Biotech Daily

Monday February 11, 2013

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PHOSPHAGENICS UP 10%, PATRYS DOWN 10%**

*** BIONOMICS NAMES LGR5 AS BNC101 CANCER STEM CELL TARGET**

*** CELLMID MIDKINE DIAGNOSTIC LICENCE OPTION TO JAPAN'S FUJIKURA**

*** HEARTWARE WARNS USERS TO CHECK DRIVELINE CONNECTOR**

*** NEXGENIA USES CSIRO'S RAFT FOR POLYMER-BASED DIAGNOSTICS**

*** PHOSPHAGENICS OXYCODONE PATCH RETURNS TO CLINICAL TRIALS**

*** US INSURER TO REIMBURSE RESONANCE'S FERRISCAN**

*** AVEXA SELLS ALL ALLIED HEALTH SHARES**

*** STEVE HARRIS REPLACES IMUGENE CHAIRMAN FABIO PANNUTI**

MARKET REPORT

The Australian stock market fell 0.24 percent on Monday February 11, 2013 with the S&P ASX 200 down 11.8 points to 4,959.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and five were untraded.

Phosphagenics was the best, up 1.5 cents or 10.3 percent to 16 cents with 1.7 million shares traded.

Allied Health climbed eight percent; Neuren was up 7.5 percent; Genetic Technologies was up 6.1 percent; Cellmid rose five percent; Bionomics was up 4.8 percent; Avita, Medical Developments and Viralytics were up more than three percent; GI Dynamics, Reva and Universal Biosensors rose more than two percent; with Anteo, Circadian, Cochlear and QRX up one percent or more.

Patrys led the falls for the second trading day in a row, down 0.3 cents or 9.7 percent to 2.8 cents with 15,000,000 shares traded, followed by Genera down 9.1 percent to 10 cents with 63,000 shares traded.

Optiscan lost 8.7 percent; Antisense fell 7.1 percent; Benitec fell 6.7 percent; Sunshine Heart was down 5.6 percent; Heartware fell 4.35 percent; Pharmaxis and Tissue Therapies lost more than three percent; Sirtex shed 2.25 percent; Alchemia was down 1.5 percent; with CSL, Mesoblast, Resmed and Starpharma down by less than one percent.

BIONOMICS

Bionomics has named the leucine-rich repeat-containing G-protein coupled receptor 5 (LGR5) as the target for its recently acquired cancer stem cell drug BNC101 (ET101).

At the time of the acquisition of Biogen Idec's San Diego spinout, Eclipse, Bionomics said that significant resources had been invested Eclipse's cancer stem cell (CSC) drug program and the Eclipse CSC Rx Discovery platform had been used to identify antibody therapeutics that inhibited the growth of cancer stem cells (BD: Sep 17, 2012).

The company said at that time that scientific and clinical research supported the concept that cancer stem cells were responsible for tumor initiation and recurrence and tended to be resistant to chemotherapy and other conventional forms of cancer treatment.

Today, Bionomics said that Eclipse founder and now Bionomics vice-president of US operations and cancer biology Dr Peter Chu would provide an update on the BNC101 LGR5 cancer program at the Molecular Medicine Tri-Conference in San Francisco, California, February 11-15, 2013.

The company said that following the completion of investigational new drug application enabling studies, BNC101 was expected to enter clinical trials in 2014.

Bionomics said that Dr Chu's presentation would give an overview of the CSC Rx Discovery platform used to discover BNC101 and other promising anti-cancer stem cell therapeutic candidates in the company's oncology pipeline and describe LGR5.

The company said that LGR5 was "a high value cancer stem cell target" and that experiments performed in Prof Hans Clevers' laboratory at the Hubrecht Institute in the Netherlands, provided direct, functional evidence that LGR5 marked cancer stem cells in mouse intestinal adenomas.

Bionomics said that LGR5 was highly over-expressed in colorectal cancer, as well as esophageal, stomach, liver and pancreatic cancer.

The company said that the high expression of LGR5 correlated with significantly increased likelihood of relapse in colorectal cancer and data frommits researchers as well as independent academic investigators indicated that LGR5 was a functional cancer stem cell target in colorectal cancer and other tumors including metastatic triple-negative breast cancer.

Bionomics said that BNC101 was a humanized monoclonal antibody, with demonstrated functional activity against cancer stem cells from primary colorectal cancer patient samples and in-vivo significantly reduced cancer stem cell frequency in serial re-implantation studies and significantly prevented re-growth in six-month studies, increasing survival and inhibiting weight loss in a cachexic (or wasting) colorectal cancer tumor model.

