Biotech Daily

Monday October 20, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: GENETIC TECHNOLOGIES UP 15%, IDT DOWN 14%**

*** ANTISENSE 'HIGHER, LONGER ATL1103 DOSE FOR ACROMEGALY'**

*** STARPHARMA DEP-DOCETAXEL LONGER DURATION, FEWER SPIKES**

*** SIRTEX COMPLETES 'TOXICITY-FREE' KIDNEY CANCER DOSING**

*** CANADA APPROVES ADMEDUS CARDIOCEL**

*** LBT WINS $250k SOUTH AUSTRALIA GRANT FOR WOUNDVUE**

*** AVITA 2nd STRIKE BOARD SPILL AGM**

*** DR MEL BRIDGES, PARMA TAKE 5% OF ANATARA**

MARKET REPORT

The Australian stock market was up 0.91 percent on Monday October 20, 2014 with the S&P ASX 200 up 47.7 points to 5,319.4 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and one was untraded.

Genetic Technologies was the best, up 0.2 cents or 15.4 percent to 1.5 cents with 375,000 shares traded, followed by Compumedics up 13.0 percent to 13 cents with 48,813 shares traded.

Cellmid and Uscom climbed eight percent or more; Analytica and Osprey were up more than five percent; Antisense was up 4.8 percent; Anteo, Circadian and Starpharma were up more than three percent; Phosphagenics rose 2.7 percent; Living Cell, Medical Developments and Viralytics were up more than one percent; with Benitec, Cochlear, Nanosonics, Resmed and Sirtex up by less than one percent.

IDT led the falls, down three cents or 13.6 percent to 19 cents with 1,900 shares traded.

Oncosil fell 8.3 percent; Acrux and GI Dynamics lost more than six percent; Biotron and Clinuvel fell more than four percent; Impedimed, Pharmaxis and Universal Biosensors were down more than three percent; Alchemia and Mesoblast shed more than one percent; with CSL down 0.2 percent.

ANTISENSE THERAPEUTICS

An Antisense investor conference has been told that a stronger dose of ATL1103 for acromegaly for a longer period of time should be safe and produce greater efficacy.

The Manchester-based Christie UK National Health Service Trust endocrinologist Prof Peter Trainer and Antisense chief investigator in the ATL1103 trial for acromegaly told the meeting in Melbourne that the results from the phase II, randomized, open label study of two doses of ATL1103 indicated that the drug was well-tolerated and if administered at a larger dose than 200mg once or twice weekly and for a longer period of time than the 13 week dosing end-point, it could result in the normalization of insulin-like growth factor-1 (IGF-I) levels in a significant number of patients with acromegaly.

Prof Trainer said that acromegaly was most frequently the result of a tumor in the pituitary gland which released growth hormone to the liver, which in turn resulted in an over-expression of IGF-I causing the excessive growth symptoms that typified the disease.

Prof Trainer said that acromegaly was associated with a decrease in life expectancy by about 10 years especially when combined with diabetes or heart disease.

Prof Trainer said that complete removal of the tumor was the best method to deal with acromegaly but was not always possible and not always successful.

He said that a range of other measures were used including radiation therapy and drug therapy but all had complications or side effects.

Prof Trainer said that 20mg pegvisomant, or Somavert, daily, was able to reduce IGF-I levels by about 45 percent at 12 weeks of treatment and reduce symptoms of acromegaly including soft-tissue swelling.

Prof Trainer said that in the phase II ATL1103 study one patient in each of the two treatment groups withdrew from the study after the final dose and the total of four serious adverse events were considered not drug-related.

He said that scatterplots of patients in the trial on a dose per weight basis showed that lighter patients on the higher dose had a greater change in IGF-I levels.

Prof Trainer said that the positive safety data suggested that ATL1103 might be tolerated at higher doses.

He said that while the 200mg once-weekly dose did not result in a change in mean IGF-I levels, the twice weekly dose resulted in a 26 percent mean reduction of IGF-I, one week after the 13 week treatment ($p < 0.0001$), IGF-I had not reached its nadir at week 13, and IGF-I had normalized in two higher-dose patients in the trial.

Antisense managing director Mark Diamond told the investor meeting that ATL1103 had a number of advantages over pegvisomant, including much reduced cost and more convenient administration of once or twice weekly injections instead of daily.

Mr Diamond said that the cost of pegvisomant was likely to the reason that it was only used in 25 percent of the second-line cases of acromegaly.

Mr Diamond said that Somavert had estimated sales of about $US200 million a year.

Mr Diamond said that the next step for ATL1103 would be to partner it for a phase III trial and that discussions were being held with a number of companies.

