Biotech Daily

Monday December 15, 2014

Daily news on ASX-listed biotechnology companies

Vale WEHI's Prof Don Metcalf

*** ASX, BIOTECH DOWN: USCOM UP 18%, OPTISCAN DOWN 13%**

*** WEHI TRIALS TETRALOGIC'S BIRINAPANT FOR HEP B CURE**

*** LIVING CELL IMPLANTS FOURTH NTCELL FOR PARKINSON'S**

*** LONG TERM STUDY BACKS CLINUVEL SCENESSE FOR EPP**

*** PRIMA CLEARED FOR PIVOTAL CVAC PANCREATIC CANCER TRIAL**

*** CELLMID RAISES $1.3m, JAPAN MIDKINE ANTIBODY GRANTED**

*** KINETIC TAKES 7% OF OSPREY**

*** ACTINOGEN APPOINTS PFIZER'S DR BILL KETELBEY CEO**

*** BLUECHIIP APPOINTS MICHAEL OHANESSIAN DIRECTOR**

*** AVEXA HAILS COAL CONTRACT TO FUND PIVOTAL ATC FOR HIV TRIAL**

*** PROF DON METCALF (26.2.1929-15.12.2014)**

MARKET REPORT

The Australian stock market fell 0.6 percent on Monday December 15, 2014 with the S&P ASX 200 down 33.5 points to 5,186.1 points. Six of the Biotech Daily Top 40 stocks were up, 22 fell, six traded unchanged and six were untraded.

Today's Market Report is truncated due to a fault at Commsec Iress, which provides the data for the Report. No sub-editors have been hurt, yet.

Uscom was the best, up 3.5 cents or 18.4 percent to 22.5 cents with 10,000 shares traded. IDT was up 9.4 percent; Living Cell climbed 8.3 percent; Clinuvel was up 5.5 percent; Benitec was up 3.6 percent; with Phosphagenics up 1.6 percent.

Optiscan led the falls, down 0.7 cents or 13.2 percent to 4.6 cents with 619,789 shares traded. Neuren and Sirtex lost more than eight percent; Analytica, Anteo, Atcor and GI Dynamics fell seven percent or more; Patrys and Starpharma fell more than five percent; Biotron was down 4.55 percent; with Ellex, Impedimed, Nanosonics, Oncosil and Tissue Therapies down more than three percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers are recruiting up to 50 patients for a phase I/IIa trial of Tetralogic's birinapant to cure chronic hepatitis B.

WEHI said that Dr Marc Pellegrini, Dr Greg Ebert and colleagues developed the treatment in collaboration with the Malvern, Pennsylvania-based Tetralogic Pharmaceuticals and the trial would be held at sites across Australia and New Zealand.

The Institute said that a vaccine for hepatitis B virus had been available since 1982, but more than two billion people were infected with the virus, most recovering, but up to 10 percent developing a chronic infection, with children most at risk.

The Institute said that more than 780,000 people died every year from complications associated with chronic hepatitis B infection, including cirrhosis and liver cancer.

WEHI said that the Tetralogic's birinapant, triggered the breakdown of inhibitors of apoptosis proteins that prevented infected cells from self-destructing.

Dr Pellegrini said the proteins could be targeted to allow infected cells to die.

"Our preclinical models have shown that birinapant kills infected liver cells, while not harming uninfected cells," Dr Pellegrini said.

"Used in conjunction with an existing treatment for hepatitis B, this drug has the potential, for the first time, to functionally cure chronic hepatitis B infections," Dr Pellegrini said.

"Patients who develop chronic infections can be treated with drugs that prevent the virus from replicating, reducing the amount of virus in the liver, but do not completely eliminate the virus," Dr Pellegrini said.

"These patients are dependent on anti-viral drugs that need to be taken for a very long period of time to reduce the risk of virus-induced liver damage and the complications that come with it," Dr Pellegrini said.

"Our new therapy combines an existing anti-viral drug, which reduces the viral load, with birinapant that promotes efficient killing of hepatitis B infected cells and clearance of the virus from the system," Dr Pellegrini said.

"We are really excited that this treatment has entered phase I/IIa clinical trials as it is a culmination of many years work in developing new strategies to tackle chronic infections," Dr Pellegrini said.