The company said that BNC101 was "highly active" in-vivo against cancer stem cells from colorectal cancer patient tumors with multiple underlying gene mutations and did not show any evidence of toxicity in a preliminary safety analysis.

Bionomics said the BNC101 clinical strategy is to target colorectal cancer and other solid tumors expressing LGR5 where there was a high rate of relapse within 12 months of standard of care therapy.

The company said that Dr Chu would chair the February 12, 2103 morning session entitled 'Translational Considerations' and 'Updates from the Clinic', that included cancer stem cell experts from companies including Verastem, Oncomed, Dainippon Sumitomo, Immunocellular Therapeutics and Pfizer.

Bionomics said that scientist Dr Kristen Smith would give a seminar on February 12, on 'Identification and Characterization of Cancer Stem Cells'.

Bionomics was up two cents or 4.8 percent to 43.5 cents.

CELLMID

Cellmid says it has an option agreement to supply anti-midkine diagnostic antibodies to Fujikura Kasei Co which develops and distributes latex particles for medical diagnostics.
Cellmid said it would receive an initial fee and a further payment should Fujikura elect to exercise its licence option, as well as royalties on any future midkine diagnostic products sold by Japan's Fujikura.
The company said the licence agreement was conditional on Fujikura being able to reach a limit of detection (LOD) of 500 picogram/mL midkine in serum on its proprietary latex diagnostic platform.
Cellmid said that its MK-ELISA detected midkine to a limit of 8.0 picogram/mL and Fujikura was planning to achieve a LOD close to that level on its latex platform using the same antibody pair.
Cellmid said that healthy individuals usually had serum midkine levels below 500 picogram/mL.
The company said that a latex-based test with a 500 picogram/mL LOD meant that the test would be able to identify individuals with elevated midkine levels, which could lead to the development of a number of cancer diagnostic products.
Cellmid said that Fujikura had regulatory and product development programs to accelerate the path to market and a latex-based assay would be "highly beneficial for the commercial launch of any midkine diagnostic product, as it is widely used and accepted in pathology laboratories" and was preferred as it could be automated, reducing processing costs.
Fujikura's head of medical project division Dr Hideyuki Kuroda said his company was "very excited about this opportunity as the midkine diagnostic platform lends itself to multiple, high value product development opportunities".
Cellmid chief executive officer Maria Halasz said she was confident Fujikura's expertise in latex-based diagnostics would ensure success for a midkine test.
"Fujikura is the ideal partner for us as they have a strong focus on building their medical diagnostic business and consider midkine an important part of this commercial expansion," Ms Halasz said.
Cellmid was up 0.1 cents or five percent to 2.1 cents with 17.7 million shares traded.

HEARTWARE INTERNATIONAL

Heartware says it has begun "a voluntary field correction" telling healthcare professionals to inspect the driveline connector housing of the pump in routine clinic visits.
Heartware said that "a small number of events", 11 of about 2900 implants, had been confirmed where the rear portion of the Heartware ventricular assist device (HVAD) pump driveline connector housing became partially or fully separated from the front portion of the driveline connector after extended use.
The company said that "in the unlikely event of a separation, a repair may be necessary" and if left unattended, electrical connection to the controller could be affected and an alarm could result.
Heartware said that none of the confirmed events had resulted in harm to the patient and that in the event of a separation, hand tightening of the connector housing could be sufficient as a temporary measure; but, healthcare professionals were instructed to contact Heartware to arrange for an inspection and permanent repair.
The company said that no product replacement or exchange was required.
Heartware said that the field correction was not expected to have a significant impact on its financial position.
Heartware fell 11 cents or 4.35 percent to $2.42.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says Nexgenia will use its reversible addition fragmentation chain transfer (RAFT) technology to build macromolecules for immunoassays.

The CSIRO said the Seattle, Washington Nexgenia needed uniform macromolecules to ensure consistency and reproducibility of their immunoassays and the RAFT technology made “highly uniform macromolecules enabling particular functionality to be built into the macromolecules and … performance for a particular application”.

The CSIRO said that the RAFT polymer technology could work in thousands of application areas making designer macromolecules.

Nexgenia said it was developing novel polymeric in-vitro reagents that were “game-changers, creating higher speed and sensitivity attributes for new diagnostics across a wide array of applications including immunoassays for clinical diagnosis”.

