Biotech Daily

Tuesday June 16, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN; CYTOPIA UP 14%, CATHRX DOWN 16%**

*** PHARMAXIS: BRONCHITOL REDUCES CYSTIC FIBROSIS EXACERBATIONS**

*** VENTRACOR WINDING UP; DIRECTORS RESIGN**

*** PSIVIDA PAPERS SHOW DRUG USEFUL FOR MORE INDICATIONS**

*** US, AUSTRALIAN PATENTS FOR CYTOPIA COMPOUNDS**

*** CATHRX SIGNS MEDICOR'S CORIZON FOR SWISS, GERMANY, AUSTRIA**

*** IMPEDIMED SIGNS MAJOR UK BREAST CANCER CLINIC**

MARKET REPORT

The Australian stock market fell 1.72 percent on Tuesday June 16, 2009 with the S&P ASX 200 index down 69.2 points to 3,962.5 points.

Six of the Biotech Daily Top 40 stocks were up, 20 fell, 11 traded unchanged and three were untraded.

Cytopia was best, up 1.1 cents or 13.9 percent to nine cents with 214,305 shares traded, followed by Genera up 7.8 percent to 55 cents and Tissue Therapies up 5.9 percent to 18 cents. Avexa climbed 4.55 percent, with Clinuvel, Cochlear and Nanosonics up more than one percent.

Cathrx led the falls, down nine cents or 16.1 percent to 47 cents with 45,255 shares traded followed by Genetic Technologies down 12.9 percent to 6.1 cents and Impedimed down 10.1 percent to 62 cents.

Circadian lost 9.3 percent; Living Cell and Novogen fell more than eight percent; Benitec and Sunshine Heart were down more than seven percent; Biota and Phosphagenics lost more than six percent; Peplin was down 5.65 percent; Acrux, Bionomics, Chemgenex and Viralytics fell four percent or more; Starpharma was down three percent; Polartechnics shed two percent; with Alchemia, CSL and Universal Biosensors down more than one percent.

PHARMAXIS

Pharmaxis says additional results from its phase III trial of Bronchitol for cystic fibrosis show decreased rates and longer time to protocol-defined pulmonary exacerbation.

Pharmaxis said the data was presented at the European Cystic Fibrosis Conference in Brest, France on June 12, 2009 by Dr Diana Bilton of London's Royal Brompton Hospital.

The company said the multi-centre, randomized, double blind, placebo controlled, 26 week study, with an optional six month open-label uncontrolled period was conducted in 40 centres in the UK, Ireland, Australia and New Zealand.

The primary endpoint was to assess whether Bronchitol improves lung function as measured by a change in forced expiratory volume in one second (FEV1) when administered twice a day for six months.

Pharmaxis said the key secondary endpoint was to assess whether Bronchitol improved lung function in patients treated with the most commonly used cystic fibrosis therapeutic, recombinant human deoxyribonuclease or rhDNase marketed as Pulmozyme. Additional endpoints included changes in the forced vital capacity of the lung, pulmonary exacerbations and antibiotic use. Safety evaluation included the incidence of adverse events and the microbiology of sputum samples.

There was a clinically meaningful change from baseline (119mL) and placebo (93mL) at week 26 with Bronchitol for FEV1 ($p<0.001$). Bronchitol showed an immediate and sustained improvement in lung function (FEV1) over the 26 weeks ($p<0.001$).

For the subgroup of patients on concomitant rhDNase there was also a significant improvement in FEV1 from baseline (88mL) and from placebo (109mL) at week 26 with Bronchitol ($p=0.001$). Again, there was an immediate and sustained improvement in FEV1 over the 26 week period of the study ($p=0.003$).

While the study was not powered to show a reduction in the secondary endpoint of exacerbation, the rate of a protocol-defined pulmonary exacerbation (PDPE) per subject for the 26 weeks was lower for Bronchitol compared to control with an overall reduction in rate of 25 percent ($p=0.2$).

There was a non-significant reduction in time to first protocol-defined pulmonary exacerbation ($p=0.1$) for the intention-to-treat group, however, for the per-protocol population, those mostly compliant with therapy who stayed in the study, there was a significant increase in time to first protocol-defined pulmonary exacerbation ($p=0.026$).

