Biotech Daily

Monday June 27, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 21%, VIRALYTICS DOWN 15%**

*** BIOTA'S INAVIR MISSES PROPHYLAXIS ENDPOINT**

*** LIVING CELL BEGINS ARGENTINA TYPE1 DIABETES TRIAL**

*** PREMIER BLIGH LAUNCHES QUEENSLAND LIFE SCIENCES**

*** PATRYS PAT-SMC REDUCES MELANOMA METASTASES IN MICE**

*** FDA APPROVES VIRALYTICS PHASE II CAVATAK MELANOMA TRIAL**

*** EMA DETAILS OBJECTIONS TO PHARMAXIS BRONCHITOL**

*** IMMUNE SYSTEM ANTI-CANCER MDX-1097 US ORPHAN DRUG**

*** IMMURON PLACEMENT RAISES $690k**

*** LLOYDS & CASSANOVE TAKES 9% OF CYCLOPHARM**

*** HELICON REQUESTS ACQUISITION TRADING HALT**

*** GENERAL INVESTMENT CEASES IN FERMISCAN**

MARKET REPORT

The Australian stock market fell 1.03 percent on Monday June 27, 2011 with the S&P ASX 200 down 46.3 points to 4,461.8 points. Nine of the Biotech Daily Top 40 stocks were up, 24 fell, two traded unchanged and five were untraded. All three Big Caps fell.

Optiscan was the best, up one cent or 20.8 percent to 5.8 cents with 294,830 shares traded, followed by Psivida up 7.9 percent to $3.96 with 8,648 shares traded. Genetic Technologies climbed 5.9 percent; Alchemia was up 1.7 percent; with Cellestis, Clinuvel, Heartware, Impedimed and Starpharma up less than one percent.

Viralytics led the falls, down 1.4 cents or 15.4 percent to 7.7 cents with 81.3 million shares traded, followed by LBT down 12.5 percent to 3.5 cents with 25,000 shares traded and Biota down 10.5 cents or 10.3 percent to 91.5 cents with 1.4 million shares traded. Virax lost 9.1 percent; QRX and Sunshine Heart fell more than seven percent; Living Cell lost 6.15 percent; Prana fell 5.7 percent; Cathrx, Cellmid and Phosphagenics fell four percent or more; Benitec, Nanosonics and Pharmaxis were down more than three percent; with Acrux, Anteo, Cochlear, CSL and Tissue Therapies shedding more than two percent.

BIOTA HOLDINGS

Biota says its phase III prophylaxis trial of about 200 patients for influenza drug Inavir or CS-8958 failed to meet its efficacy endpoints.

Biota said that in data presented at the Japanese Society of Chemotherapy last week (June 23-25, 2011), the trial demonstrated the protective efficacies of a single, inhaled dose of CS-8958 of 20mg and 40mg, as measured by the risk reduction rate, were 43.7 percent and 43.2 percent, respectively, but the preset endpoint was 70 percent.

Biota said that subjects received one of two dose levels of CS-8958 or placebo.

The company said that possible reasons for the lower protective efficacies were the low infection rate within families in the placebo group (8.6%) and the growth in public awareness, resulting in the use of other preventative infection measures during the 2009 H1N1 influenza pandemic.

Biota chief executive officer Peter Cook told Biotech Daily that low cross-infection rate reduced the numbers to inconclusive and a different design could produce better results.

Mr Cook said that a longer duration seasonal study compared to the shorter in-house design in this study could provide the power for greater significance.

“There are a number of alternative study designs that could be done to overcome the limitations of the in-home study design,” Mr Cook said.

Mr Cook said that no decision had been made by Daiichi Sankyo, which remained keen to have Inavir registered for prophylactic purposes.

Biota said the study was a multi-center, placebo-controlled, double-blind trial that evaluated prevention and safety of laninamivir octanoate (CS-8958 or Inavir) in families of influenza A and B sufferers measuring influenza transmission to other members of the household with a confirmed influenza-infected patient.

Biota said there were no restrictions on other preventative measures undertaken such as the use of masks, hand washing or isolation of the infected patient.

The company said Daiichi Sankyo had significant sales of Inavir in Japan since its approval in September 2010, for the treatment of influenza and a phase III trial in adults with influenza A or B demonstrated that a single inhaled dose of CS-8958 had equivalent safety and efficacy to Tamiflu (oseltamivir) dosed twice daily for five days.

Biota fell 10. 5 cents or 10.3 percent to 91.5 cents with 1.4 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says it has enrolled its first two patients in its Argentina phase II clinical trial of Diabecell porcine islets of Langerhans for type 1 diabetes.

