Biotech Daily

Tuesday November 16, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHOSPHAGENICS UP 14%; COMPUMEDICS DOWN 15%**

*** GLAXOSMITHKLINE READY FOR BRAF-I PHASE III MELANOMA TRIAL**

*** SHAREHOLDERS REQUISITION ACUVAX BOARD SPILL**

*** DR RICHARD OPARA QUITS SUBSTANTIAL ACUVAX HOLDING**

*** SHEEP DATA TAKES MESOBLAST TO PHASE II CARDIAC TRIAL**

*** PHOSPHAGENICS, 3M SIGN 'CONSULTANCY' DEAL ON PAIN PATCH**

*** NEUREN PHASE I BRAIN INJURY TRIAL SUPPORTS FEMALES IN PHASE II**

*** CORRECTION: PROGEN**

*** AVITA RECELL WOUND TREATMENT LAUNCHED IN MIDDLE EAST**

*** CHEMGENEX VOTES ON NOTE SHARES**

*** SMALL DISSENT AT CELLESTIS AGM OVER REMUNERATION**

*** SIRTEX, FOUNDER DR BRUCE GRAY BACK TO COURT FOR APPEAL**

*** RENLYN BELL TAKES 13% OF KARMELSONIX**

*** SOLAGRAN SELLS 2,021 OF HOPED FOR 78,000 BOTTLES OF ROPREN**

MARKET REPORT

The Australian stock market was up 0.26 percent on Tuesday November 16, 2010 with the S&P ASX 200 up 12.3 points to 4700.3 points. Fourteen Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and eight were untraded. All three Big Caps were down.

Phosphagenics was best, up 1.5 cents or 14.3 percent to 12 cents with 16.7 million shares traded, followed by Circadian up 12.8 percent to 66 cents with 18,793 shares traded and Prana up 10.3 percent to 16 cents with 164,619 shares traded. Heartware was up 9.5 percent; Immuron and Tissue Therapies were up seven percent or more; Benitec was up 6.7 percent; Mesoblast was up 4.2 percent; Bionomics and Sunshine Heart were up more than three percent; Impedimed rose 2.5 percent; with Acrux up 1.9 percent.

Compumedics led the falls, down two cents or 15.4 percent to 11 cents with 174,000 shares traded, followed by Cellmid down 6.25 percent to 4.5 cents with 10 million shares traded. Viralytics lost more than 5.3 percent; Cathrx was down 3.85 percent; Starpharma shed 2.7 percent; with Alchemia and Nanosonics down more than one percent and the three Big Caps down by less that one percent.

GLAXOSMITHKLINE

Glaxosmithkline says it is ready to begin a phase III trial of the BRAF-inhibitor (BRAF-i) for melanoma GSK2118436 in Australia before the end of 2010.

Glaxosmithkline has received a great deal of public attention following early results that produced a “very significant reduction in tumor size” and a “nearly 80 percent partial remission rate” for the difficult to treat cancer.

In a media briefing in Sydney, the principal investigator for the Glaxosmithkline BRAF-I trials Prof Richard Kefford said the results heralded “a most exciting time for melanoma” a field in which he had worked for 30 years.

Prof Kefford said Australia had the highest rate of melanomas in the world, it was the fourth most common cancer in both men and women in Australia and accounted for about 10 percent of all cancers and the rates of incidence are increasing.

Although most patients were cured, 1,500 to 2,000 developed metastatic tumors and they were resistant to all forms of chemical treatment.

Prof Kefford said that two new drugs, Roche’s RG7204 and Glaxosmithkline’s GSK2118436 had changed the inability to treat these tumors.

But he said at this stage the drugs were not a cure and all patients eventually relapsed.

Prof Kefford said finding why they had relapsed was a central question, but a provisional median progression-free survival of 8.3 months was “a giant leap forward in melanoma”.

Glaxosmithkline said in a media release that the phase III randomized, open-label study would compare the efficacy, safety, and tolerability of GSK2118436 to dacarbazine.

