Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHARMAXIS UP 50%; OPTISCAN DOWN 14%**

*** PHARMAXIS JUMPS 70% ON BRONCHITOL EUROPEAN APPROVAL**

*** SINGAPORE APPROVES MESOBLAST PHASE II AMD TRIAL**

*** PRIMA, DUBAI CITY HOSPITAL PARTNER FOR CVAC IN THE MIDDLE-EAST**

*** BENITEC WINS MORE EURO, US PATENTS**

*** PHYLOGICA AGM FOR 15m DIRECTOR 'INCENTIVE SHARES'**

MARKET REPORT

The Australian stock market was up 2.73 percent on Monday October 24, 2011, with the S&P ASX 200 up 113.1 points to 4,255.0 points.

Twenty of the Biotech Daily Top 40 stocks were up, nine fell, five traded unchanged and six were untraded. All three Big Caps were up.

Pharmaxis was the best, jumping 70.2 percent to $1.60 at the open and closing up 47 cents or 50 percent at $1.41 with 14.8 million shares traded, followed by Compumedics up 1.2 cents or 15.4 percent to nine cents with 30,000 shares traded.

Phosphagenics climbed 9.4 percent; Living Cell was up 8.45 percent; LBT was up 7.1 percent; Nanosonics and Prima rose more than six percent; Alchemia and Benitec climbed more than five percent; Sunshine Heart and Universal Biosensors were up more than four percent; Acrux, Cochlear, Genetic Technologies, Mesoblast and Starpharma were up more than three percent; with Anteo, Bionomics, Biota, Clinuvel, CSL, Resmed and Tissue Therapies up more that one percent.

Optiscan led the falls, down one cent or 14.3 percent to six cents with 6,241 shares traded.

Antisense lost 9.1 percent; Prana fell three percent; Allied Health, Heartware, Impedimed and Viralytics shed two percent or more; with Reva down 1.7 percent.

PHARMAXIS

Pharmaxis jumped 70.2 percent to $1.60 following European approval of Bronchitol for cystic fibrosis late on Friday October 21, 2011.

The European Medicines Agency's Committee for Medicinal Products for Human Use overturned its previous refusal to grant marketing authorization of Bronchitol for cystic fibrosis as an add-on therapy to best standard of care (BD: May 25, Jun 27, 2011).

The Committee restricted Bronchitol to adult cystic fibrosis patients and Pharmaxis chief executive officer Dr Alan Robertson told Biotech Daily that the adult market was 66 percent of the total number of cystic fibrosis patients in Europe.

Dr Robertson said the company was required to conduct a further paediatric trial for approval for patients aged six to 17 years.

In a telephone conference today, Dr Robertson said the additional trial would be of much shorter duration that the pivotal trial, taking "one to two months", cost about $1.5 million to $2 million, but he would not be drawn on how long it might take to complete.

Dr Robertson said the company had accumulated data on children in trials to date and was confident that the drug would be approved.

"We'll be filing as soon as we can for six years and over," Dr Robertson said.

Dr Robertson said the European paediatric trial and finalizing European approval was in parallel with filing the new drug application for Bronchitol for cystic fibrosis to the US Food and Drug Administration, which was expected to be done by April 2012, with approval 10 months after filing, if the process went smoothly.

Dr Robertson said that final European marketing approval should be completed in January with stocks on the shelves by April and Bronchitol was the first new drug approved for cystic fibrosis in 15 years.

He said Pharmaxis would begin the roll-out in Germany which had 100 cystic fibrosis centres and the UK with 50 centres and then cover all 27 European Union countries.

Pharmaxis chief operating officer Gary Phillips told the telephone conference that Bronchitol would be priced at or "below where Pulmozyne was priced" at $12,000 per patient per year and plans to gain reimbursement were underway with each country having different processes.

Dr Robertson said the difference between the eight percent benefit figure generally used by his company to describe the phase III trial results and the two to three percent benefit described by the European Committee for Medicinal Products for Human Use was caused by the Committee using a different endpoint.

He said Pharmaxis found an eight percent benefit using the measure of forced expiration volume of air over one second (FEV-1) comparing patients tested before and after the use of Bronchitol, consistent with the FDA protocol, but the Committee compared the post-Bronchitol result to a "percentage predicted" basis.

