Biotech Daily

Wednesday December 7, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 47%, LIVING CELL DOWN 7%**

*** ANTISENSE PARTNER INTEREST ON PHASE I ATL1103 SUCCESS**

*** BIOTRON CLAIMS BIT225 HEPATITIS C EFFICACY AT 3 MONTHS**

*** VIRALYTICS POSTER SHOWS CAVATAK, CHEMO SYNERGY**

*** AUSTRALIAN LEADERS TAKES 9% OF ATCOR**

*** FEDERAL $100m INNOVATION INVESTMENT FUND OPENS**

*** JAPANESE PATENT FOR ANTEO'S MIX&GO**

*** ALLIED APPOINTS EX-AVEXA CEO DR JULIAN CHICK COO**

*** USCOM'S ROB PHILLIPS REPLACES CEO JOE TRYGAR; CO SEC**

*** CORRECTION: BIOGRID AUSTRALIA**

MARKET REPORT

The Australian stock market climbed 0.72 percent on Wednesday December 7, 2011 with the S&P ASX 200 up 30.5 points to 4,292.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, nine fell, 10 traded unchanged and seven were untraded.

Optiscan was the best on no news, up four cents or 47.1 percent to 12.5 cents with 526,403 shares traded, followed by Antisense up 15.6 percent to 3.7 cents with 232.9 million shares traded.

Phylogica climbed 9.3 percent; Anteo and Phosphagenics were up more than six percent; Nanosonics was up 5.4 percent; Genetic Technologies, Neuren and QRX were up more than four percent; Impedimed was up 3.7 percent; Heartware and Mesoblast rose more than two percent; with Acrux and CSL up more than one percent.

Living Cell led the falls, down 0.4 cents or 7.0 percent to 5.3 cents, with 283,500 shares traded.

Allied Health lost 4.8 percent; Bionomics and Viralytics were down more than three percent; Tissue Therapies shed 2.4 percent; with Alchemia and Reva down more than one percent.

ANTISENSE THERAPEUTICS

Antisense says its phase I trial of ATL1103 targeting the growth hormone receptor (GHr) met the primary objective of assessing safety, tolerability and pharmacokinetics.

Antisense said that a pharmaceutical company previously interested in ATL1103 wanted to move to licencing due diligence, but Antisense was planning to take the compound to its own phase II trial.

Antisense said the phase I trial showed ATL1103 was safe and well tolerated at the doses employed, with the pharmacokinetic data “as expected being in line with the general clinical experience with second generation antisense drugs”.

The company said the trial assessed biological markers relevant to ATL1103’s potential therapeutic action, including the drug’s effect on blood levels of the hormone insulin-like growth factor 1 (IGF-I).

Antisense said the trial was not designed to assess the efficacy of ATL1103, but ATL1103 demonstrated the relevant pharmacological activity to support further development as a potential treatment for acromegaly and other growth hormone and IGF-I related disorders, including diabetic eye and kidney complications and some cancers.

The company said it was planning for a phase II clinical trial of ATL1103, initially in patients with acromegaly.

The trial’s principal investigator the University of Melbourne’s Prof Albert Frauman said the safety and tolerability profile of ATL1103, along with preliminary indications of the drug’s relevant pharmacological activity “are encouraging and support the ongoing development of ATL1103 for a patient group such as those with acromegaly who would benefit from a new treatment option”.

The randomized, placebo-controlled, double-blind study administered four dose levels of ATL1103 as a single injection in 24 patients starting at 25mg and escalating to 75, 250 and 400mg or placebo.

The multiple dose stage was to be undertaken in 12 subjects, with eight receiving six subcutaneous doses of 250mg of ATL1103 and four receiving placebo over 21 days.

Antisense said the subjects were monitored to Day 35 with no serious adverse events reported, but two subjects withdrew for reasons not related to safety.

The company said that all adverse events were reported as “mild to moderate” with injection site reactions the majority of all the adverse events reported in the trial.

Antisense said there was one elevation in the liver enzyme ALT reported as an adverse event in the multiple dose stage but ALT levels returned to normal during the dosing phase, suggesting no residual or cumulative effect of the drug.

The company said the effect of ATL1103 on serum IGF-I was assessed as a change in IGF-I levels versus baseline for treated subjects and this group showed a trend in reduction in IGF-I levels from Day 14 to Day 28, with a significant effect ($p = 0.034$) at Day 21 with a seven percent reduction in mean IGF-I levels versus baseline.