Nexgenia said it had a grant from Washington State’s Life Sciences Discovery Fund for a project with CSIRO to commercialize the manufacturing process for the polymer reagents.

CSIRO’s chief of materials science and engineering Dr Cathy Foley said it was “very pleasing to see our RAFT technology providing competitive advantage for start-up companies like Nexgenia”.

“This technology is ideally suited for applications requiring novel, high functioning polymers,” Dr Foley said.

PHOSPHAGENICS

Phosphagenics says it is preparing to re-enter the clinic with its lead transdermal tocopheryl phosphate mixture or TPM technology oxycodone patch by April 2013.

Phosphagenics said the patch had been refined with Tesa Labtec GmbH and would conduct a small phase I pharmacokinetic trial.

In 2011 Phosphagenics was completing the optimization of its tocopheryl phosphate mixture (or TPM) oxycodone patch with 3M for pivotal phase II/III trials, but the work led to crystallization issues and Phosphagenics engaged Labtec for assistance with the patch (BD: May 23, 2011; May 23, 2102).

Today, Phosphagenics said that extensive testing indicated that all crystallization issues had been resolved.

Phosphagenics chief executive officer Dr Esra Ogru said the TPM oxymorphone patch would also be in a clinical trial by April and the two opioid candidates were “the implementation of the company’s strategy to leverage the powerful TPM platform delivery technology to develop a range of innovative transdermal products that are capable of managing all levels of chronic pain.”

Phosphagenics was up 1.5 cents or 10.3 percent to 16 cents with 1.7 million shares traded.

ALLIED HEALTHCARE GROUP, AVEXA

Avexa through its subsidiary AVI Capital has sold its 81,689,680 shares in Allied Healthcare Group for $2,042,242 or 2.5 cents a share.

In 2010, Avexa spent $1.5 million of its then $22.5 million cash on a 24 percent stake in the then unlisted Allied Medical (BD: Sep 2, Nov 11, 2010).

Shortly after the Allied merger with Biomd, Avexa held 96,000,000 Allied Health shares or 16.9 percent of the company (BD: Jun 29, Jul 14, 2011).

Allied Health was up 0.2 cents or 8.0 percent to 2.7 cents with 4.3 million shares traded.

Avexa was unchanged at 1.7 cents.

RESONANCE HEALTH

Resonance says that Medical Mutual of Ohio has notified its members that Ferriscan was medically necessary and eligible for reimbursement.
Resonance said that reimbursement would be for patients falling within defined criteria for treatment across a broad range of indications and prior authorization was not required before Ferriscan can be performed.
Resonance said the decision was “a very positive outcome for Ferriscan and patients with iron overload in the US”.
The company said the Medical Mutual decision followed positive insurance coverage from the Massachusetts-based Blue Cross Blue Shield and Kaiser Permanente, with prior authorization.
Resonance said it was actively expanding the availability of Ferriscan in the US to further assist in gaining approvals for reimbursement by medical insurers and make the diagnostic more accessible to patients.
Resonance was untraded at 1.7 cents.

IMUGENE

Imugene says executive chairman Fabio Pannuti has resigned from the board, effective immediately, to be replaced by director Steve Harris as non-executive chairman.
Imugene said that Dr Nicholas Ede had been appointed as executive director and Paul Hopper continued as a non-executive director.
Imugene had been developing a pig and poultry vaccine which was being developed with Novartis until a surprise end of contract (BD: Sep 2, 2011).
Last year, Imugene changed direction acquiring the Linguet technology for 100 million shares from Consegna group whose then managing director was Mr Pannuti (BD: May 2, 2012).
In October, Viralytics executive chairman Paul Hopper replaced long serving Imugene chief executive officer Dr Warwick lamb as a director (BD: Oct 31, 2012).
Earlier this month, Mr Pannuti resigned as Consegna’s executive chairman and recently-appointed director Martin Rogers was appointed non-executive chairman with Michael Johnson appointed executive director (BD: Feb 1, 2013).
Imugene said that Dr Ede had “a record of successfully evolving research concepts to commercial products and processes” and had more than 25 years experience in drug discovery and international business development at Chiron, Eqitx, Mimotopes and Adistem.
Imugene said that Dr Ede held a Graduate Certificate in Innovation from Melbourne Business School and a PhD from Monash University and had published more than 50 scientific papers and patents.
Imugene fell 0.2 cents or 16.7 percent to one cent.