WEHI said that the study was sponsored by Tetralogic in collaboration with Nucleus Network in Melbourne and hospitals across Australia and New Zealand.

LIVING CELL TECHNOLOGIES

Living Cell says that the final patient has been successfully implanted in its phase I/IIa trial of its NTCell encapsulated pig choroid plexus brain cells for Parkinson's disease.

Living Cell said the phase I/IIa clinical trial at Auckland City Hospital, led by Dr Barry Snow, was an open-label investigation of the safety and clinical effects of NTCell in patients who no longer responded to therapy.

The company Cell said it expected to present the results of the 26-week trial at the Congress of Parkinson's Disease and Movement Disorders in San Diego in June 2015.

Living Cell chief executive Dr Ken Taylor said that the success of the implant procedure meant that its clinical program was on track.

"The treatment phase of the trial has been completed on schedule," Dr Taylor said.

"We believe NTCell has the potential to be the first disease-modifying treatment for patients who are failing the current conventional treatment for Parkinson's disease," Dr Taylor said.

Living Cell was up half a cent or 8.3 percent to 6.5 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says a longitudinal study has concluded that Scenesse “exhibits a good clinical effectiveness and good safety in [erythropoietic protoporphyria]”.

Clinuvel said that study ‘Long-term observational study of afamelanotide in 115 patients with erythropoietic protoporphyria’ was published in the British Journal of Dermatology, with an abstract at: http://onlinelibrary.wiley.com/doi/10.1111/bjd.13598/abstract.

The company said that the study reported on the use of Scenesse, or afamelanotide 16mg, for erythropoietic protoporphyria at two porphyria centres, the San Gallicano Dermatological Institute in Rome and the Triemli Municipal Hospital in Zurich, where 115 patients had been treated for up to eight years.

The abstract said that since Scenesse was first made available in 2006, the number of patients treated rose until June 2014, when 66 percent of all erythropoietic protoporphyria (EPP) patients known to the centers were treated.

“Only three patients considered afamelanotide not to meet their expectations on symptom improvement [and] 23 percent quitted the treatment for other, mostly compelling reasons such as pregnancy or financial restrictions,” the abstract said.

The abstract said that the quality of life scores measured by an erythropoietic proto-porphyria-specific questionnaire increased after starting afamelanotide, with minor adverse events attributable to afamelanotide, predominantly nausea, recorded.

“Based on the durably improved [quality of life] scores, the high compliance and the low discontinuation rates, we conclude that afamelanotide exhibits a good clinical effectiveness and good safety in EPP under long-term routine conditions,” the abstract concluded.

In a media release, Clinuvel said that the European Medicines Agency had recommended Scenesse for marketing authorization for adult erythropoietic protoporphyria patients and it expected to make the drug available in a number of European countries in 2015, with an initial focus on the centres involved in the development program (BD: Oct 27, 2014).

The company said that the European Commission was expected to ratify the EMA’s decision by the end of 2014.

Clinuvel chief executive officer Dr Philippe Wolgen said that the Italian and Swiss programs had been “of great importance to the lives of EPP patients in these two countries but also for those patients who appear to have travelled from abroad to receive treatment, as shown by the data published”.

“The programs have also provided Clinuvel with commercial experience in advance of European marketing authorization,” Dr Wolgen said.

“We are in the process of scaling up across the region to serve a larger cohort of patients,” Dr Wolgen said.

Clinuvel said that the published data was collected from clinical trials, compassionate use programs and special access schemes and following trials of the drug in both countries, Italian regulatory authorities allowed prescription and granted reimbursement of Scenesse in 2010, with Swiss private health insurers enabling reimbursement in 2012.

The company said that Scenesse was reimbursed by four regions across Italy and 14 health insurers in Switzerland, with a further six private insurers across Europe covering the cost of supply to non-Swiss patients in Switzerland.

Clinuvel acting chief scientific officer Dr Dennis Wright said that the British Journal of Dermatology paper “adds to the growing evidence from clinical trials, special access schemes and conditions of use that Scenesse is safe, effective and clinically relevant for EPP patients over the long-term”.

Clinuvel was up 22 cents or 5.5 percent to $4.20.

