Biotech Daily

Thursday June 19, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: UNIVERSAL BIO UP 8%,**
- BIOTRON, CIRCADIAN DOWN 8%

*** PATIENT DATA BACKS PHARMAXIS BRONCHITAL CF TRIALS**

*** ALCHEMIA STARTS PHASE I COLORECTAL CANCER TRIAL**

*** SIMAVITA REQUESTS $10m CAPITAL RAISING TRADING HALT**

*** RODON TO MANUFACTURE CELLMID'S CAB102 FOR CANCERS**

*** NUSEP COMPLETES $6m 1st TRANCHE IN PRIME**

*** HUNTER HALL TAKES 5% OF GI DYNAMICS**

*** ISONEA APPOINTS DAVID ASHMORE DIRECTOR**

MARKET REPORT

The Australian stock market climbed 1.59 percent on Thursday June 19, 2014 with the S&P ASX 200 up 85.5 points to 5,468.2 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, and 13 traded unchanged. All three Big Caps were up.

Universal Biosensors was the best, up 1.5 cents or 8.3 percent to 19.5 cents with 9.7 million shares traded.

Antisense climbed 7.4 percent; Living Cell rose six percent; GI Dynamics and Tissue Therapies were up more than five percent; Oncosil, Psivida and Uscom were up more than four percent; Admedus and Mesoblast climbed more than three percent; Genetic Technologies, Impedimed and Prana rose more than two percent; Cochlear, Nanosonics and Resmed were up more than one percent; with Acrux, Benitec, Clinuvel and CSL up by less than one percent.

Biotron and Circadian led the falls, both down 8.3 percent to 11 cents and 22 cents, respectively, with 654,054 shares traded and 98,306 shares traded, respectively.

Osprey lost five percent; Analytica and Neuren fell more than four percent; Bionomics, Prima and Starpharma shed more than two percent; with Phosphagenics and Sirtex down more than one percent.

PHARMAXIS

Pharmaxis says that evidence provided from European clinics using Bronchitol for cystic fibrosis patients supports the evidence in previous clinical trials for regulatory approval.

Pharmaxis chief executive officer Gary Phillips said that presentations of data from 124 UK patients at the European Cystic Fibrosis Conference in Gothenburg, Sweden "reinforce the fact that clinics are adopting Bronchitol as an increasingly important part of their standard of care in cystic fibrosis and are able to repeat the benefits shown in the clinical studies".

Mr Phillips said the conference was "a valuable opportunity for [cystic fibrosis] centres to exchange information on their experiences with Bronchitol".

Pharmaxis said that the conference was attended by more than 2,000 European healthcare professionals and included abstract presentations from a number of European centres highlighting results for Bronchitol (400mg mannitol powder) in the treatment of adult patients which were consistent with results from the large phase III clinical trials.

The company said that of the 124 patients at three UK centres, there was a greater than 90 percent pass rate when performing the Bronchitol initiation dose assessment.

Mr Phillips told Biotech Daily that the Bronchitol initiation dose test was the first dose of Bronchitol given to all prospective patients "to make sure that they are not hypersensitive to the drug before they get given a full prescription to take home with them".

"Patients who do not experience a drop in lung function beyond defined limits are deemed to have passed and are then eligible for a Bronchitol prescription," Mr Phillips said.

"The rates of passing this test are similar to that seen in the trials, which is reassuring," Mr Phillips said.

Pharmaxis said that the authors from two London centres reported that those patients who continued on Bronchitol showed a statistically significant improvement in forced expiratory volume over one second (FEV1) achieved on top of best standard of care.

The company said that 20 patients at London's King's College Hospital, experienced a significant increase in mean FEV1 of 124mL ($p = 0.014$) and FEV1 percentage change predicted of 4.4 percent ($p = 0.004$) at two months post- initiation dose assessment.

Pharmaxis said that 50 adult patients at the Royal Brompton Hospital provided data for follow up, which was continuing after about six weeks of treatment, showing improvement of median FEV1 from 1.47L to 1.61L ($p = 0.02$) and median FEV1 percentage predicted from 44 percent to 50 percent ($p = 0.03$).

The company said that the Germany's University Hospital Mainz presented results from a pilot prospective, observational study that indicated inhaled dry powder mannitol might influence lung clearance index (LCI) in adult cystic fibrosis patients with well-preserved lung function with FEV1 of more than 70 percent predicted, showing an average change in the LCI of 4.6 percent ($p = 0.044$) and supporting the need for further investigation.

Mr Phillips said that lung clearance rate was a relatively new measure of efficacy being reported for cystic fibrosis patients, which had not been used in regulatory studies for drug approvals, but was "gaining in acceptance so this trial result from Germany attracted significant attention".

"Lung clearance index is an alternative measure of lung physiology that sheds light on the amount of unused space or trapped air in the lungs and the uneven distribution of airway obstructions as they develop," Mr Phillips said. "It is claimed to show early changes in the small airways before they can be detected by other lung function measures such as FEV1 and is particularly gaining traction in monitoring disease development in children."

Pharmaxis said that Bronchitol for cystic fibrosis patients aged over six years in Australia and for patients aged 18 years and over throughout the European Union.

Pharmaxis was unchanged at 6.1 cents.

