Biotech Daily

Wednesday October 21, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CIRCADIAN UP 13.5%; OPTISCAN DOWN 11%**

*** JOURNAL ARTICLE BACKS AVITA RECELL FOR FACIAL DEFECT REPAIR**

*** PHARMAUST FINAL PHASE I/II PPL-1 SOLID TUMOR DATA**

*** UP TO 26% OF LBT AGM OPPOSE DIRECTOR KATE COSTELLO**

*** BIOTRON AGM FOR 5m CEO REPLACEMENT OPTIONS**

*** MMJ REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** GOLDMAN SACHS BELOW 5% OF NANOSONICS**

MARKET REPORT

The Australian stock market was up 0.24 percent on Wednesday October 21, 2015, with the ASX200 up 12.7 points to 5,248.3 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, 14 fell and five traded unchanged. All three Big Caps fell.

Circadian was the best, up 3.5 cents or 13.5 percent to 29.5 cents, with 25,388 shares traded, followed by Uscom up 12.9 percent to 17.5 cents with 3,823 shares traded.

Compumedics climbed 9.1 percent; both Polynovo and Tissue Therapies rose 7.7 percent; Actinogen was up 6.8 percent; Biotron was up 5.7 percent; Avita, IDT and Prana improved more than four percent; Impedimed, Oncosil, Prima and Viralytics were up more than three percent; Bionomics and Nanosonics rose two percent or more; Acrux, Ellex, Psivida and Universal Biosensors were up one percent or more; with Sirtex up 0.4 percent.

Optiscan led the falls, down half a cent or 11.4 percent to 3.9 cents with 84,000 shares traded.

Osprey lost 8.5 percent; Genetic Technologies fell 5.6 percent; Antisense shed 4.4 percent; Cellmid and Neuren were down three percent or more; Benitec, Living Cell and Pro Medicus shed more than two percent; Admedus, Anteo, Atcor, Medical Developments and Resmed were down more than one percent; with Cochlear, CSL and Mesoblast down by less than one percent.

AVITA MEDICAL

Avita says an article on four patients reports that Recell provides “clinically significant improvements in the aesthetic outcomes of repaired complex facial defects”.

Avita said the report, entitled ‘Surface-optimized free flaps for complex facial defects after skin cancer’ published in the Journal of Cranio-Maxillo Facial Surgery reported on the repair of facial defects resulting from surgical removal of non-melanocytic skin cancers.

An abstract is at: http://www.jcmfs.com/article/S1010-5182(15)00288-7/abstract and said the authors were affiliated with the Munich, Germany-based Technische Universität and the Glasgow, Scotland-based Southern General Hospital.

The company said that surgeons faced challenges balancing functional needs with patient’s aesthetic standards when repairing the facial region following surgical removal of non-melanocytic skin cancers, “which frequently results in extensive tissue loss requiring a plastic surgery technique called a free-flap”.

Avita said that harvesting remote free-flaps of skin along with subcutaneous tissue from other parts of the body and transferring them to the recipient region often resulted in mismatched skin color, volume and elasticity, all of which impaired facial appearance.

The abstract said that post-ablative facial non-melanocytic skin cancer defects in four patients were reconstructed using remote free flaps, including radial forearm, scapular, para-scapular and anterolateral thigh flaps.

“Four months later, a split-thickness skin graft was acquired from the retro-auricular region to generate a non-cultured autologous epidermal cell (NCAEC) suspension,” the abstract said.

“The flap surfaces were de-epithelialized and the NCAEC suspension was sprayed onto the flap surface to improve the mismatch between facial and flap color [and] debulking was also carried out,” the article said.

The article said that all flaps survived the 11 to 21 month follow-up, the secondary operation was accompanied by a delay in re-epithelialization in one case, and no split-thickness skin graft donor-site problems occurred.

The abstract concluded that “facial reconstruction with a free flap results in a mismatch of color and texture [but] secondary correction of the flap surface by de-epithelialization and NCAEC application significantly improves the aesthetic outcome”.

Avita said that the secondary procedure using the Recell regenerative epithelial suspension (RES) “improved the pigment, volume, texture and elasticity of free flaps in the facial region”.

The company said that all treated flap areas “healed uneventfully and by 12 months after the secondary treatment, all patients presented with sufficient color and volumetric matching of the flaps and with healed donor sites”.

Avita chief executive officer Adam Kelliher said the article was “one of the many real-world aesthetic applications of our unique Recell technology”.

“Cancer in the facial region can be severely debilitating and its removal can cause considerable loss of tissue, making reconstruction a delicate procedure,” Mr Kelliher said.

“Positive outcomes from this study, demonstrating treatment using Recell significantly improves aesthetic outcomes of repaired complex facial defects, hold substantial promise for patients undergoing [non-melanocytic skin cancers] tumor removal and indicate the potential of RES to aesthetically improve a variety of other surgical reconstructions,” Mr Kelliher said.

Avita said that its Recell technology allowed physicians “to quickly create, at point of care, regenerative epithelial suspension using a small sample of the patient’s skin that can then be applied to the skin defect as treatment.

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

PHARMAUST

Pharmaust says its phase I/II trial of PPL-1 for solid tumors shows biomarker anti-cancer activity and that the drug is safe, despite palatability issues.

Pharmaust said that the trial results were provided by CPR Pharma Services, which worked with the IDT Australia-owned CMax facility at the Royal Adelaide Hospital.

In July, the company said that the seventh and final patient showing “meaningful suppression of key cancer marker p70S6K” having been administered the 25mg/kg higher dose of PPL-1 and that the drug demonstrated “a very good safety profile as compared with many other established anti-cancer drugs and … PPL-1 showed activity against cancer through the suppression of a key cancer marker” (BD: Jul 23, 2015).