There was a clinically meaningful change from baseline (129mL) and control (113mL) at week 26 with Bronchitol for forced vital capacity (FVC) of the lung ($p=0.002$).

Additionally, treatment with Bronchitol showed an immediate and sustained improvement in lung capacity (FVC) over the 26 week treatment period ($p<0.001$).

There were a similar number of adverse events and serious adverse events per treatment group, with no deaths in the study.

Respiratory adverse events that were more common with Bronchitol compared with placebo, included cough (25.4% compared to 20.3%), haemoptysis (11.9% compared to 8.5%) and pharyngolaryngeal pain (13.6% compared to 4.2%).

There were similar rates between the groups for adverse events of particular interest including wheezing, asthma, bronchospasm (Bronchitol 4.5% compared to 5.9%).

At screening, seven percent of patients were ineligible to participate due to suspected undiagnosed hyper-reactive airway disease.

Overall infections were lower in the Bronchitol group (Bronchitol 39% compared to 47.5%).

There was no difference in microbial growth for specific micro-organisms between treatment groups, confirming that Bronchitol does not contribute to the bacterial load in the lung.

Pharmaxis was unchanged at $2.59.

VENTRACOR

Ferrier Hodgson says Ventracor has entered a deed of company arrangement to sell its assets and all former directors have resigned.

Ferrier Hodgson deed administrator Steven Sherman told the ASX that he Peter Gothard had been appointed deed administrators on June 15, 2009.

The notice to the ASX said directors John Ward, Jeffrey Goodman, Elizabeth Nosworthy, Ross Harricks, Peter Crosby and William Curran resigned on June 11, 2009.

Ventracor has been in a suspension since February 10, 2009 and last traded at 8.3 cents.

PSIVIDA

Psivida says two peer-reviewed papers show that fluocinolone acetonide inhibits vascular endothelial growth factor (VEGF) production and protects retinal cells and function.

Psivida said the findings support expanding the treatment indications for the company's lead product, Iluvien, an injectable, sustained-release drug delivery system that releases the corticosteroid fluocinolone acetonide into the eye. Iluvien is licenced to Alimera Sciences and in phase III clinical trials for diabetic macular oedema.

Psivida said the first study, 'Fluocinolone inhibits VEGF expression via glucocorticoid receptor in human retinal pigment epithelial (ARPE-19) cells and TNF-alpha-induced angiogenesis in chick chorioallantoic membrane' was published in the April issue of Journal of Ocular Pharmacology and Therapeutics.

The authors including Psivida chief executive officer Dr Paul Ashton and the University of Nebraska Medical Centre's Surya Ayalasomayajula and Uday Kompella said flucinolone inhibited proliferation of ARPE-19 cells and tumor necrosis factor-alpha-induced angiogenesis in chorioallantoic membranes.

Dr Ashton said vascular endothelial growth factor inhibition was one method of treating wet age-related macular degeneration and was the mechanism of action for the most effective FDA-approved treatment for the disease.

The second study 'Photoreceptor neuroprotection in Royal College of Surgeons rats via low-dose intravitreal sustained-delivery of flucinolone acetonide' published on line in Investigative Ophthalmology & Visual Science, studied the neuroprotective effects of fluocinolone acetonide delivered through a Medidur-device in the rats.

Dr Ashton co-authored the report with the Detroit-based Kresge Eye Institute and found that chronic intravitreal infusion of fluocinolone acetonide preserved both the structure of the retina and retinal function.

Psivida said the findings suggest Iluvien may have a therapeutic role in human degenerative eye diseases including dry age-related macular degeneration and retinitis pigmentosa.

Dr Ashton said the two studies showed for the first time that fluocinolone acetonide acted as both a vascular endothelial growth factor inhibitor as well as a neuroprotective.

Dr Ashton said those properties supported expanding the use of Iluvien beyond diabetic macular oedema to wet and dry age-related macular degeneration for which phase II trials are currently underway and other degenerative conditions such as retinitis pigmentosa.

He said no approved treatment for these conditions provide both vascular endothelial growth factor inhibitive and neuroprotective qualities.

Psivida said initial data from its 950-patient trials for diabetic macular oedema were expected by the end of the year, with a new drug application filing expected early in 2010.

Psivida was unchanged at $2.20.

