Biotech Daily

Wednesday September 15, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: VIRALYTICS UP 10%, ANTISENSE DOWN 12.5%**

*** VIRALYTICS: 'CAVATAK EFFICACY IN BRAIN TUMORS IN MICE'**

*** AVITA AWARDED $US1.8 MILLION SCAR, DYSPIGMENTATION CONTRACT**

*** CELLMID TAKES $8.5m LA JOLLA COVE NOTE**

*** AUSTIN HEALTH, LUDWIG GAIN $1.5m NUCLEAR MEDICINE LAB**

*** AGENIX HEPATITIS B DRUG CLEARS FIRST CLINICAL SAFETY HURDLE**

*** EASTLAND PRESENTS RWANDA MALARIA DATA**

*** BIODIEM APPOINTS CATHY CROPP PROJECTS MANAGER**

*** CBIO DIRECTOR DR DENNIS FEENEY GOES NON-EXECUTIVE**

MARKET REPORT

The Australian stock market climbed 0.76 percent on Wednesday September 15, 2010, with the ASX200 up 35 points to 4661.5 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and six were untraded.

Viralytics was best, up 0.3 cents or 9.7 percent to 3.4 cents with 8.2 million shares traded, followed by Cellmid up five percent to 2.1 cents with 7.4 million shares traded.

Optiscan, QRX and Tissue Therapies climbed more than two percent; with Bionomics, Chemgenex, Heartware, Pharmaxis, Phosphagenics and Sirtex up more than one percent.

Antisense led the falls, down 0.2 cents or 12.5 percent to 1.4 cents with 4.3 million shares traded.

Prana lost 7.1 percent; Prima fell 3.1 percent; Biota and Starpharma shed more than two percent; with Immuron, Impedimed and Patrys down more than one percent.

VIRALYTICS

Viralytics says pre-clinical data shows that injection of Cavatak cleared six of eight cases of human malignant glioblastomas in mice.

Viraltyics said the data from the study at the University of Newcastle in New South Wales and the University of Toronto would be presented at the European Study Group on the Molecular Biology of Picornaviruses underway in St Andrews, Scotland.

The presentation entitled 'Coxsackievirus A21 as an oncolytic agent against malignant glioma' shows the response of human malignant glioblastomas grown in the cranial cavity of mice directly injected with Cavatak.

The presentation said that 12 days after a single Cavatak intra-cranial injection, four of four mice had total tumor clearance; in the multiple Cavatak injection group, two of four mice had total tumor clearance; whereas all four saline treated U87-lenti mice showed high levels of bioluminescent intensity.

"Overall, these initial studies demonstrate an important proof-of-concept that indicates the company should progress research into this cancer indication," the presentation said.

Viralytics chief scientist and director Dr Darren Shafren co-authored the presentation.

The presentation said that malignant gliomas were the most common tumors of the central nervous system and respond poorly to surgery, radiotherapy and chemotherapy.

The disease is fatal within two years of onset of symptoms, despite conventional therapy.

Coxsackievirus A21 (CVA21) is a naturally occurring common-cold virus that has shown potent anti-cancer activity against malignant melanoma, multiple myeloma, as well as prostate and breast cancer, the presentation said.

The selective targeting of CVA21 was based on the over-expression of the viral-cell entry receptors, intercellular adhesion molecule-1 (ICAM-1) and/or decay accelerating factor (DAF) by many cancer cells compared to normal cells.

The poster said that in vitro analysis of Cavatak infection in glioma cells showed that Cavatak was able to infect the glioma cell lines and corresponded with the expression of the viral cell-entry receptor ICAM-1 on the cell surface.

The in vivo study showed that a single intracranial injection of Cavatak into athymic nude mice bearing malignant glioma tumors was effective at early time points.

However regrowth was observed in some virus-treated mice.

Three of four animals treated with a single intra-cranial injection of Cavatak followed by multiple intra-peritoneal injections of Cavatak were tumor-free upon bioluminescent imaging.

Viralytics said in its media release that over the next 12 months it intended to conduct larger pre-clinical studies as well as conduct a specialized toxicology study using a novel transgenic or humanized mouse model licenced from a European research institute.

The company said it would consult closely with Australian neurosurgeons to ensure the data emerging from the preclinical and toxicology programs supports the commencement of human trials in the minimum time possible.

Viralytics said there was forecast to be 48,000 cases of primary brain cancer in the developed world in 2011, with treatment costing more than $20,000.

The company said glioma was a cancer arising from the glial cells and was the most common type of primary brain cancer, with mortality compared to incidence "very high".