The study, known as BRF113683, was undergoing ethics approval and would enroll subjects with BRAF-mutant advanced (stage III) or metastatic (stage IV) melanoma and builds on the phase I and phase II trials.

“Following on the early results from the phase I and II BRAF inhibitor trials which have recently been reported, the phase III trial will help to determine how this new compound will compare to existing treatments,” Prof Kefford said.

Glaxosmithkline said that about 50 percent of human melanomas involved a mutation of the gene for the BRAF protein causing activation of this protein.

The investigative agent, GSK2118436, binds to the activated form of the BRAF protein in the melanoma cell, causing the cell to stop proliferating.

Glaxosmithkline said it was conducting clinical trials with investigational agents targeting a range of pathway proteins, involved in melanoma cell growth.

The company said one study would explore whether, when used in combination, its MEK inhibitor (MEK-i) and BRAF-i could provide better patient outcomes in certain tumor types such as melanoma.

Glaxosmithkline said MEK proteins were another component of the signaling pathway in melanoma involved in cell growth.

The company said it BRF113220 was a phase I, open-label, dose-escalation study and it would investigate the safety, pharmacokinetics, pharmacodynamics and clinical activity of the BRAF-i GSK2118436 in combination with the MEK-i GSK1120212 in subjects with BRAF-mutant metastatic melanoma.

Glaxosmithkline said it had an ongoing phase III study in the adjuvant immunotherapy treatment of melanoma, with MAGE-A3 in melanoma.

The company said the potential new agent was an investigational therapeutic vaccine designed to target a single specific antigen or protein, called MAGE-A3, which belonged to a family of antigens known as MAGE.

This study will enroll patients with resected melanoma with macroscopic lymph node involvement and free of disease after surgery. Patients must be ‘MAGE-A3 positive’ to be eligible for the trial and will be tested if considering enrolment.

ACUVAX

Acuvax says it has received a notice under section 249D of the Corporations Act 2001 requesting a meeting to remove chairman Patrick Elliott and director Dr Yvonne Foong.
Acuvax said the notice proposed the election of Lloyd Flint and Keong Chan as directors.
The company said that under section 249D the directors were required to call and arrange a meeting on the request of members with at least five percent of the votes that may be cast at the general meeting and the meeting must be called within 21 days of the request and be held within two months of the notice.
Acuvax said the notice contained a 'requesting shareholder statement' that was required to be circulated to all members of the company with the notice of meeting.
Acuvax said the statement "contains a number of factual inaccuracies [and] some potentially defamatory statements".
Acuvax said the directors were seeking legal advice in relation to the statement.
Acuvax was untraded at 0.3 cents.

ACUVAX

Former chairman Dr Richard Opara has ceased his substantial holding in Acuvax, having held as much as 86 percent of the company.
Dr Opara held the shares through his companies Chopin Opus One and Chopin Holdings.
Dr Opara's ceasing substantial shareholder notice said that he had sold 406,000,000 shares for $638,000 or 0.157 cents a share.
The previous notice said Dr Opara and Chopin One held 437,927,500 shares leaving the group with 31,927,500 shares or 4.4 percent of Acuvax.
When Dr Opara first became substantial in Acuvax in 2004 – previously known as Avantogen and prior to that Australian Cancer Technology – he acquired 5,600,000 shares at prices ranging from 17.5 cents to 42 cents.
In 2006, Avantogen's RP101 was being investigated as a treatment co-administered with cytotoxic drugs with the aim of preventing the development of resistance to chemotherapy (BD: May 30, 2006).
In 2005 Avantogen announced dramatic results observed in the clinical pilot study of Resprotect in which 13 pancreatic cancer patients in stage III and IV of disease were treated with RP101 and gemcitabine plus cisplatin. The results indicated that the 50 percent probability of survival was increased to an average of 15 months, from the historic 7.5 months obtained at the same institution under otherwise similar conditions during the previous year.
Avantogen shares were worth 10 cents by May 2006.
In September 2006, Chopin One made a takeover bid for Avantogen, for the 48 percent of shares not held by Chopin and Dr Opara, at two cents a share, when the last trading price was 5.1 cents (BD: Sep 20, 2006).
By December 2007, companies associated with Dr Opara and Chopin Opus One were believed to hold up to 86 percent of Avantogen, although the company's annual report said ANZ Nominees held 86.59 percent of the company and at that time Chopin Opus One was last known to own 77.8 percent of Avantogen (BD: Dec 4, 2007).
Acuvax held a 26 percent stake in Hawaii Biotech developing vaccines for Dengue fever and West Nile virus and had hoped to raise funds to buy those assets when Hawaii Biotech declared itself bankrupt (BD: Jun 30, 2010).
In July this year Merck & Co Inc's $3.5 million acquisition of Hawaii Biotech's West Nile virus and Dengue fever vaccine and diagnostic assets effectively left Acuvax without any significant compounds to develop (BD: Jul 22, 2010).