Dr Robertson said that even using the higher standard the review by the Committee decided that the benefit outweighed the risks.

The Committee said that two adverse events in the trial were a narrowing of the airways in the lung and the coughing-up of blood.

Dr Robertson said both had been referred to in the trial results, as broncho-constriction and haemoptysis, respectively.

He said haemoptysis was a symptom of cystic fibrosis and there was no difference between patients receiving 400mg Bronchitol (mannitol) and the 50mg mannitol control.

Dr Robertson told Biotech Daily that there were no current plans for a capital raising saying there were a number of different ways of addressing the company's balance sheet which has three quarters of cash at the current burn rate.

Pharmaxis closed up 47 cents or 50 percent at $1.41 with 14.8 million shares traded.

MESOBLAST

Mesoblast says Singapore has approved a randomized, placebo-controlled, 18-patient, phase II trial of neovascular, or wet, age-related macular degeneration.

Mesoblast said the Singapore Health Sciences Authority approved the trial of its allogeneic or off-the-shelf adult stem cell therapy for patients with proliferation of leaky blood vessels in the eyes

The company said that wet age-related macular degeneration (AMD) caused sudden and, severe central vision loss and caused about 90 percent of all blindness in the elderly.

Mesoblast said it was developing a stem cell therapeutic product for treating various vascular diseases of the eye, including wet AMD and diabetic macular oedema.

The company said wet AMD was expected to grow to about three million US citizens by 2020, from 1.7 million today, with about 200,000 new cases diagnosed each year.

Mesoblast said the current standard-of-care was repeated intraocular injections using an anti-vascular endothelial growth factor (VEGF) agent, such as Lucentis and Avastin, but treatment needed to be maintained for the long-term as cessation of repeated injections resulted in rapid disease recurrence and risk of vision loss.

The company said wet AMD affected 1.9 percent of people in Asia aged 65 years or older, with up to 55 percent of cases in Chinese, Japanese, and Malay populations caused by polypoid choroidal vasculopathy, a disorder of eye blood vessel proliferation that was different from the wet form in North America and Europe and anti-VEGF therapy did not result in adequate regression of lesions with photodynamic therapy the first line.

Mesoblast said its adult stem cells “may be effective for both forms of wet AMD since they have successfully reduced excessive blood vessel formation and leakiness in several preclinical studies”.

The company said that a study at the Lions' Eye Institute in Western Australia in 30 rodents with laser-induced excessive blood vessel formation showed that a single intra-ocular injection of its adult stem cells prevented development of leaky blood vessels beyond day-7 after laser-induced damage.

Mesoblast said that eyes treated with its mesenchymal precursor adult stem cells had 39 percent and 32 percent non-leaky vessels at days 14 and 28, compared to seven percent and two percent non-leaky vessels in the controls ($p < 0.05$).

At day 28, nine percent of vessels in eyes treated with a single stem cell injection were severely leaking, compared to 28 percent of vessels in control eyes ($p < 0.05$).

The company said that a trial at Charles River, Canada, in 42 non-human primates with laser-induced excessive blood vessel formation showed that combining a single injection of Mesoblast’s allogeneic cells with an injection of the anti-VEGF agent Lucentis resulted in a synergistic, and superior, outcome compared with Lucentis alone in reducing severity of blood vessel leakage within two weeks ($p < 0.05$), preventing relapse of severe vessel leakage by days 28-42 ($p < 0.05$), reducing total formation of new blood vessels ($p < 0.01$) and preventing retinal detachment by day 42 ($p < 0.01$).

Mesoblast said its phase II trial would evaluate the safety and effectiveness of a single intraocular injection of allogeneic mesenchymal precursor cells combined with the anti-VEGF agent Lucentis in newly-diagnosed wet AMD patients, compared to Lucentis alone.

Mesoblast chief executive, Professor Silviu Itescu said that “results to date suggest that a single injection of Mesoblast’s allogeneic cells may be effective for patients with wet AMD, either in combination with an anti-VEGF agent for the form seen in North America/Europe or in combination with photodynamic therapy for the PCV form seen in Asia”.

“This signals a clinical strategy by Mesoblast to increasingly target the emerging and very accessible large Asian healthcare markets,” Prof Itescu said.

Mesoblast was up 32 cents or 3.3 percent at $9.99.