He said that Antisense expected to hear from the US Food and Drug Administration in the immediate future about it investigational new drug application for a phase IIb trial of ATL1102 for multiple sclerosis.

Mr Diamond said that the FDA had set a target date of October 17, 2014 to reply and that the company expected the response shortly.

Antisense was up half a cent or 4.8 percent to 11 cents.

STARPHARMA HOLDINGS

Starpharma says that a pharmacokinetics analysis shows that its dendrimer-docetaxel has a “substantially extended duration ... and reduced peak levels of drug”.

Starpharma said that the preliminary pharmacokinetics analysis from its phase I clinical trial’s first cycle of dosing for several patients with solid tumors, confirmed beneficial features that were also seen in earlier preclinical studies for dendrimer enhanced docetaxel, compared with docetaxel, or Taxotere (BD: Jan 23, 2014).

Starpharma chief executive officer Dr Jackie Fairley told Biotech Daily that the phase I trial would recruit 25 to 30 patients, pending the number of escalations required to reach maximum tolerated dose.

The company said that the dendrimer-enhanced docetaxel, or DEP docetaxel, had “a very substantially extended duration of exposure, greatly increased extent of total exposure to drug and reduced peak levels of drug”.

Starpharma said that in preclinical studies DEP docetaxel demonstrated “significantly improved anti-cancer efficacy and reduced toxicity and the current clinical trial is being conducted to assess DEP docetaxel in cancer patients”.

Dr Fairley said that the pharmacokinetic profile seen with DEP docetaxel in humans “fits very well with our preclinical data and these findings also support the likely explanations for the improved efficacy and improved tolerability previously seen with DEP docetaxel in animal models”.

“To date in the trial, there have been no reports of drug-induced nausea, hair loss, fluid retention, or indeed neutropenia, which is the most important dose-limiting toxicity for Taxotere,” Dr Fairley.

Starpharma said the data indicated that when equivalent doses of Taxotere and DEP-docetaxel were intravenously administered to patients, DEP-docetaxel resulted in a much greater exposure to the cancer drug, docetaxel, and this outcome could be expected to result in higher levels of exposure of cancer tissue to the drug.

Starpharma said the increased drug exposure was in addition to the significant cancer-tissue targeting observed with DEP-docetaxel in preclinical studies,

The company said that the peak level of docetaxel achieved with DEP-docetaxel was lower, as intended, and exposure to docetaxel occurred over a much longer period of time, due to release of docetaxel from the dendrimer occurring gradually.

Starpharma said the gradual release pharmacokinetic profile afforded by DEP-docetaxel indicated that the dendrimer was acting as a depot for docetaxel, avoiding the initial excessive spike in plasma docetaxel levels observed following dosing with Taxotere.

The company said that the plasma half-life, a parameter used to evaluate the duration of drug level in the blood, of docetaxel when administered as DEP-docetaxel was substantially longer, about eight times on average, than the plasma half-life of the equivalent dose of the approved form of docetaxel, Taxotere.

Starpharma said that when compared with the initial rapid phases of docetaxel plasma clearance, the data showed that the plasma half-life of DEP-docetaxel was about 150 times longer.

The company said that for a given dose of DEP-docetaxel, the extent of drug exposure, for total docetaxel, was 500 to 800 times higher for DEP-docetaxel than an equivalent dose of docetaxel.

Starpharma said that for a given dose of DEP-docetaxel, the peak blood level of docetaxel was 50 to 100 times lower than an equivalent dose of Taxotere.

The company said that the lower peak blood level avoids the spike in drug levels, also due to the gradual release of docetaxel from the dendrimer.

Starpharma was up 2.5 cents or 3.9 percent to 67 cents.

SIRTEX MEDICAL

Sirtex says it has completed recruitment of the 12 patients in its dose escalation trial of SIR-Spheres for renal cell carcinoma, with no toxicity reported.

Sirtex said that the renal SIR-Spheres or Resirt study was a first-in-human study that aimed to determine how high a radiation dose could be delivered to renal cell carcinomas using SIR-Spheres microspheres, with a secondary aim is to determine the potential effectiveness of SIR-Spheres microspheres in treating renal cell carcinoma.

The company said the study sought to recruit three patients at each of four successively higher radiation dose levels and recruitment of patients at the highest radiation dose level of 200 grays or 20,000 rads, had been completed.

Sirtex said that no toxicity related to SIR-Spheres microspheres had been reported in any of the 12 study patients, including the three patients treated at the highest radiation dose.

The company said that given the absence of any toxicity at the highest radiation dose level, it would expand the Resirt study to recruit additional patients at higher radiation dose levels beyond 200 grays.