PRIMA BIOMED

Prima says it has regulatory approval to begin a single-arm, pilot trial for CVac in pancreatic cancer patients in remission, in Bulgaria, Poland and Germany.

Prima said that up to 40-patient trial, known as CAN-301, was a phase II trial to evaluate the safety and tolerability of CVac in patients who were in remission with resected stage I or stage II adeno-carcinoma of the pancreas, with or without front-line chemotherapy or radiation therapy, and looking at the maintenance treatment of these patients.

The company said that trial, co-funded by the European Union and the Free State of Saxony, had a secondary objective of progression-free survival and overall survival.

Prima said that annual incidence of pancreatic cancer in the major markets of the US, Western Europe and Japan was about 99,000 a year, with about 20,000 a year suitable for surgical resection and about 80 to 95 percent of those who survived surgery potentially benefitting from CVac treatment.

The company said the trial would be the first time that CVac was applied to a larger homogenous group of patients in a cancer indication other than ovarian cancer.

Prima said that pancreatic cancer was “one of the most aggressive forms of cancer” and for patients who present early, surgery was the most promising treatment, but the five-year survival rates were about 10 to 20 percent, with a median survival of 18 to 24 months following surgery.

Prima was unchanged at 3.5 cents.

CELLMID

Cellmid says it has raised $1.3 million in a placement at 2.3 cents a share and has been granted a Japanese patent entitled ‘Antibody recognising C-domain of midkine’.

Cellmid said the funds would progress its CAB102 program towards phase I clinical trials and to invest in commercial activities associated with its consumer health business.

The company said that Hawkesbury Partners acted as lead manager for the placement.

Separately, Cellmid said that the Japanese Patent Office granted the patent claims covering antibodies and antibody fragments, including its lead clinical candidate CAB102, which bound to a critical functional site in the C-domain of growth factor midkine.

The company said that the granted claims also covered the use of any such antibody for prevention and treatment of cancer, autoimmune disease, inflammatory disease, and any disease attributed to cell migration, with antibodies to the C-domain of midkine in general also covered.

Cellmid said that published studies showed the midkine C-domain conveyed most of the disease promoting activities attributed to midkine, so blocking the C-domain was a potential treatment option in any midkine-related disease.

Cellmid chief executive officer Maria Halasz said that granted patent was “yet another important piece of Cellmid’s comprehensive [intellectual property] protection”.

“Cellmid’s patent coverage for CAB102 and other therapeutic antibodies now extends across cancer, inflammatory and autoimmune diseases, multiple sclerosis and surgical adhesion,” Ms Halasz said.

Cellmid said the patent extended its global protection for CAB102 and similar antibodies-equivalent patents had been granted in Europe and Australia.

The company said its patent portfolio included 87 patents in 20 patent families, which covered use of midkine and anti-midkine agents for therapeutic purposes in a number of diseases, as well as the use of midkine as a diagnostic marker in cancer and other disorders.

Cellmid was unchanged at 2.8 cents with 7.4 million shares traded.

OSPREY MEDICAL

The Melbourne-based Kinetic Investment Partners says it has increased its substantial holding in Osprey from 7,143,309 shares (5.93%) to 8,670,725 shares (7.04%).
Kinetic said it bought and sold shares in a large number of trades between October 30, 2013 and December 11, 2014, with the single largest most recent acquisition 360,109 shares for $198,060 or 55 cents a share on December 9, 2014.
Kinetic is part of Challenger Financial Services, its principals are Jonathan Findlay, Richard Sharp and Anthony Porto.
Osprey was untraded at 50 cents.