PRIMA BIOMED

Prima says it has a formal partnership with the Dubai City Hospital to commercialize its CVac immunotherapy for ovarian cancer in the Middle East (BD: May 31, 2011).
The company said it expected to begin sales of CVac in Dubai before the end of 2011, which was “a significant milestone for Prima”.
Prima has begun a US phase II/III CVac trial, but last reported results from a phase IIa trial in 2006, with four of 19 patients benefiting from the drug (BD: May 16, 2006).
Prima chief executive officer Martin Rogers told Biotech Daily that CVac was essentially a blood product using the patient’s own blood which had been treated to create the vaccine.
Mr Rogers said the Dubai regulatory process required previously safety and efficacy data and would include data from the US phase IIb trial which completed enrolment last month (BD: Sep 12, 2011) along with a number of other regulatory requirements.
Mr Rogers said it was not unusual for patient’s own blood products to be treated differently to a new chemical entity by regulators.
Prima said Dubai would be the first commercialization of CVac, allowed it to provide cancer treatment in the Middle East and generate revenues.
The City Hospital’s Dr Fadi Mikhael said the approval was “a huge milestone for cancer care not only in Dubai but the region as a whole”.
“This treatment offers hope to thousands of women living in the Middle East who are suffering from ovarian cancer,” Dr Mikhael said.
Prima also announced the launch of a therapeutic apheresis or blood separation program with Dubai City hospital to remove “harmful proteins, chemicals or cells in blood that cause disease” and to be used for blood disorders, kidney problems, metabolic diseases, neurological disorders and auto-immune conditions.
The company said it was the first time this service had been offered in Dubai.
Prima was up one cent or 6.1 percent to 17.5 cents.

BENITEC

Benitec says the European Patent Office has granted one of Benitec and CSIRO’s key platform patents in the ‘Graham’ patent family, entitled ‘Control of Gene Expression’.
Benitec chief executive officer Dr Peter French said the grant was “further significant validation of this technology in key markets”.
The company said the patent was owned by the Commonwealth Scientific and Industrial Research Organisation and Benitec was the exclusive licensee for human therapeutics.
Benitec said the patent included claims to a synthetic gene which can reduce the expression of a target gene.
The company said the synthetic gene comprised multiple copies of a nucleotide sequence of greater than 20 nucleotides, which was substantially identical to the nucleotide sequence of a target gene.
In the US, further patent applications have been allowed or granted which complement Benitec’s existing focus on hepatitis viral therapies including ‘Synthetic Genes and Genetic Constructs Comprising Same’ scheduled for issue on November 1, 2011 and ‘Synthetic Genes and Genetic Constructs’ scheduled for issue on November 8, 2011.
Benitec said the US Patent and Trademark Office issued a notice of allowance on October 19, 2011 for a patent application covering “a construct with a specific enhancer and promoter for expressing RNA silencing agents in liver cells”.
The company said the technology was developed with researchers at Stanford University and was a tool for silencing genes in the liver, such as in treatment of viral hepatitis.
Benitec was up 0.1 cents or 5.3 percent to two cents with 30 million shares traded.

PHYLOGICA

Phylogica shareholders will vote to issue 15,000,000 incentive shares to directors Dr Paul Watt and Nick Woolf, replace the employee option plan and elect directors.

Phylogica's chief operating officer Mr Woolf told Biotech Daily that the incentive shares were a "tax-efficient option scheme".

The 9,000,000 shares for chief executive officer Dr Watt and 6,000,000 shares for Mr Woolf vest in three tranches from June 3, 2014 to June 3, 2016 and have an issue price of 6.4 cents.

The Phylogica notice of annual general meeting said the company would provide interest-free "limited recourse loans" for the executives to acquire the shares, worth up to $576,000 to Dr Watt and up to $384,000 to Mr Woolf.

The loans would only be worth accessing if the recipients remain with the company at the time of vesting and the share price is above 6.4 cents.

The company said shareholders would vote on a resolution to replace the employee option plan with a long term incentive share plan.

Phylogica said shareholders would also vote on the re-election of directors Bruce McHarrie and Dr Doug Wilson.

The meeting will be held in the Seminar Room, Telethon Institute for Child Health Research, 100 Roberts Road, Subiaco, Western Australia on November 24, 2011 at 9.30pm AWST).

Phylogica was unchanged at 5.9 cents.