Living Cell said it had approval to enroll eight type 1 diabetes patients, including those with unstable diabetes and severe hypoglycaemia (BD: May 3, 2011).

The company said the two patients had begun the pre-transplant phase of the trial to establish a stable baseline from which to compare the post-treatment data and determine whether the endpoints had been reached.

Living Cell said the two patients were scheduled to receive the first of their two implants in August at the dose of 5,000 islet equivalents per kilogram of body weight, followed three months later by their second implant at the same dose.

The company said that both patients had pre-existing severe hypoglycaemia and long term complications from their diabetes.

The trial’s principal investigator Dr Adrian Abalovich said that unstable diabetes has a significant impact on the health of patients and can cause long term complications.

Living Cell medical director Prof Bob Elliott said enrollment was “an important milestone”.

Living Cell fell 0.4 cents or 6.15 percent to 6.1 cents.

QUEENSLAND LIFE SCIENCES

Queensland Clinical Trials Network says Premier Anna Bligh formally launched the State industry organization Queensland Life Sciences at BIO 2011 in Washington overnight.
The Network said that Queensland Life Sciences stakeholders had secured about $2 million in industry support matching the Queensland Government's contribution.
Queensland Life Sciences chairman Dr Peter Riddles said it was an extension of the Queensland Government's commitment to building infrastructure and attracting world-class individuals to form the basis of a life sciences industry in Queensland which 10 years ago, was not even imagined possible.
"Biotechnology and the industries it will enable in the future are a key part of Queensland's economic prosperity," Dr Riddles said.
Queensland Clinical Trials Network (QCTN) said Life Sciences Queensland would formally commence operations on July 1, 2011 and the board would include Queensland Biotechnology Fund chief executive officer Dr Cherrell Hirst, Alchemia chief executive officer Dr Pete Smith and Clinical Network Services chief executive officer Prof Anthony Webber, with QCTN chief executive officer Mario Pennisi appointed the organization's inaugural chief executive officer.
The media release said that before the formal establishment of the organization, the board had undertaken initiatives including leading a Queensland presence at the JP Morgan Meeting in San Francisco and supporting Queensland at the World Congress of Industrial Biotechnology.
"Each of these events has already led to key interactions and to the identification of opportunities for the Queensland life sciences industry which will be pursued with the assistance of Premier Anna Bligh at BIO," Mr Pennisi said.
For more information go to: www.lsq.com.au.

PATRYS

Patrys says a mouse model of PAT-SM6 for human metastatic melanoma has demonstrated proof-of-concept.
Patrys said the preclinical study of the natural human antibody was conducted by contract research organization Vivopharm, which measured the reduction of metastases using the C8161 tumor model, a highly metastatic human melanoma cell line derived from a patient with advanced disease.
The company said the cells typically metastasized aggressively after injection into athymic nude mice, a common animal model with low immunity.
Patrys chief executive officer Dr Marie Roskrow said that treatment with Patrys' antibody PAT-SM6 "resulted in a highly statistically significant reduction of metastases in test animals".
"Four different concentrations of PAT-SM6 were tested and all groups performed equally well when compared to control animals, resulting in a dramatic reduction of metastases," Dr Roskrow said.
"PAT-SM6 proved to be as effective as the commercial standard of care drug dacarbazine," Dr Roskrow said.
"This is the first time that PAT-SM6 has been tested in such an aggressive tumor model and we are very excited by the results," Dr Roskrow said.
Patrys said PAT-SM6 was in a phase I clinical trial for melanoma at Royal Adelaide Hospital and the company was extending its preclinical program to generate additional data and evidence to supplement the ongoing clinical program (BD: Jun 20, 2011).
Patrys fell 0.1 cents or 1.1 percent to nine cents with 1.2 million shares traded.

VIRALYTICS

Viralytics says the US Food and Drug Administration has lifted its clinical trial hold and the US Cavatak phase II late stage melanoma trial would begin immediately.

Last month, the company said the trial hold over the trial design relating to the technical definition of efficacy measurements to be used in the proposed trial and the timing of independent patient safety review (BD: May 23, 2011).

Viralytics said today the trial would have up to 63 patients of which 54 would be evaluable and was a single arm intra-tumoral trial injecting Cavatak to multiple tumors on up to 10 separate occasions over an 18-week period.

The company said the primary end-point would be a measure of immune-related progression-free survival at six months.

Viralytics managing director Bryan Dulhunty said the FDA allowance of the trial was “a significant milestone” and the company would appoint a clinical research organization to recruit clinical sites and begin the trial.

Viralytics fell 1.4 cents or 15.4 percent to 7.7 cents with 81.3 million shares traded.