Sirtex said that the objective of expanding the study was to fully define the optimum radiation dose, prior to launching a pivotal study of SIR-Spheres microspheres for the treatment of renal cell carcinoma, the main type of kidney cancer.

University of Western Sydney professor of medical oncology and principal investigator Prof Paul de Souza said the study was “the first study in the world using SIR-Spheres to treat cancers outside the liver”.

“While some of our patients have experienced encouraging tumor control, we haven’t seen any toxicity from treatment,” Prof de Souza said.

“We now need to examine additional higher radiation dose levels and look forward to defining the optimum radiation dose to take forward into a definitive trial,” Prof de Souza said.

Sirtex said that in 2012, about 3,500 Australians and 58,000 Americans were diagnosed with kidney cancer and during the past 20 years there had been a five-fold increase in the incidence of kidney cancer and a two-fold increase in mortality.

The company said that surgery was the main treatment for earlier stages of kidney cancer, but advanced kidney cancer carried a poor prognosis.

Sirtex said that a significant unmet need existed for patients not able to undergo surgery or who had advanced stage disease that was not addressable by surgery.

Sirtex was up 14 cents or 0.6 percent to $22.50 with 239,674 shares traded.

ADMEDUS

Admedus says that Health Canada has granted Cardiocel a medical device licence and it is available for sale and use by cardiac surgeons throughout Canada.

Admedus said that Adapt-treated bovice cardiac tissue was used for repairing heart defects, including heart valves.

The company said that Cardiocel had Conformité Européenne (CE) mark and US Food and Drug Administration 510k clearance and is available in Australia under the early access Authorised Prescriber Scheme.

Admedus said Cardiocel was used by heart surgeons to treat patients at centres across Australia, Europe and the US.

Admedus chief executive officer Lee Rodne said that the Canadian approval was “another important step in the global launch of Cardiocel and will add revenue growth for the Admedus Group”.

Admedus was unchanged at 13 cents with 3.8 million shares traded.

LBT INNOVATIONS

LBT says it has been awarded a $250,000 grant from the South Australian Government's bioscience agency, Bio-SA, to develop its Woundvue wound management technology.
LBT said that Woundvue was proposed to be a hand-held device for imaging, analyzing and reporting on the status and progress of chronic wound healing.
The company said that the device was based on a proprietary intelligent digital imaging technology platform, which was being commercialized in a series of automated instruments for the automated intelligent imaging, reading and reporting of culture-plates in microbiology laboratories.
LBT said that the grant would be applied to the early stages of proving-up the concept for Woundvue, including the design and testing of a prototype image capture system and the analytical algorithms that will form the basis of the new system.
LBT chief executive officer Lusia Guthrie said that the grant would provide "an important kick-start for a technology that we believe has the potential to fill an important niche in the global diagnostics market".
"Woundvue has enticing commercial prospects and we are very grateful to Bio-SA for sharing our vision and assisting in these critical early stages of its development," Ms Guthrie said.
LBT said that an estimated 50 million people globally suffered from chronic wounds open for six weeks or more and the market for treatment was $US60 billion a year.
The company said that Bio-SA grants were repayable, in the form of a royalty on income from the intellectual property or other revenue generated from the project, but not until the grantee was able to derive an income from the project.
LBT was up 1.5 cents or 13.0 percent to 13 cents.

AVITA MEDICAL

The Avita annual general meeting will vote on a potential second strike board spill, along with the election of directors.
Last year, the Avita remuneration report was opposed by 80,523,745 votes or 75.22 percent, providing the first trigger for a potential board spill at this year's annual general meeting (BD: Nov 25, 2013).
The Corporations Act (Section 250U) provides for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.
If the spill vote fails, the trigger is reset to no opposition.
Avita said that the meeting would vote on the election of directors Lou Panaccio and Ian Macpherson, and the adoption of the employee performance rights plan and the 10 percent placement capacity.
The meeting will be held at the offices of Grant Thornton, Redwood Room, Level 17, 383 Kent Street, Sydney on November 21, 2014 at 11.30am (AEDT).
Avita was unchanged at 10 cents.

ANATARA LIFESCIENCES

The Queensland-based Parma Corp and Bridges Family Trust say they hold 5,079,230 shares or 16.48 percent of Anatara.

In a substantial shareholder notice, Anatara chairman and Parma director Dr Mel Bridges said that between July 15, 2010 and October 17, 2014 he acquired 5,075,230 shares for $352,283 or 6.9 cents a share, and on October 9, 2014 acquired a further 4,000 shares for $2,000 or 50 cents a share, the same price as its initial public offer (BD: Oct 16, 2014).

Anatara was up 1.5 cents or 4.05 percent to 38.5 cents.