ALCHEMIA

Alchemia says the first of 50 patients has been enrolled in its clinical trial of HA-irinotecan with cetuximan (Erbitux) for second-line treatment of metastatic colorectal cancer.
Alchemia said that the trial at up to 10 sites was an investigator-sponsored trial supported by Alchemia and Merck Serono SA and led by Royal Melbourne Hospital principal investigator Prof Peter Gibbs.
The company said that Erbitux was marketed by the Darmstad, Germany-based Merck KGaA.
The company said that the primary objective of this study, to be known as the Chime trial (cetuximan and hyaluronic acid (HA) irinotecan), was to evaluate the safety of HA-irinotecan, as part of the folinic acid (leucovorin), fluorouracil and irinotecan (FOLFIRI) treatment regimen, in combination with cetuximan.
Alchemia said the trial was scheduled to run for about 24 months.
Alchemia chief scientific officer Prof Tracey Brown said the start of the trial "achieves another milestone in the clinical development of HA-irinotecan as this study will be the first use of a Hyact drug within an antibody-containing regimen, which is the current and future standard of care for cancer patients".
Hyact is the platform technology acquired with Meditech in 2006, from which HA-irinotecan was developed (BD: Mar 9, Aug 15, 2006; Nov 7, 2011).
Prof Gibbs said his group was "very pleased to have the first patient enrolled".
"Due to the potential therapeutic benefit that HA-irinotecan can add to cancer patients, we expect steady enrolment to this study," Prof Gibbs said.
"The goal of this trial is to demonstrate that HA-irinotecan, when administered as part of the FOLFIRI regimen, is well tolerated when used in combination with Erbitux which is a current standard of care in the treatment of metastatic colorectal cancer patients," Prof Gibbs.
Alchemia said that HA-irinotecan was also in a pivotal 415-patient phase III trial for the treatment of metastatic colorectal cancer, which was continuing (BD: Nov 28, 2013).
The company said colorectal cancer was one of the most common cancers, with more than 1.2 million new cases diagnosed annually and was the second leading cause of cancer deaths in the US, claiming more than 50,000 lives each year.
Alchemia was unchanged at 49.5 cents.

SIMAVITA

Simavita has requested a trading halt pending the release of an announcement in relation to an $9.6 million capital raising at 45 cents a share and Chess depositary interest (CDI).
Trading will resume on June 23, 2014 or on an earlier announcement.
Simavita said that the trading halt was "in order to ensure consistency and compliance with and between the ASX and the [Toronto Stock Exchange]".
The company said that the placement would be in two tranches with the first for $3.96 million and the second of $4.5 million requiring shareholder approval.
Simavita said a share plan offering up to $15,000 in shares would be offered and hoped to raise $1.08 million.
The company said that the record date was June 18, the offer would open on June 25 and close on July 25, 2014.
Simavita is developing a urinary incontinence management system for aged care facilities.
Simavita last traded at 49 cents.

CELLMID

Cellmid says it has contracted Biotecnol SA subsidiary Rodon Biologics to manufacture its humanised anti-midkine antibody CAB102 for trials in multiple oncology indications.
Cellmid said that the Lisbon, Portugal-based Rodon would engineer a high-yielding Chinese hamster ovary cell-line expressing CAB102, along with the processes necessary to manufacture and formulate the drug for first in human trials.
The company said that CAB102 was its lead oncology drug following antibody humanization and pre-clinical testing and it hoped to begin human clinical trials “in early 2015” (BD: May 7, 2014).
Cellmid said that Biotecnol SA biopharmaceutical development subsidiary Biotecnol Ltd was responsible for the humanization of the antibody; Rodon produced the humanized candidates for initial screening and had tested CAB102’s manufacturability and stability in small-scale production runs as part of the humanization program.
Cellmid said that it and the Herfordshire, UK-based Biotecnol Ltd had a co-development agreement to engineer novel anti-cancer Tribodies (BD: April 15, 2014).
Cellmid chief executive officer Maria Halasz said that contracting Rodon Biologics to manufacture CAB102 “makes sense for many reasons”.
“Cellmid and Rodon Biotecnol have collaborated closely during the humanization of CAB102 establishing a very productive working relationship,” Ms Halasz said.
“Also critical in our decision was their deep understanding of the specific manufacturing requirements for our planned clinical trial notification scheme-based clinical studies,” Ms Halasz said.
Cellmid said that the manufacturing collaboration was the third project between the parties and aligned well with the ongoing anti-MK Tribody program.
The company said it allowed for “seamless transition by Rodon from manufacturability studies to actual cell line development and manufacture ... expected to save up to six months in the company’s product development program”.
Cellmid was unchanged at 2.5 cents.

NUSEP HOLDINGS

Nusep says the $S6.55 million ($A5.6 million) first tranche investment in its Singapore subsidiary Prime Biologics has been competed (BD: May 12,2014).
Nusep said that Malaysia’s Xeraya Capital Labuan through affiliate, Pulau Manukan Ventures Labuan and Singapore’s JP Asia Prime Capital Pte Ltd werer the primary investors.
The company said that the funds would be used to continue to develop Prime’s technology to separate proteins albumin and intravenous immunoglobulin from human blood plasma, as well as repay loans from Nusep to Prime.
Nusep said it would use some of the funds to repay debts and assist in the development of other applications from the core membrane separation technology.
Nusep was up 0.3 cents or 4.6 percent to 6.8 cents.

GI DYNAMICS

Hunter Hall Investment Management has become a substantial shareholder in GI Dynamics with 25,403,348 shares (5.36%).
The Sydney-based Hunter Hall said it acquired the shares between October 10, 2013 and June 17, 2014.
GI Dynamics was up three cents or 5.2 percent to 61 cents.

ISONEA

Isonea says it has appointed David Ashmore as a non-executive director and he will be the chairman of the audit, risk and compliance committee.

Isonea said that Mr Ashmore was a former senior partner at Grant Thornton Australia and continued as the chairman of Saferoads Holdings.

Isonea was up 1.5 cents or 6.7 percent to 24 cents with 1.8 million shares traded.