Viralytics said the median survival time for glioblastoma patients receiving standard treatment is 15 months and brain cancer was typically managed using a multidisciplinary approach that incorporates radical surgery followed by a regime of radiotherapy and chemotherapy.

Viralytics was up 0.3 cents or 9.7 percent to 3.4 cents with 8.2 million shares traded.

AVITA MEDICAL

Avita says it has been awarded a $US1.8 million ($A1.92 million) US Government contract for the treatment of scars and dyspigmentation.

Avita said the contract was through the Department of Interior's national business center in support of the Department of Defense and was part of the Office of Technology Transition and Joint Improvised Explosive Device Defeat Organization's 'Limb Salvage and Regenerative Medicine Initiative'.

Avita said the grant followed a competitive approval process and was in addition to the $US1.9 million awarded by the US Armed Forces Institute of Regenerative Medicine to support a US study for treatment of burns currently under way (BD: May 27, 2009).

The company said the goal of the Limb Salvage and Regenerative Medicine Initiative program was to advance technologies that return wounded personnel to active duty, restore their limb, muscular and skin form or function and included the conduct of successful US Food and Drug Administration clinical trials for those validated technologies.

Avita said the contract recognized the contribution its Recell spray-on skin product could make in the treatment of scarred, damaged or discolored skin.

The company said the contract would fund an FDA clinical trial for treating scars and dyspigmentation with Recell and an investigational device exemption would be prepared in conjunction with the US Department of Defense sponsors and key investigators.

Avita quoted an unnamed spokesperson for the Office of Technology Transition saying that the "Initiative selected Recell as it thinks it will be a quantum advance over the existing ability to treat and re-grow tissue and to substantially reduce the effects and appearance of scarring and thereby profoundly assist in the treatment and rehabilitation of wounded warriors suffering from disfigurement and impeded function due to combat injuries".

Avita said that according to the American Society for Aesthetic Plastic Surgery in the US about 580,000 people a year seek surgical treatment for remodeling existing scars and 600,000 obtain surgical treatment from cosmetic surgeons for skin discoloration, acne scarring and other skin defects and a substantial percentage of these patients could benefit from treatment with Recell.

Avita chief executive officer Dr William Dolphin said the contract, was "another substantial endorsement of Recell".

Avita was up one cent or 9.5 percent to 11.5 cents with one million shares traded

CELLMID

Cellmid says it has signed an $US8 million ($A8.5 million) non-binding convertible note with the San Francisco-based La Jolla Cove Investors.

Cellmid said the convertible note comprised eight notes of $US1,000,000.

The company said the funds would be used to accelerate its product development including the therapeutic programs for autoimmune diseases, cancer, heart attack and alopecia as well as for advancing the midkine diagnostic portfolio.

Cellmid said the interest rate was 4.75 percent a year payable monthly in cash or fully paid ordinary shares.

The company said the conversion price would be the lesser of nine cents for the first 12 months and 15 cents after 12 months or a 20 percent discount of the three lowest volume weighted average price prices during the 21 trading days prior to the conversion date.

La Jolla Cove was limited to holding no more than 9.99 percent of Cellmid's shares.

Cellmid was up 0.1 cents or five percent to 2.1 cents with 7.4 million shares traded.

AUSTIN HEALTH, LUDWIN INSTITUTE FOR CANCER RESEARCH

The Victoria Government says the Australian Nuclear Science and Technology Organisation will invest $1.5 million to assist Austin Health detect and treat cancer.

A media release from the Victorian Government said the Australian Nuclear Science and Technology Organisation (ANSTO) funds would go to the construction of a state-of-the-art laboratory at Austin Hospital.

Health Minister Daniel Andrews said the Victorian Government provided $4.3 million for a new cyclotron at Austin Health's Centre for Positron Emission Technology in July, 2009.

"The combination of our ongoing investment in high-cost capital medical equipment and the strong research partnership between Austin Health and the Ludwig Institute for Cancer Research has attracted this nationally-significant investment from ANSTO," Mr Andrews said. "The ANSTO investment will support Austin Health and the Ludwig Institute for Cancer Research to continue conducting cutting-edge clinical cancer research and boost Victoria's reputation as a national centre of medical research excellence."

The media release said Austin Health's Centre for Positron Emission Technology (PET) was the largest academic PET centre in Australia and had "an international reputation as a leader in research into cancer and neurological disorders".

The Government said cyclotron technology produced radioactive isotopes, which were injected into patients before they have positron emission technology scans to locate cancers and diagnose other medical conditions.

