Biotech Daily

Monday March 25, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: USCOM UP 10%, OSPREY DOWN 13%**

*** VIRALYTICS CLAIMS 5 CAVATAK OBJECTIVE TUMOR RESONSES**

*** PHOSPHAGENICS PATCH DELIVERS OXYMORPHONE**

*** PSIVIDA, ALIMERA RESUBMIT ILUVIEN TO FDA; DELIVERY DELAYS**

*** ASIA UNION DECREASES, DILUTED TO 11% IN TISSUE THERAPIES**

*** IMMURON REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market was up 0.46 percent on Monday March 25, 2013 with the S&P ASX 200 up 22.9 points to 4,990.2 points.

Nine of the Biotech Daily Top 40 stocks were up, 16 fell, 12 traded unchanged and three were untraded.

Uscom was the best, up two cents or 10 percent to 22 cents, with 35,000 shares traded.

Benitec climbed 8.3 percent; Cellmid was up 5.3 percent; Medical Developments was up 4.5 percent; Tissue Therapies was up 3.1 percent; QRX rose 2.2 percent; both Genetic Technologies and Universal Biosensors were up 1.3 percent; with CSL and Heartware up by less than one percent.

Osprey led the falls, down six cents or 12.8 percent to 41 cents with 12,500 shares traded, followed by Patrys down 11.4 percent to 3.1 cents with 1.2 million shares traded and Pharmaxis down 10.5 percent to 38.5 cents with 2.8 million shares traded.

Clinuvel lost 8.2 percent; Atcor, Avita, Phylogica and Reva fell four percent or more; Circadian and Viralytics were down more than three percent; Alchemia, Psivida and Sirtex shed two percent or more; Acrux and Starpharma were down more than one percent; with Cochlear, Mesoblast and Resmed down by less than one percent.

VIRALYTICS

Viralytics says that five of 10 patients at Utah's Huntsman Institute have had objective tumor responses, with reduction in both Cavatak injected and non-injected lesions.
Last year, Viralytics said the phase II trial achieved an interim efficacy milestone of three objective responses in the first 13 patients recruited (BD: Dec 13, 2013).
Viralytics said at that time that an objective response was defined as a reduction in total body tumor burden of more than 30 percent relative to baseline assessed by computed tomography (CT) scan analysis or CT scan and physical calliper measurements.
The company said that subject to safety criterion also being satisfied, the trial could proceed to further recruit up to about 63 patients, 54 of which were to be evaluable.
Today, Viralytics said that principal investigator Prof Robert Andtbacka presented a summary of the clinical trial at the Hemonc [Haematology and Oncology] Today Melanoma and Cutaneous Malignancies meeting in New York on March 22, 2013.
Viralytics said that Cavatak was generally well tolerated, with patients attending an average of 8.9 injection visits.
The company said that three patients at the Salt Lake City, Utah-based Huntsman Cancer Institute met the primary endpoint of immune-related progression-fee survival based on investigator assessment at six months with two patients progressing to the extension study.
Dr Andtbacka said that early results with Cavatak were "encouraging".
Viralytics said Dr Andtbacka's presentation was entitled 'Current Status of Injectable Therapy' and was available on its Viralytics website.
Viralytics fell one cent or 3.1 percent to 31.5 cents.

PHOSPHAGENICS

Phosphagenics says that a phase I trial has shown that its tocopheryl phosphate mixture or TPM technology oxymorphone patch has delivered the opioid into the bloodstream.
Phosphagenics said that the single dose phase I study, at the CMax clinical research facility at the Royal Adelaide Hospital, established that a single dose application of the patch was able to successfully deliver oxymorphone into the bloodstream for the 72-hour duration of the study.
Phosphagenics chief executive officer Dr Esra Ogru said the "outstanding" phase I results validated further clinical development of the oxymorphone patch.
"The phase I results are an important milestone in our opioid program," Dr Ogru said.
"We now plan to progress the further development of the oxymorphone patch in tandem with our TPM-oxycodone patch for the management of chronic systemic and topical pain," Dr Ogru said.
Phosphagenics said it expected to undertake a multi-dose and phase II clinical trial of oxymorphone by the end of 2013.
The company said that oxymorphone was a semi-synthetic molecule, 3.5 times more potent than oxycodone and seven times more potent than morphine.
Phosphagenics said that oxymorphone had low bioavailability when delivered orally and was an ideal candidate for transdermal delivery.
The company said that the oxymorphone market of more than $600 million was dominated by Endon Pharmaceuticals oral Opana ER, approved by the US Food and Drug Administration for moderate to severe chronic pain.
Phosphagenics was unchanged at 13 cents with 2.3 million shares traded.

PSIVIDA

Psivida says that US licencee Alimera hopes to resubmit its new drug application to the US Food and Drug Administration for Iluivien for diabetic macular oedema, this week.
Psivida said that Alimera would provide data from two pivotal phase III clinical trials and the resubmission will focus on the safety of Iluivien and those patients with considered insufficiently responsive to available therapies.
In 2001, the FDA provided Alimera a 'complete response letter' refusing approval for Iluvien (BD: Nov 14, 2011).
In December 2010, the FDA asked Alimera to provide 36-month data (BD: Jan 16, 2011).
Mr Leedman told Biotech Daily at that time that the endpoint for the pivotal trial was significance at 24 months, but the best result was achieved at 30-months with the lower dose of the steroid flucocinolone acetonide and the treatment retained statistical significance at 33-months (BD: Nov 14, 2011).
Today, the company said that Alimera had approval for Iluvien for the sub-group of patients considered insufficiently responsive to available therapies in a number of European Union countries (BD: April 26, May 8, 2012).
Psivida said that approval in the US would entitle it to a $25 million milestone payment from Alimera and 20 percent of net profits from US sales.
The company said that Alimera had reported that shipments of Iluivien to the German market were expected to begin by July 2013 on acceptance from the Medicine and Health products Regulatory Agency of the intended commercial batch size, a delay from Alimera's previous expectation that this would occur by April 2013, with shipments to the UK expected by July 2013 for treatment of privately insured patients.
Psivida said that Alimera's submission for a UK patient access scheme for Iluivien had been filed and was being considered, despite a previous final guidance that Iluivien was not a cost-effective treatment for chronic diabetic macular oedema.
Psivida fell four cents or two percent to $1.96.

TISSUE THERAPIES

Asia Union Investment has decreased its holding in Tissue Therapies from 23,010,000 shares to 22,985,000 shares and been diluted from 13.64 percent to 10.74 percent.
The Sydney-based Asia Union said it sold 25,000 shares for $13,580 or an average price of 55.32 cents a share and was diluted in a placement (BD: Feb 25, 2013).
Asia Union said it bought shares including 4,860,005 shares at 50 cents each in a placement rights issue on May 11, 2011 and 2,000,000 shares for $740,000, or 37 cents a share, on November 30, 2011 ((BD: Dec 5, 2011).
Tissue Therapies was up half a cent or 3.1 percent to 16.5 cents.

IMMURON

Immuron has requested a trading halt pending "an announcement … in respect of a proposed capital raising".
Trading will resume on March 27, 2013 or on an earlier announcement.
Immuron last traded at 0.8 cents.