and data from the UK's National Health Service were used to calculate the average cost of treating hospitalized pulmonary exacerbations for a UK adult cystic fibrosis patient at GBP10,096 ($A16,654) a year.

Pharmaxis chief executive officer Gary Phillips said the analyses informed early decision-making to ensure patients receive a long-term benefit from Bronchitol treatment.

"The analysis also highlights the value to healthcare systems of improved cost-effectiveness and cost-efficiency when investing in Bronchitol," Mr Phillips said.

Mr Phillips said that in clinical trials patients continued to the end of the study period irrespective of whether they were improving or deteriorating but in the clinic physicians "make recommendations to continue on treatment based on the individual response of their patients to treatment".

"Of particular importance is that patients in this sub-group who show any improvement in lung function at six weeks, so called 'responders', also show a trend to larger reductions in the rate of exacerbations in the longer term," Mr Phillips said.

The company said that other analyses presented for the first time covered adult patients who were not receiving recombinant human deoxyribonuclease (rhDNase or Pulmozyme).

Pharmaxis said that in this sub-population, patients treated with Bronchitol demonstrated a statistically significant (113ml, $p = 0.004$) improvement in lung function compared to standard of care and a 50 percent reduction in the incidence of hospitalized exacerbations, compared to those that received best standard of care alone.

The company said that rhDNase non-user patients that responded after six weeks of Bronchitol treatment, experienced a further improvement in lung function (177ml) compared to baseline and 61 percent fewer exacerbations over the 26 week period, compared to receiving standard of care alone.

Pharmaxis said that several other sub-populations had been identified that showed similar improvements in lung function and a reduction of exacerbations following treatment with Bronchitol and these sub-populations would be the subject of future publications.

Mr Phillips said the sub-population of patients not taking rhDNase was a group with high medical need as many have previously tried rhDNase and are seeking new treatments".

"As well as the improvements in lung function and reduced exacerbations reported, the Bronchitol patients were also discharged earlier from hospital when they did have exacerbations, and spent less time interacting with specialist and family physicians, both of which are high-cost services," Mr Phillips said.

Pharmaxis was up one cent or 6.9 percent to 15.5 cents with 2.5 million shares traded.

CLINUVEL

Clinuvel says the delay in its US phase III study of Scenesse (afamelanotide 16mg) for erythropoietic protoporphyria (EPP) is in the hands of the contract research organization.
In a 'Letter from the CEO', Clinuvel chief executive officer Dr Philippe Wolgen responded to questions from shareholders and said the CUV039 trial data was "still in the hands of the contract research organization" (BD: May 23, 2012).
"It may be that these results will also be made available to the [European Medicines Agency] as confirmatory analyses of the earlier EPP studies," Dr Wolgen said.
Clinuvel had expected the US phase III trial results and European approval by July 2013, but in April said European approval could take until the end of 2013 (BD: April 5, 2013).
In 2010 and 2011, Clinuvel reported positive results from a 91-patient Australian and European phase III study of Scenesse for erythropoietic protoporphyria as well as a 74 patient European study (BD: Jul 13, 2010; Jan 22, 2012).
Dr Wolgen said that the company was not allowed to speculate on timelines and outcome of the European regulatory review.
"We don't want our knuckles rapped at this stage," Dr Wolgen said. "I can only elaborate my board mandate was laid out to me in 2005: 'to explore the safety and medical utility of afamelanotide and if deemed safe to make it available for those groups of patients who need the drug most'. I believe we have fulfilled this mandate."
"In 2010, the independent scientific and technical committee of the Italian regulator [Agenzia Italiana del Farmaco] reviewed Clinuvel's data, sought numerous expert opinions and made Scenesse available for EPP patients," Dr Wolgen said.
"Independently, numerous Swiss medical officers reviewed the data on Scenesse and published positive reports to insurers to make the drug available for Swiss patients," Dr Wolgen said.
Dr Wolgen said that "Clinuvel had, and has, little reason to cast clinical doubt that it is developing a meaningful drug".
Dr Wolgen said the vitiligo program was awaiting the final safety analyses and analyses on pigmentary retention of the US CUV102 trial (BD: Mar 13, 2011; Dec 19, 2012).
"At the same time our teams are preparing an Asian trial, and the intention is to evaluate the use of Scenesse in an Asian population with darker skin complexion," Dr Wolgen said.
Clinuvel was up 14.5 cents or 7.8 percent to $1.995.

GI DYNAMICS

GI Dynamics says that five new European centres have begun offering its Endobarrier treatment for obesity and type 2 diabetes.
GI Dynamics said that along with three new centres in Germany it had expanded its commercial presence into Spain and Switzerland.
GI Dynamics chief commercial officer Mark Twyman said the company was "continuing to invest in supporting the expansion of Endobarrier therapy in the European Union, an important region of the world where reimbursement is critical to long-term sales growth".
"In addition to expanding our commercial footprint in Europe, we continue to make important progress in self-pay markets and look forward to sharing updates on these efforts in the near future," Mr Twyman said.
GI Dynamics was up 4.5 cents or 8.1 percent to 60 cents.