ACTINOGEN MEDICAL

Actinogen says it has appointed former Pfizer senior executive Dr Bill Ketelbey as its chief executive officer, effective from January 5, 2015.
Actinogen said that Dr Ketelbey was an experienced healthcare and pharmaceutical sector professional, with 30 years experience, including senior medical and management roles with Pfizer.
The company said that Dr Ketelbey was a qualified medical doctor from the University of the Witwatersrand, South Africa, a Masters of Business Administration graduate from Macquarie University and had specialist expertise in pharmaceutical medicine including neurological drugs.
Actinogen said that most recently Dr Ketelbey was Pfizer's primary care regional vice-president and Pfizer Australia and New Zealand medical director.
The company said that Dr Ketelbey was responsible for leading the development of medicines in a range of therapeutic areas including Alzheimer's disease and was in charge of the Australia and New Zealand development, launch and commercialization of Aricept or donepezil, an acetyl-cholinesterase inhibitor, for Alzheimer's disease.
Actinogen said that Dr Ketelbey was involved in developing monoclonal antibodies directed at amyloid plaques, a hallmark of Alzheimer's disease.
The company said that Dr Ketelbey would be responsible for overseeing the development and commercialization of Xanamem (formerly UE2343) for Alzheimer's disease and mild cognitive impairment, with a phase II study planned for late 2015.
Actinogen chairman Martin Rogers said the appointment was "a real coup for shareholders".
The company said that Dr Ketelbey's remuneration package was majority performance based, with any performance consideration dependent on share price appreciation and regulatory approvals.
Actinogen was unchanged at four cents.

BLUECHIIP

Bluechiip says it has appointed Michael Ohanessian as a non-executive director effective from today.
Bluechiip said that Mr Ohanessian was currently the managing director and chief executive officer of investment administration technology provider Praemium.
The company said that Mr Ohanessian was with Mobil Oil for 10 years before joining Boston Consulting Group and was Vision Biosystems chief executive officer for seven years, before joing Genetic Technologies as chief executive officer and had been involved in investment management and corporate advice with Lion Capital.
Bluechiip fell 1.5 cents or 15 percent to 8.5 cents.

AVEXA

Avexa says its US coal investment has its first sales contract which will lead to funds for its phase III apricitabine or ATC trial for HIV (BD: Nov 5, 2012; Jun 25, 2014).

Avexa said that Coal Holdings USA had its first sales contract for coal from the North Pratt coal mine for 100,000 tons for 2015 at a fixed price, expected to about 15 percent of the expected annual production.

Avexa said it had a 30 percent stake in Coal Holdings and made the investment to fund its drug assets and in particular, revenues from the mine would be for the development of apricitabine.

Avexa chairman Iain Kirkwood said the contract was “a significant milestone for Avexa and ATC”.

“The expected revenues from this investment will soon be available to finance the initiation of the long-awaited final phase III trial,” Mr Kirkwood said.

Avexa was unchanged at 1.4 cents.

PROF DON METCALF

The Walter and Eliza Hall Institute says that “with great sadness ... we announce the death of Prof Donald Metcalf, an outstanding medical researcher whose discovery of colony stimulating factors has benefited more than 20 million people worldwide”.

WEHI said that Prof Metcalf joined the institute in 1954 as a medical graduate, supported by the Cancer Council Victoria’s Carden Fellowship, an award he held until his retirement in September 2014.

The Institute said that Prof Metcalf’s studies of how blood production was controlled led to his speculation that there must be a biological mechanism, one or more hormones, that controlled white blood cell production.

WEHI said he termed them colony stimulating factors (CSFs) and they were the focus of more than 50 years of research.

The Institute said that Prof Metcalf led researchers to characterize and purify four separate CSFs and he recognized that CSFs had a potential role in clinical medicine, and his team was among the first in the world to discover the genes for CSFs.

WEHI said that Prof Metcalf was a central figure in the clinical trials of CSFs in the 1980s, assessing whether CSFs could boost immune cell numbers in cancer patients whose immune system was weakened as a side effect of the chemotherapy, leaving the patient susceptible to infection, with G-CSF, or Neupogen, approved for use in 1991.

The Institute said that a estimated 20 million people had been treated with CSFs.

WEHI said that Prof Metcalf was a mentor to hundreds of young researchers who worked with him, and an inspiration to thousands of scientists around the world.

The Institute said that among his many honors and awards were the Companion of the Order of Australia (1993), the Albert Lasker Award for Clinical Medical Research (1993), the Gairdner Foundation International Award (1994), the Royal Medal of the Royal Society (1995), the Victoria Prize (2000) and the Prime Minister’s Prize for Science (2001).

The Walter and Eliza Hall Institute community offers its sincere condolences to Prof Metcalf’s wife Jo, daughters Kate, Johanna, Penelope and Mary-Ann, grandchildren James, Martin, Patrick, Elizabeth, Rose and Robert and their extended families.