Pharmaust said in July that three patients completed the 28-day treatment period, with one patient not included in the cancer marker results as they only received one dose.

The company said at that time that one patient received the 25mg/kg dose with the other patients treated with 5mg/kg doses.

In July, Pharmaust executive chairman Dr Roger Aston said “the suppression of tumor marker, p70S6K, … was highly significant when the data from seven patients is combined and analyzed at day three of treatment ($p < 0.0004$) and at day seven ($p < 0.002$)”.

Today, Pharmaust said that the trial, entitled ‘A Phase I Study of the Tolerability, Safety and Pharmacokinetics of Oral Monepantel (MPL or PPL-1) in Individuals with Treatment-Refractory Solid Tumors’ investigated the primary objectives of safety, tolerability, dose-limiting toxicities and maximum tolerated dose if achieved of PPL-1 in humans with treatment-refractory solid tumors and describe the multiple-dose pharmacokinetics of PPL-1 in participants with treatment-refractory solid tumors.

The company said that secondary objectives were to evaluate evidence for PPL-1’s anti-cancer activity, using conventional measures of cancer response and disease progression and exploratory pharmaco-dynamic and tumor markers and establish a recommended starting dose for phase II studies in patients with treatment-refractory cancer.

Pharmaust said that PPL-1 demonstrated “a very good safety profile” as compared with other anti-cancer drugs and while it was well-tolerated in humans, adverse events related to study medication included nausea, vomiting, diarrhoea, and decreased appetite, with “poor palatability … believed to be the major contributor” and the company was investigating reformulation options.

The company said that the pharmaco-kinetics of PPL-1 indicated rapid absorption and peak blood levels in four to six hours following oral administration, with blood levels of PPL-1 in line with the levels observed for other anticancer drugs.

Pharmaust said that evaluation of white blood cells of patients who received PPL-1 for either three or seven consecutive days showed that the levels of the p-4E-BP1 cancer marker were significantly reduced as compared to its levels at Day 1 before treatment.

The company said that of the four subjects with post-dose response evaluation criteria in solid tumours (Recist) tumor assessment at a dose level of 5mg/kg, two were classified as stable disease and two were classified as progressive disease.

Pharmaust director Robert Bishop said responses and differences between the 5mg/kg and 25mg/kg dose would be detailed at the annual general meeting on October 27, 2015.

Dr Aston said it was “a very strong result for our phase I trial which will now allow us to proceed as soon as possible to a phase II evaluation of PPL-1”.

“Preliminary discussions with physicians at both the Royal Adelaide Hospital and at Clinical Research Centres in the UK signal strong interest to evaluate PPL-1 where first line therapy has failed,” Dr Aston said.

Pharmaust said the next stage was for clinical trials with PPL-1 and chemotherapy.

Pharmaust was unchanged at 0.5 cents with 8.7 million shares traded.

LBT INNOVATIONS

LBT says its annual general meeting voted significant dissent against the re-election of director Kate Costello.
LBT said that the re-election vote was opposed by 10,340,799 votes (26.0%), with 29,477,573 votes (74.0%) in favor.
The company's most recent Appendix 3B new issue announcement said that LBT had 114,723,367 shares on issue, meaning that the votes against Ms Costello amounted to 9.0 percent of the company, sufficient to requisition extraordinary general meetings.
The remuneration report and the re-election of director Caroline Popper were passed overwhelmingly.
LBT was up half a cent or 3.1 percent to 16.5 cents.

BIOTRON

Biotron will vote to grant chief executive officer Dr Michelle Miller 5,000,000 options with 2,000,000 exercisable at 15 cents and the balance at 18 cents by November 30, 2018.
Biotron said that the options would vest in three tranches and would replace 5,000,000 options which were due to expire on October 30, 2015.
In 2010, Biotron proposed issuing Dr Miller 1,000,000 options exercisable at 15 cents, 1,000,000 options at 20 cents and 3,000,000 options at 25 cents (BD: Oct 27, 2010).
Biotron said that shareholders would vote on the remuneration report, the incentive option plan and the re-election of directors Dr Susan Pond and Michael Hoy.
The meeting will be held at Level 3, 66 Hunter Street, Sydney, on November 24, 2015 at 11.30am (AEDT).
Biotron was up 0.3 cents or 5.7 percent to 5.6 cents.

MMJ PHYTOTECH

MMJ Phytotech has requested a trading halt "pending an announcement regarding a proposed capital raising".
Trading will resume on October 23, 2015 or on an earlier announcement.
MMJ last traded at 37.5 cents.

NANOSONICS

The Delaware-based Goldman Sachs Group says it has ceased its substantial shareholding in Nanosonics, again.
Following the notice after the market closed on October 19 that it had again become substantial in Nanosonics with 14,750,081 shares or 5.20 percent Goldman Sachs said after the market closed last night that it had reduced its holding to below the five percent substantial threshold (BD: Oct 2, 5, 15, 16, 20, 2015).
Goldman Sachs said that UK subsidiary Rothesay Life returned 1,121,368 shares "to the counterparty under a repurchase agreement" for no applicable consideration.
Previously, under a counterparty agreement, Goldman Sachs said it had returned, lent and borrowed shares held by subsidiaries, Rothesay Life, JP Morgan Chase, RBC Dexia Australia, HSBC Custody Nominees and the Bank of New York Mellon (BD: Apr 13, 2015).
Nanosonics was up four cents or 2.8 percent to $1.47.