Biotech Daily

Tuesday November 6, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN:**
- UNIVERSAL BIOSENSORS UP 12%, GENETIC TECHNOLOGIES DOWN 8%

*** CSL112 'MAY REDUCE RECURRENT CARDIAC RISK'**

*** ENDO ENDS PHASE III BIONICHE UROCIDIN BLADDER CANCER TRIAL**

*** NOVOGEN'S MEI PHARMA RAISES $26m**

*** CYCLOPHARM REQUESTS ENTITLEMENT OFFER TRADING HALT**

*** DR BERNARD HOCKINGS TAKES 6.7% OF PHYLOGICA**

MARKET REPORT

The Australian stock market was up 0.24 percent on Tuesday November 6, 2012 with the S&P ASX 200 up 10.7 points to 4,484.8 points.

Seven of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and eight were untraded. All three Big Caps were up.

Universal Biosensors was the best, up 12 cents or 11.65 percent to $1.15 with 186,804 shares traded.

Benitec climbed 7.1 percent; Phylogica was up 4.2 percent; Ellex rose 2.6 percent; Clinuvel, Cochlear, Living Cell, Nanosonics and Resmed were up more than one percent; with CSL up 0.85 percent.

Genetic Technologies led the falls, down one cent or 8.3 percent to 11 cents with 169,436 shares traded.

Cellmid and GI Dynamics lost more than five percent; Optiscan, Prima and Viralytics fell four percent or more; Compumedics, Phosphagenics and Prana were down more than three percent; Anteo, Pharmaxis, Starpharma and Tissue Therapies shed more than one percent; with Acrux, Alchemia, Mesoblast and Sirtex down by less than one percent.

CSL

CSL says that infusions of CSL112, a novel formulation of apolipoprotein A-I, rapidly increased the presence of key biomarkers associated with reverse cholesterol transport.

CSL said that that the blood plasma-derivative apolipoprotein A-I (apoA-I) was the main component of high-density lipoprotein (HDL)and the phase I trial showed that CSL112 was associated with the removal of cholesterol from arteries, which was then transported to the liver for clearance.

CSL said that rapid removal of cholesterol following a cardiac arrest could play a role in stabilizing vulnerable plaque lesions and lowering the high risk of subsequent events.

CSL's head of clinical and translational science strategy and study lead author Dr Andreas Gille said that CSL112 "dramatically elevated measures of cholesterol efflux capacity, a newly recognized marker of HDL function and rapidly raised blood levels of apoA-I".

CSL said that data from two CSL112 phase I studies was presented at the American Heart Association meeting in Los Angeles, California, November 3-7, 2012, demonstrating a positive safety and pharmacokinetic profile, warranting phase II development for the early reduction of recurrent cardiovascular events in acute coronary syndrome patients.

CSL said that biomarkers of cholesterol movement following infusions of CSL112 were observed in 36 healthy subjects.

The company said that three dosing regimens were studied: four once-weekly infusions of 3.4g, four once-weekly infusions of 6.8g, and eight twice-weekly infusions of 3.4g.

CSL said that subjects were randomized to CSL112 or placebo and all biomarker responses were dose dependent and showed similar magnitude and time course after the first and last infusions.

CSL said that an overall elevation in cholesterol efflux capacity, Pre-Beta1-HDL, and HDL in serum or plasma was observed among all dosing regimens, with Pre-Beta1-HDL increased 20-fold among dosing regimens as well as cholesterol efflux capacity and Pre-Beta1-HDL peaking immediately following infusion, returning to near baseline at 24 hours.

The company said that HDL level increased following Pre-Beta1-HDL, peaked at 24 to 48 hours, and sustained elevation 72 hours after infusion.

The company said that safety and pharmacokinetic profiles were separately evaluated in the 36 healthy patients receiving the three dosing regimens of CSL112, with no treatment-emergent serious adverse events reported, no abnormalities observed in serum biochemistry, hematology and urine parameters and no significant changes seen in platelet function, vital signs or electro-cardiogram associated with CSL112 treatment.

CSL said that the most common adverse event reported was vessel puncture site haematoma (18 of 36), which was reported by similar proportions of patients receiving either CSL112 or placebo.

CSL's head of cardiovascular therapeutics and study co-author Dr Samuel Wright said that the development of products that increased cholesterol efflux from the artery wall was an emerging area in atherosclerosis discovery.

"Prior approaches have centered on addressing only HDL cholesterol levels," Dr Wright said. "CSL112 holds promise as a new therapy that may be used in addition to other treatments, such as anti-platelet agents, to provide early event reduction."