Antisense said that ATL1103 had a significant effect on reducing growth hormone binding protein (GHBP) by 16 percent ($p = 0.007$) at Day 21, suggesting that GHr expression was being reduced and providing strong support for the drug working via its intended, unique, antisense mechanism of action.

The company said that ATL1103 also significantly reduced insulin-like growth factor binding protein 3 and acid labile subunit of the insulin-like growth factor binding protein complex, both consistent with its effect on IGF-I and the fact that they are regulated by growth hormone with, as expected, there was no effect on growth hormone levels.

Antisense chief executive officer Mark Diamond said the company completed the trial “on budget and ahead of schedule”.

Antisense was up half a cent or 15.6 percent to 3.7 cents with 232.9 million shares traded.

BIOTRON

Biotron says that final data presented on its 24-patient, phase IIa trial of hepatitis C drug candidate BIT225 showed evidence of improved benefit at three months.

Biotron published interim data “good antiviral activity” in hepatitis C virus patients and the orally administered, small molecule BIT225 in combination with the current standard of care for treating hepatitis C interferon and ribavirin had greater reductions in viral levels than patients receiving interferon and ribavirin alone (BD: Oct 10, 2011).

The company said at that time that patients receiving the 400mg dose of BIT225 showed the greatest levels of virus reduction.

Biotron said that principal investigator Dr Tawesak Tenwandee from Siriraj Hospital, in Bangkok, Thailand, presented the data from the 28 day study at the Frontiers in Drug Development for Anti-Retroviral Therapies (DART) hepatitis conference in Hawaii, December 4-8, 2011.

The company said patients continued with the standard of care for a further 44 weeks, with follow-up visits at two and three month time points as well as at 48 weeks.

Biotron said that 87 percent of trial subjects who had received BIT225 achieved a complete early viral response, defined as virus levels in the blood below the level of detection, less than 50 international units/ml at 12 weeks, compared to 63 percent of patients who received standard of care alone.

The company said that the data from the four week time point, when treatment concluded, was also presented showing that patients who received BIT225 had significantly less virus that those who had received standard of care alone, with an average of about 90 percent less virus in the cohort receiving 400 mg of BIT225.

Biotron said the three month data demonstrated that BIT225 continued to provide additional benefit to patients after the conclusion of dosing.

Biotron chief executive officer Dr Michelle Miller said the results further validated plans to progress the program.

“These results are impressive,” Dr Miller said.

“To have close to 90 percent of patients achieving a complete [early viral response] after three months is extremely encouraging and demonstrates the clinical benefit of BIT225,” Dr Miller said.

“We have now established that BIT225 significantly increases the response to the current … treatment, with improved outcomes for those patients infected with [hepatitis C] genotype 1, the most common form of hepatitis C and the most difficult variant to treat,” Dr Miller said.

“It was also demonstrated that BIT225 was generally well tolerated,” Dr Miller said.

Biotron said that the standard of care was associated with a range of significant side effects and the most common side effect that was possibly associated with BIT225 was nausea during the first week of the study, which could be formulation-related and expected to be overcome with further formulation development.

Biotron said BIT225 targeted the viral protein p7, which had “crucial roles in virus replication and reproduction”.

The company said p7 was a new target and BIT225 is a first-in-class, direct-acting antiviral and as well as being synergistic with current approved treatments, preclinical studies demonstrated that BIT225 also worked well in vitro with some polymerase inhibitors, another new drug class that is in clinical development.

The company said that BIT225 was also in development for treatment of HIV, with a phase Ib/IIa trial in progress. And the drug “offers a unique opportunity for potential use in the HIV/HCV co-infected population”.

Biotron was up two cents or 18.2 percent to 13 cents with 1.65 million shares traded.

VIRALYTICS

Viralytics says that a poster presentation shows synergy between the oncolytic activity of Cavatak and the cytotoxic action of some standard chemotherapy formulations

Viralytics said the poster on the pre-clinical activity of Cavatak in combination with standard chemotherapy regimes in human melanoma models was presented yesterday at the Australian Society of Virology Meeting in Kingscliff , New South Wales.