MESOBLAST

Mesoblast says its off-the-shelf stem cells have been injected safely and effectively into the coronary arteries of sheep after cardiac arrest to prevent heart failure.
Mesoblast said the preclinical results were presented at the American Heart Association's conference in Chicago showing that an intra-coronary infusion of mesenchymal precursor cells increased blood vessel numbers, prevented scar formation and significantly improved heart muscle function after cardiac arrest, thereby preventing heart failure.
The company said that on the basis of the results, it would proceed with multi-center phase II clinical trials of its Revascor product delivered by intra-coronary infusion in cardiac arrest attack patients immediately after they undergo a standard angioplasty and stent procedure to open a blocked coronary artery.
Mesoblast said the study of 30 sheep was performed at the Erasmus University Medical Center in Rotterdam where the sheep underwent a large anterior myocardial infarct and received an infusion into the coronary arteries of either saline (10 sheep) or mesenchymal precursor cells, at dosages of 12.5, 25, or 37.5 million cells (7, 7, 6 sheep/group).
Mesoblast said that after two months, myocardial function, as measured by ejection fraction, was significantly higher in every dose group than in controls, with no significant differences between any of the dosages.
Overall, ejection fraction in treated subjects was a mean of 12 points higher than in controls (54.4 +/- 1.1% compared to 42.5 +/- 3.6%; $p<0.001$).
Mesoblast said that every tested dose significantly reduced left ventricular dilation, with mean end systolic volumes in treated subjects 66 +/- 1.0 mL compared with 98.6 +/- 5.1 mL in saline-treated controls ($p<0.001$).
The company said that, in comparison to controls, every dose significantly reduced scar formation and fibrosis in heart muscle (50% mean reduction, $p<0.005$) and significantly increased blood vessel formation (69% mean increase in capillary density and 122% mean increase in arterioles, both $p<0.001$).
The study's principal investigator and head of molecular cardiology at the Erasmus University's Thoraxcenter Prof Eric Duckers said the data was "the most compelling data that I have ever seen regarding a cell therapy approach in cardiovascular disease".
Mesoblast said cardiac arrest was the single biggest killer of Americans with about 7.3 million American adults having had at least one arrest and more than 1.1 million patients having a first cardiac arrest each year.
The company said that about 80 percent of patients survived the initial arrest and most patients underwent an early angioplasty of the blocked artery accompanied by implantation of a metal stent to keep the artery open for the long-term.
Mesoblast said its Revascor mesenchymal precursor cell product would be developed as a simple off-the-shelf therapy for use in conjunction with angioplasty and stent procedures to prevent the complication of heart failure in those surviving a major cardiac arrest.
Mesoblast climbed as high as $3.11 closing up 12 cents or 4.2 percent at $2.99.