CSL said further data presented at the American Heart Association meeting showed that a single infusion of CSL112 at dose levels of 5.0 to 135 mg/kg immediately caused dose-proportional elevation in apoA-I and changes to key biomarkers of the early steps in reverse cholesterol transport and CSL112 was observed to have strong anti-inflammatory properties in human blood ex-vivo, potentially beneficial in the reduction of inflammation associated with cardiovascular events.

CSL was up 40 cents or 0.85 percent to $47.40 with 624,620 shares traded.

NOVOGEN, MEI PHARMA

Novogen and its US subsidiary, MEI Pharma both climbed strongly on a $US27.5 million ($A26.4 million) placement to fund MEI development programs led by Pracinostat.
Prior to the placement Novogen held 63.5 percent of MEI Pharma (formerly Marshall Edwards).
Novogen said that the financing was led by new investors Vivo Ventures and New Leaf Venture Partners with participation from additional institutional investors, including RA Capital Management and Three Arch Opportunity Fund, among others.
New Leaf managing director Dr Srini Akkaraju said his company helped build a syndicate of long-term investors allowing MEI Pharma to pursue development of Pracinostat.
“We are particularly encouraged by Pracinostat’s evidence of clinical activity in haematologic malignancies with large unmet medical needs, such as myelodysplastic syndrome and acute myeloid leukemia,” Dr Akkaraju said.
Vivo Ventures managing partner Dr Albert Cha said that Pracinostat had “the potential to become a best-in-class compound”.
MEI Pharma said it had agreements for 55,000,000 shares of common stock and warrants to purchase up to 38,500,000 additional shares of common stock.
The company said that each unit of one share and a warrant to purchase 0.7 of a share would be sold for 50 US cents, with warrants exercisable at 52 US cents per share, with warrants exercisable on issue and expiring five years from issue.
MEI Pharma said the funds were for the clinical development of Pracinostat, an oral histone deacetylase inhibitor acquired by the company in August, 2012, and its Novogen-licenced isoflavone-based drug candidates.
On the Nasdaq last night, MEI was up 31 US cents or 79.5 percent to 70 US cents, with Novogen up 81 US cents or 53.6 percent to $US2.32.
On the ASX today, Novogen was up 2.5 cents or 38.5 percent to nine cents.

BIONICHE LIFE SCIENCES

Bioniche says licencing partner, Endo Pharmaceuticals has discontinued its phase III trial of Urocidin for non-muscle-invasive bladder cancer.
In 2010, Bioniche raised $30 million to list on the ASX and develop Urocidin opening on January 27, 2011 at its initial public offer price of $1.50 and closing at $1.52.
Bioniche said in 2010 that it had run its own registration-directed phase III trial of Urocidin for patients whose cancer was refractory or not responsive to standard treatment with bacillus Calmette-Guérin (BCG) and Endo planned to conduct an additional phase III trial.
Bioniche said following a successful second phase III trial, Endo would submit data to the US Food and Drug Administration for registration of Urocidin.
In 2011 Bioniche said that Endo had paid an up-front fee of $US20 million in July 2009, and was eligible for $US110 million in milestone payments (BD: Feb 17, 2011).
Bioniche said that its first 129-patient phase III trial showed a 25 percent one-year disease-free survival rate, comparing favorably to existing treatments (BD: Feb 18, 2011).
Bioniche’s net loss for the year to June 30, 2012 was $C24,188,000 on revenue of $C31,797,000 ($A31,159,740), primarily from animal health products (BD: Sep 13, 2012).
Today, Bioniche said that the Endo trial had “not been recruiting at the expected rate and, after recent discussions with the US Food and Drug Administration regarding the current clinical trial design, Endo has decided to end the study before its scheduled completion”.
The company said that with Endo it was considering potential next steps for the program.
In Toronto last night Bioniche fell 15.8 percent to 40 Canadian cents (38.6 Aust cents).
On the ASX today Bioniche was untraded at 45 cents.

CYCLOPHARM

Cyclopharm has requested a trading halt “pending an announcement concerning an entitlement offer”.
Trading will resume on November 9, 2012 or on an earlier announcement.
Cyclopharm last traded at 17 cents.

PHYLOGICA

Perth cardiologist Dr Bernard Hockings has increased his substantial shareholding in Phylogica from 26,462,263 shares (6.53%) to 31,462,263 shares (6.74%).
The change of substantial shareholding notice said that the Nedlands, Western Australia-based B Hockings private superannuation fund acquired 5,000,000 shares for BEF and DL Hockings on August 21 and November 5, 2012 for $112,000 or 2.24 cents a share.
Phylogica was up 0.1 cents or 4.2 percent to 2.5 cents.