ANSTO chief executive officer Dr Adi Paterson said the arrangement with Austin Health and the Ludwig Institute would "give medical researchers access to the use of long-lived isotopes that we cannot make with a nuclear reactor".

"Of even greater significance is that the three major clinical and research organizations involved in this project each bring synergy of different areas of technical and research expertise that has great potential for discovery," Dr Paterson.

AGENIX

Agenix says its newly-acquired hepatitis B compound AGX-1009 does not inhibit Cytochrome P450 and can progress towards clinical trials.

Agenix said many anti-viral compounds failed to reach clinical trials because they interfered with Cytochrome P450, a group of enzymes involved in drug metabolism by the liver and the company had independent confirmation that AGX-1009 did not inhibit Cytochrome P450 at concentrations well above its likely effective antiviral dose.

Agenix executive chairman Nick Weston said the result "significantly reduces a major risk for the pre-clinical development of AGX-1009 and puts us on track for clinical trials of this next generation treatment for hepatitis B patients".

Agenix said it acquired AGX-1009 from China's Institute of Medicinal Biotechnology last week (BD: Sep 8, 2010).

The company said AGX-1009 was a nucleotide analogue reverse transcriptase inhibitor and its closest competitor was expected to be the Glaxosmithkline Gilead Tenofovir DF which gained US Food and Drug Administration approval for hepatitis B in 2008.

Agenix said the body converted AGX-1009 into an active compound that interfered with the function of hepatitis B DNA polymerase, which was essential for the replication of the hepatitis B virus.

The company said AGX-1009 was a next generation pro-drug that preliminary testing indicated would be an effective, once daily treatment for chronic hepatitis B patients, including those in which the virus has developed resistance to current drugs.

Agenix was up 0.4 cents or 13.8 percent to 3.3 cents.

EASTLAND MEDICAL SYSTEMS

Eastland has presented the detailed data from its 30-patient Rwandan trial of sub-lingual Artimist for paediatric malaria.

Two presentations entitled 'Pharmacokinetics of Artemether Sublingual Spray' and 'Sublingual Artemether in Severe Childhood Malaria' were delivered at the Interscience Conference on Antimicrobial Agents and Chemotherapy conference in Boston, September 12 to 15, 2010.

The company previously released its headline data from the 30 patient study showing Artimist equaled the safety and efficacy of intravenous quinine (BD: Apr 28; Jul 28, 2010).

Eastland said the presentations "received an exceptional amount of interest from the pharmaceutical, academic and investment communities".

The company said the presentations showed the speed of Artimist absorption from the sub-lingual or under-the-tongue spray route and emphasized the clinical response rate of patients administered Artimist, when compared to the World Health Organisation recommended standard of care, intravenous quinine.

The study principal investigator Dr Stephen Rulisa said that Artimist was "highly acceptable to patients, carers and staff, especially due to the ease of administration".

"It is capable of delivering a highly effective anti-malarial treatment that does not require additional expertise such as setting up [intra-venous] lines and preparing medications, resulting in the most rapid possible administration," Dr Rulisa said.

Eastland said it would progress the initial opportunities identified by the Sydney-based AFG Venture Group.

The company said the Artimist clinical dossier would be further strengthened through data obtained from the planned multi-country confirmatory trial which has received ethics approval and was due to start on schedule.

Eastland was up 0.6 cents or 13 percent to 5.2 cents with 3.9 million shares traded.

BIODIEM

Biodiem has appointed Cathy Cropp as projects manager, primarily responsible for the live attenuated influenza vaccine vector and BDM-I anti-microbial projects.

Biodiem said Ms Cropp was a microbiologist with more than 20 years experience in international quality compliance, manufacturing and drug, biologicals and vaccine development.

The company said Ms Cropp had considerable knowledge in regulatory affairs and clinical development strategies and the development and implementation of manufacturing processes for investigational new therapeutic agents appropriate for clinical use.

Biodiem said Ms Cropp had been responsible for taking technologies through the discovery phase into clinical trials.

As projects manager at the Institute of Drug Technology Ms Cropp oversaw the National Institute of Health contract for an HIV project consortium of six research institutes and two public companies.

Biodiem said that as project manager for Virax, Ms Cropp was responsible for the establishment of the manufacturing facilities and processes in addition to developing strategies for regulatory and quality compliance to take products to clinical trials.

Biodiem was untraded at 15 cents.

CBIO

CBio says its head of global development and licencing Dr Dennis Feeney has resigned from that position with effect from September 30, 2010.

The company said Dr Feeney would remain on the board as a non-executive director and would provide consulting services on an ad-hoc basis.

CBio was up one cent or 5.3 percent to 20 cents.