PHOSPHAGENICS

Phosphagenics says it has signed a consultancy agreement with 3M Corp, the first stage of the commercial development of its oxycodone patch for pain.
Phosphagenics said the details of the arrangement were not disclosed.
Phosphagenics chief executive officer Dr Esra Ogru said that working with 3M supported the commercial development of the tocopheryl phosphate mixture transdermal patch.
Phosphagenics was up 1.5 cents or 14.3 percent to 12 cents with 16.7 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says a phase I trial of NNZ-2566 for traumatic brain injury in healthy females has shown the drug safe and well-tolerated at the highest dose planned for phase II trials.
Neuren said there were no serious adverse events reported and reported adverse “were generally mild and the incidence of adverse events was exactly the same in patients who received drug as in those who received placebo”.
The company said the blood levels of NNZ-2566 in female subjects were directly comparable to those in males, so that no adjustment of dose based on gender would be required for the phase II trial.
Neuren said the independent data safety and monitoring committee recommended that females be included in the phase II trial.
Neuren said it was preparing a protocol amendment for submission to the US Food and Drug Administration and institutional review boards to include female patients in the phase II traumatic brain injury trial.
Neuren said the amendment was expected to be submitted to its trial collaborator, the US Army Walter Reed Hospital before the end of November 2010 and to the FDA soon after.
The company said the about 25 to 30 percent of traumatic brain injury patients admitted to hospitals were female.
Neuren chief executive officer Larry Glass said the phase I trial confirmed the safety profile of NNZ-2566 established in previously completed phase I studies and validated the company’s decision to utilize a buffer for drug reconstitution and justify inclusion of female patients in phase II.
“We will begin enrolling female patients as soon as the protocol amendment is approved by the FDA and IRBs,” Mr Glass said. “This will help us meet our enrolment goals as the Intrepid-2566 study progresses and ensure that women will have equal access to the potential benefits of the drug”.
The phase I study was conducted under an FDA investigational new drug application by the Nucleus Network at the Alfred Medical Research Education Precinct Centre for Clinical Studies in Melbourne.
Neuren said the trial involved five cohorts of eight patients in total with six receiving the drug and two receiving placebo (saline).
The company said the total dose administered was increased from cohort to cohort following review by an independent data safety and monitoring committee.
Neuren said the highest dose was a 10 minute bolus or loading dose of 20mg of drug per kg of body weight (mg/kg) followed by 72 hours of continuous infusion at 6mg/kg/hr.
Neuren said the phase I study was the first safety study to employ the buffered infusion product which was being used in the phase II traumatic brain injury trial of NNZ-2566.
The company said the buffered solution significantly reduced the incidence of infusion site reactions and had no detectable effect on safety or pharmacokinetics.
Neuren said the incidence of infusion site reactions was the same in patients receiving drug and those receiving placebo.
Neuren was up 0.2 cents or 11.1 percent to two cents with 17.2 million shares traded.

PROGEN

Last night’s article on Progen’s phase I tumor trial included a sentence incorrectly attributed to Bionomics, which separately announced positive anti-anxiety data in rats.
The sub-editor is no more.
Progen was up half a cent or 1.5 percent to 33 cents.
Bionomics was up one cent or three percent to 34 cents.

AVITA MEDICAL

Avita says its regenerative wound treatment Recell spray-on skin has been launched in the Middle East.
Avita said the Amman Jordan-based RX Medical had been appointed as its distributor and was a leading distributor of medical products throughout the Middle East.
The company said that about 120 plastic surgeons and dermatologists attended workshop sessions in Jordan and Kuwait over four days in October, 2010, organized by RX Medical and conducted by Paris France-based plastic reconstructive and aesthetic surgeon Dr Jean Michel Rives.
Avita said key attendees included the presidents of plastic surgeon associations in Jordan, Kuwait and Saudi Arabia.
The company said Dr Rives had conducted more than 65 Recell procedures during the previous six months at his clinic in Paris.
Avita said three hospitals were visited in Jordan and Kuwait and six Recell procedures were conducted during the tour.
The company said procedures included treatment of a paediatric acute burn, a case of severe hypopigmentation on the face, three vitiligo patients and one scar revision, with audio-video hook-up allowing live transmission of the surgery to viewing facilities and each procedure was witnessed by up to 20 invited surgeons.
Dr Rives said his clinic “achieved remarkable results with the use of Recell in a wide range of applications and procedures”.
“Recell provides an exceptional technology for the improvement of outcomes in aesthetic and plastic procedures not available with other techniques,” Dr Rives said.
Avita said the Middle East was a significant potential market with large populations, a well developed and wealthy middle class and excellent healthcare systems.
Avita was unchanged at 11 cents.