CYTOPIA

Cytopia says it has a US patent allowance for lead compound CYT387 and a granted Australian patent for CYT997.
Cytopia said it was “continuing to expand its patent monopoly over the JAK2 enzyme target”.
The US patent application was entitled ‘Method of selecting or designing a compound which interacts with JAK2’ and had been allowed by the US Patent and Trademark Office.
Cytopia said the patent used the JAK2 crystal structure first solved by Cytopia and Monash University and published in the journal ‘Blood’ on January 1, 2006 (Vol 107, No 1, pp 176-183).
Cytopia said it was also the exclusive licencee of several granted patents for the validated drug targets JAK1 and JAK2 and had developed a library of new chemical entities which inhibit JAK2.
The company said the most advanced compound was CYT387, a novel oral JAK2 inhibitor expected to begin phase I clinical trials for myelofibrosis by the end of 2009.
Cytopia said CYT997 was an anti-cancer vascular disrupting agent in phase II clinical trials, being developed under the protection of a broad set of patent applications.
Cytopia said it had secured the grant of the Australian patent, which covered a novel class of compounds including CYT997, sealed on June 4, 2009 and covered new chemical entities as well as methods of use of tubulin inhibitors.
Cytopia said the patent had a 20 year term expiring on December 3, 2024, with a possible extension of up to five years.
The company said corresponding patent applications were under examination in Europe, India, China, Israel and New Zealand and were awaiting examination in the US, Japan, Mexico, South Korea, Canada and Brazil. A patent has been granted in South Africa.
Cytopia was up 1.1 cents or 13.9 percent to nine cents.

CATHRX

Corizon GmbH will distribute Cathrx’s cardiac catheter products in Germany, Austria and Switzerland.
Cathrx said Corizon was an affiliate of Medicor Medical Supplies and a specialist distributor servicing the cardiology and electrophysiology industry in those countires.
The company said the agreement with Corizon would “significantly expand Cathrx’s distribution network”.
In addition to its own five specialists, Corizon can access Medicor’s network of more than 20 field engineers across the region.
Medicor managing director Heinz Gerhards said the agreement “comes at an exciting time for us”.
“The industry is expanding rapidly at the moment and we are pleased to be able to supply our specialized network with some of the most advanced products available today in Europe,” Mr Gerhards said.
“We are very impressed by the innovations developed by the Cathrx team, the products offer some unique features which we know are valued by our customers,” Mr Gerhards said.
Cathrx chief executive officer Neil Anderson said the addition of representation in Germany and its adjacent markets “maintains the published schedule of our sales roll-out in Europe and thus our commercialization plan”.
Cathrx fell nine cents or 16.1 percent to 47 cents.

IMPEDIMED

Impedimed says the breast cancer team at the Great Western Hospital in Swindon, UK has adopted its L-Dex U400 lymphoedema diagnostic device.

Impedimed's chief executive officer Greg Brown told Biotech Daily that signing up the third National Health Service hospital and a major breast cancer clinic to a preventative strategy for detecting lymphoedema was a major breakthrough.

He said the Great Western Hospital would test all of its breast cancer patients every three months.

Mr Brown said the L-Dex U400 cost $US14,500 ($A18,319) with each test requiring new electrodes and costing $10 to $15.

The Great Western Hospital's breast and endocrine surgeon Dr Nathan Coombs said his team would use the L-Dex technology to assess breast cancer patients for fluid retention of the arm [or lymphoedema] from pre-surgical baselines.

"This pre-emptive strategy allows the opportunity for early assessment of the disorder," Dr Coombs said.

"In this way we hope to audit the outcome for our breast cancer patients at GWH and deliver a timely response and intervention to any early detection of lymphoedema," Dr Coombs said.

Mr Brown said the UK was one of the first socialized health systems to implement lymphoedema guidelines through the Northern Ireland Clinical Resource Efficiency Support Team guidelines.

"This clear recognition of lymphoedema as a major healthcare issue and the commitment to improve lymphoedema services is representative of the pro-active nature of healthcare professionals at every level working within the UK healthcare system," Mr Brown said.

"It is encouraging to see the focus applied to the early assessment and possible prevention of the progression of this debilitating disorder," he said.

"Impedimed is heartened to see the growing recognition and willingness to include lymphoedema care from day one for all breast cancer patients," Mr Brown said.

Impedimed fell seven cents or 10.1 percent to 62 cents.