PHARMAXIS

Pharmaxis says the European Medicines Authority’s Committee for Medicinal Products for Human Use has detailed its objections to registering Bronchitol for cystic fibrosis.

Pharmaxis said the Committee’s major concern was “their view that the effectiveness and benefit of Bronchitol had not been established”.

“It was not clear to the [Committee] that the improvement in lung function would be sufficient to improve the patient’s condition and that the extent of the improvement was difficult for them to ascertain since the results of the studies were, in their view, inconsistent across the different age groups,” the company said.

Pharmaxis said it did “not concur with this opinion and … [had] appropriate grounds upon which to request a re-examination of the European Bronchitol marketing application”.

The company said it would complete a review of the opinion, including discussions with the EMA and obtain advice from external specialist regulatory consultants, before requesting a re-examination, which needed to be lodged within 15 days.

Pharmaxis chief executive officer Dr Alan Robertson said Bronchitol improved lung function and was “responsible for a significant reduction in the incidence of exacerbations”.

“Furthermore, the sustained improvements in lung function now seen out to 12 months with Bronchitol are crucial in a disease where an accelerated loss of lung function is largely responsible for the early death of the patient,” Dr Robertson said.

“We have a clear understanding of the task in hand and are well advanced in our preparation,” Dr Robertson said.

Pharmaxis said that in two phase 3 clinical trials, Bronchitol improved mucus clearance by three-fold relative to control ($p < 0.0001$) and lung function after the six-month trial, as measured by forced expiratory volume in one second (FEV1), improved by 7.3 percent relative to baseline ($p < 0.001$) and by 3.8 percent relative to control ($p < 0.001$) and that Bronchitol achieved this on top of existing cystic fibrosis treatments.

The company said cystic fibrosis patients normally lost one to two percent of their lung function each year.

Pharmaxis said Bronchitol reduced overall pulmonary exacerbation incidence by 29 percent ($p = 0.039$) relative to control and pulmonary exacerbations were associated with subsequent FEV1 decline in both adults and children with cystic fibrosis.

Pharmaxis closed down 3.5 cents or 3.7 percent at 90 cents with 934,264 shares traded.

IMMUNE SYSTEM THERAPEUTICS

Immune System says the US Food and Drug Administration has provided orphan drug designation for its MDX-1097 antibody treatment for blood cancer.
Immune System said the effective exclusivity period for orphan drugs in the US was 12 years with the potential for an accelerated FDA review process.
Immune System chief executive officer Alan Liddle said it was “another positive step towards achieving our business goal of developing an effective treatment for patients suffering from multiple myeloma”.
The company said the FDA granted orphan drug designation for MDX-1097 based on review of the application, which included clinical and preclinical data demonstrating a favorable efficacy and safety profile.
Immune System said the designation was the first awarded for its portfolio of antibody platform technologies being developed to target and treat a range of other cancers and diseases with major unmet clinical needs.
The company said MDX-1097 was a genetically-engineered antibody that bound to a target protein found on the cell surface of some types of blood cancer.
Immune System said it expected the antibody would potentially reduce the number of cancerous cells in multiple myeloma patients and improve patient health and wellbeing.
Immune System is a private company.

IMMURON

Immuron says it has raised $689,745 through the placement of seven cent shares to sophisticated and professional investors.
Immuron made the disclosure in the body of Appendix 3B new issue announcements today and on May 12, 2011.
The company said the shares came with attaching options and a further $23,215 of shares were issued to consultants in lieu of fees, with $9,188 in shares issued to a director in lieu of director’s fees and $1,000 in shares issued to staff under a staff share plan.
Immuron said a total of 10,330,682 shares and 3,315,928 options were issued in the two tranches.
Immuron was unchanged at seven cents.

CYCLOPHARM

Lloyds & Cassanove Investment Partners has increased its substantial shareholding in Cyclopharm from 12,633,680 shares (7.5%) to 14,508,613 shares (8.6%).
The London-based Lloyds & Cassanove said it acquired the 1,874,933 shares for $94,215 or an average price of 5.02 cents a share.
Cyclopharm was unchanged at five cents.

HELICON GROUP

Helicon has requested a trading halt pending an announcement “in relation to a proposed acquisition.
Trading will resume on June 29, 2011 or on an earlier announcement.
Helicon last traded at 2.3 cents.

FERMISCAN

General Investment Services has ceased its substantial holding in Fermiscan with the on-market sale of 3,750,000 shares for $30,000 or 0.8 cents a share.

The Collins Street, Melbourne-based General Investment Services gave its address as care of NWH Accounting and said in March that it became substantial in Fermiscan with 30,000,000 shares (5.18%) one cent a share.

Fermiscan fell 0.1 cents or 14.3 percent to 0.6 cents.