CHEMGENEX

Chemgenex shareholders will vote on the issue of up to 30,000,000 shares to Cephalon as part of a deal that would allow it to take a 30 percent stake in Chemgenex.
There is just one resolution to the extraordinary general meeting which will be held at RBS Morgans, Level 27, 367 Collins Street, Melbourne on December 21, 2010 at 10am.
Last month Chemgenex said the Pennsylvania-based Cephalon had taken a 19.9 percent share of the company at 70 cents a share, pending certain milestones to be achieved by March 31, 2011, along with an approximate 10 percent holding resulting from the conversion of the $15 million convertible note at 50 cents a share (BD: Oct 22, 2010).
Chemgenex was unchanged at 46.5 cents.

CELLESTIS

Cellestis shareholders approved all annual general meeting resolutions but there was dissent over increasing the maximum remuneration for non-executive directors.
The resolution to increase the total remuneration by 33 percent from $300,000 to $400,000 was passed by 15,856,091 proxy votes (89.9%) to 1,775,639 proxy votes (10.1%).
Cellestis said its remuneration report was passed by 40,450,267 proxy votes (94.3%), with 2,458,094 (5.7%) proxy votes against.
Cellestis said Ron Pitcher was re-elected as director overwhelmingly.
Cellestis fell one cent or 0.4 percent to $2.24.

SIRTEX MEDICAL

Sirtex says former chairman Dr Bruce Gray will appeal the Federal Court order to pay the company $2,575,186 plus the costs of its University of Western Australia legal case.
Sirtex said that the Federal Court ordered Dr Gray to pay Sirtex the sums (BD: Jun 11, 25, 2010.
Sirtex said that on July 5, 2010, Dr Gray filed an appeal which would be heard in the Full Court of the Federal Court on February 23, 2011.
Sirtex was up one cent or 0.2 percent to $6.11.

KARMELSONIX

Renlyn Bell Investments has increased its substantial shareholding in Karmelsonix from 79,312,121 shares (11.68%) to 87,185,924 shares (12.69%).
The substantial shareholder notice said the shares were held for the G & R Bonaccorso Family Trust along with Garry Bonaccorso and Salavente Pty Ltd.
The notice said 7,053,803 were acquired for no cost through an off-market acquisition – believed to be an internal restructure - in April and November 2010, with 820,000 shares acquired in February for $22,560 or an average price of 2.75 cents a share.
Karmelsonix fell one cent or 3.85 percent to 2.5 cents with 1.85 million shares traded.

SOLAGRAN

Solagran says it has sold a total of 2,021 bottles of Ropren in nine regions in Russia of the 78,000 bottles it had hoped to sell by the end of November.
Solagran said its distributor had “indicative orders for a further 620 bottles by the end of this month”.
Ropren is a derivative of green conifer needle extract.
In March, Solagran said Ropren was “officially launched on March 10, 2010” with 31 courses of six bottles per course sold at the end of February for $US1,150 per course (BD: Mar 12, 2010).
“Solagran remains confident of achieving the forecast previously provided of selling in excess of 13,000 courses [78,000 bottles] of Ropren by December 2010,” Solagran said at that time.
Today, Solagran said its product registration file for Bioeffective A was submitted to the United Arab Emirates Ministry of Health in October 2010 with regulatory approval expected by April 2011.
The company said the US Food and Drug Administration was due to make a decision on the approval of Bioeffective A as a new-dietary ingredient in December 2010.
Solagran was up 1.5 cents or 13.6 percent to 12.5 cents.