The poster, entitled 'Combined Coxsackievirus A21 oncolytic virotherapy and chemotherapy for the treatment of malignant melanoma' was co-authored by Viralytics chief scientist Prof Darren Shafren and presented by the University of Newcastle's Min Yuan Quah,

The poster abstract said growth in oncolytic virotherapy had led to an increased number of clinical trials and acceptance of tumor selective viruses as a cancer treatment.

The abstract said it had demonstrated that the picornavirus Coxsackievirus A21 (CVA21), had the inherent capacity to preferentially infect and destroy malignant cells bearing the viral receptor intercellular adhesion molecule-1 (ICAM-1).

The poster said that anti-cancer drugs such as dacarbazine or paclitaxel and carboplatin were tested in combination with CVA21 on five melanoma cell lines.

Two pre-clinical mouse melanoma models, an immunodeficient xenograft model and a syngeneic immunocompetent model were established to evaluate the safety and efficacy aspects of the combination therapy, the poster said.

The poster concluded that in vitro, the co-treatment of CVA21 with either dacarbazine or paclitaxel and carboplatin was found to be synergistic in most melanoma cell lines.

"Using Chou-Talalay's drug combination analysis to generate combination index values, high synergism was observed in two relatively CVA21 insensitive melanoma cell line when treated in combination with paclitaxel and carboplatin," the poster concluded.

"In vivo, the co-administration of anti-neoplastic drugs did not inhibit the oncolytic activity of CVA21 in a immune-deficient setting as tumor regression were observed in animals treated with CVA21 alone and CVA21 in combination with chemotherapy," the poster said.

"Furthermore, in the presence of an intact host immune system, the co-treatment of CVA21 with chemotherapeutics could significantly inhibit tumor growth by day 28," the poster concluded.

"The synergistic activity of Cavatak and chemotherapy both in laboratory cultures of human melanoma cells and in small animal melanoma models highlights the potential for Cavatak to be implemented with current standard of care chemotherapy regimes for treatment of malignant melanoma," Dr Shafren said.

Viralytics said the poster would be made available on its website: www.viralytics.com.

Viralytics said it was currently in multi-site patient enrolment for its US based phase II trial of Cavatak in late stage melanoma patients under an investigation new drug application allowed by the US Food and Drug Administration.

The company said it expected to complete its phase I intravenous late stage colorectal, prostate, breast and melanoma cancer safety study, shortly.

Viralytics fell 1.5 cents or 3.6 percent to 40 cents.

ATCOR MEDICAL

The Australian Leaders Fund has increased its substantial shareholding in Atcor from 10,341,938 shares (7.71%) to 11,936,907 shares (8.90%).

The Australian Leaders Fund said it most recently acquired 300,000 shares for $24,079 or an average price of 8.03 cents a share.

Atcor was up 0.3 cents or 3.9 percent to eight cents.

FEDERAL GOVERNMENT

Innovation Minister Senator Kim Carr says the fourth and final tranche of the $100 million Innovation Investment Fund third round has opened.

A Department of Innovation media release said the Federal Government would support private sector investors “to help ensure that new business ideas that originate in Australian firms and research organizations compete in global markets”.

Senator Carr said the $100 million would lead to $200 million of venture capital for early-stage investments offering a bridge to larger venture capital funds with the capacity to make significant longer-term investments.

“Through the IIF, the Australian Government aims to increase investment in growth companies and connect them with international markets,” Senator Carr said.

“Venture capital has been shown to be an effective mechanism for commercializing innovative technologies into new products, services and processes,” Senator Carr said.

“We not only want to create high-value jobs and products that will boost productivity, but also enhance our international reputation for innovation and quality research,” Senator Carr said

Senator Carr said Pharmaxis was a successful technology company supported by the Australian Government’s Innovation Investment Fund.

“Pharmaxis is a great example. It is expanding its advanced research and manufacturing facilities in Sydney with $10 million of new equipment to make its cystic fibrosis treatment and an anti-asthma drug,” Senator Carr said.

The media release quoted Pharmaxis chief executive officer Dr Alan Robertson saying that research and development “works better when it can be coupled directly to manufacturing”.

The media release said Pharmaxis backer, GBS Venture Partners acknowledged that IIF gave it its start in the venture capital industry.

GBS managing director Dr Geoff Brooke was quoted saying his company manages more than $400 million for investors, including major Australian superannuation funds.

Applications for the Innovation Investment Fund close on July 2, 2012.

Details on information seminars are available at www.ausindustry.gov.au/IIF or through the Ausindustry Hotline 13 28 46.

ANTEO DIAGNOSTICS

Anteo says the Japanese Patent Office has granted a patent entitled ‘Use of Metal Complexes’ for its Mix&Go technology.

Anteo has previous said Mix&Go could be used to bind antibodies to more than 8,000 different types of surfaces and allowed proteins or biomarkers to be detected at lower concentrations and across a broader concentration range, with improved stability and reduced lot to lot variability.

Anteo said the Japanese patent provided “further confidence in the quality of the science and security over the intellectual property in a commercially large jurisdiction”.

The company said there were many commercially important reasons to bind biological molecules onto synthetic materials as the molecules were often fragile and did not react well when exposed to non-biological conditions.

Anteo said Mix&Go had been demonstrated to allow them to retain their activity when bound and the ‘Use of Metal Complexes’ patent covers the use of Mix&Go for this binding process.

Anteo was up half a cent or 6.85 percent to 7.8 cents with 6.6 million share traded.

ALLIED HEALTHCARE GROUP

Allied says it has appointed from Avexa chief executive officer Dr Julian Chick as its chief operating officer, based in Melbourne, effective from early next year.
Allied said Dr Chick would help drive the commercialization of the product pipeline and develop further commercial opportunities.
The company said Dr Chick would retain his position as a director of 37.3 percent subsidiary Coridon, the DNA vaccine development company led by Prof Ian Frazer.
According to ASX data, Avexa owns 16.9 percent of Allied Health.
Allied said Dr Chick had 10 years experience in the biotechnology sector, most recently building the contract research and corporate advisory business at JDJ Bioservices and prior to that he was an executive at Avexa and Amrad.
The company said Dr Chick was a director of the industry body Bio-Melbourne Network.
Allied said that Dr Chick worked in the investment and banking sector at Prudential Bache, BNP Paris and Citibank and held a PhD in physiology.
Allied fell 0.2 cents or 4.8 percent to four cents with 1.1 million shares traded.

USCOM

Uscom says founder and executive chairman Rob Phillips will replace Joe Trygar as chief executive officer and Tom Rowe has been appointed company secretary
Uscom said the restructure was triggered by the rejection of two directors at last month's annual general meeting when former executive chairman Phil Kiely and director Jochen Bonitz were voted off the board (BD: Nov 22, 2011).
The company said that former chief executive officer and head of sales Joe Trygar had also resigned.
Uscom said Mr Rowe was a lawyer with qualifications in both applied finance and corporate governance and more than 10 years experience as in-house counsel and consultant to both ASX100 and small cap companies.
The company said Mr Rowe specialized in corporate transactions, capital raising, listed company secretarial practice and corporate governance.
Uscom said Carl Swindle had been appointed as the consultant in charge of development of Uscom Strategic Partnerships and would be based in California.
The company said Mr Swindle had more than 20 years experience in the medical device business and was previously employed by Edwards Life Sciences and Research Medical as business development director.
The company said the new board had reviewed operations and sales revenue from June 30 to November 22, 2011 was $290,000, the capitalized value of the company was $6.25 million and cash on hand was about $1 million.
Mr Phillips said the current financial situation reflects the prior management strategy and we are hopeful that the re-motivation of our global distribution partners, particularly in the US, "will result in a boost to revenue, while a renewed focus on cost will further consolidate the company's finances".
"Carl Swindle has been briefed to re-initiate conversations with potential international business partners and investigate opportunities to generate incremental growth," Mr Phillips said.
Uscom was untraded at 9.5 cents.

BIOGRID AUSTRALIA

Last night's edition incorrectly described Biogrid Australia as 'the Biological General Repository for Interaction Datasets' and quoted the www.thebiogrid.org website describing the entity as an online data interaction repository.

Biogrid Australia is a separate organization and its website www.biogrid.org.au says that it is "a secure research platform and infrastructure that provides access to real-time clinical, imaging and biospecimen data across jurisdictions, institutions and diseases".

The mistake was made by the sub-editor, desperate to provide readers with background information on Cart-Wheel's parent organization, who failed to triple-check the facts.

The sub-editor has left the building.