Biotech Daily

Tuesday July 24, 2012

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: SUNSHINE HEART UP 17%, ELLEX DOWN 7%**

*** MESOBLAST STEM CELLS EFFECTIVE IN ARTHRITIS SHEEP TRIAL**

*** SUNSHINE HEART HAILS 12-MONTH DATA, 1st 24-MONTH PATIENT**

*** US, CANADA APPROVE BIONICHE DOG CANCER DRUG**

*** ANDREW GOODALL INCREASES TO 20% OF NUSEP**

*** IMPEDIMED'S GREG BROWN JOINS GENETIC TECHNOLOGIES**

MARKET REPORT

The Australian stock market edged up 0.1 percent on Tuesday July 24, 2012 with the S&P ASX 200 up 4.3 points to 4,133.2 points.

Thirteen of the Biotech Daily Top 40 stocks were up, eight fell, 13 traded unchanged and six were untraded. All three Big Caps fell.

Sunshine Heart was the best, up 0.7 cents or 17.1 percent to 4.8 cents with 2.1 million shares traded, followed by Cellmid up 14.3 percent to 1.6 cents, with 236,320 shares traded and Antisense up 12.5 percent to 1.8 cents with 44.5 million shares traded.

Phylogica climbed 8.6 percent; Neuren and Prima were up more than four percent; Psivida rose 2.2 percent; Living Cell, Mesoblast, Pharmaxis, Starpharma and Tissue Therapies were up more than one percent; with Acrux up 0.3 percent.

Yesterday's best, Ellex, led the falls, retreating 1.5 cents or seven percent to 20 cents with 54,650 shares traded.

Bionomics and Circadian lost more than five percent; Avita shed 2.8 percent; Alchemia, Anteo, Biota, Cochlear and Sirtex were down one percent or more; with Resmed down 0.3 percent.

MESOBLAST

Mesoblast says a trial of its allogeneic, or off-the-shelf adult mesenchymal precursor cells in 30 sheep showed the cells were effective in treating a rheumatoid arthritis model.

Mesoblast said that a single intravenous injection of the mesenchymal precursor cells in sheep with collagen-induced arthritis concomitantly affected T cells, monocytes, macrophages and synoviocytes to simultaneously shut down tumor necrosis factor alpha (TNF-alpha) and recombinant proteins interleukin-6 (IL-6) and interleukin-17 (IL-17) cytokine pathways and improve joint pathology.

Mesoblast chief executive Prof Silviu Itescu said the results indicated that the company's immuno-modulatory mesenchymal precursor cells might differ from other biological therapies by shutting down multiple cytokine pathways simultaneously and could be a first line treatment with a superior and sustained benefit on reducing inflammation and destruction of joints in people suffering from severe rheumatoid arthritis.

Mesoblast said that rheumatoid arthritis was an autoimmune disease driven and perpetuated by pro-inflammatory cytokines such as TNF-alpha, IL-6, and IL-17 and treatments targeting any of these pathways alone were only moderately effective in rheumatoid arthritis, needed to be administered chronically and could cause unacceptable infectious adverse events.

Mesoblast said that severe joint synovial inflammation with cartilage loss and bony erosions, characteristic of human rheumatoid arthritis, occurred in sheep injected with collagen and that in a pilot study, significant numbers of mesenchymal precursor cells were detected in the involved joints or lymph nodes of arthritic sheep at 24 hours after a single injection, but not in normal sheep, indicating that mesenchymal precursor cells selectively migrated to sites of immune-mediated inflammation.

Mesoblast said that a randomized, placebo-controlled study of 30 sheep with collagen-induced arthritis, compared a single intravenous injection of allogeneic mesenchymal precursor cells (MPCs) at three doses (0.3, 1.0 and 2.0 million MPCs/kg) to saline.

The company said that after 30 days, joint synovial tissues from arthritic sheep were examined and compared with saline-treated controls.

Mesoblast said that sheep receiving 2.0 million MPCs/kg showed an 88 percent reduction in IL-6 levels ($p = 0.029$), 83 percent mean reduction in TNF-alpha levels ($p = 0.049$), 53 percent reduction in IL-17 levels ($p = 0.005$) and a 52 percent reduction in infiltrating monocytes and macrophages ($p = 0.009$).

The company said that mesenchymal precursor cell-treated animals had a 31 percent mean reduction in histopathology severity scores compared with controls ($p = 0.025$).

Mesoblast said that intermediate effects was seen with 1.0 million MPCs/kg, and the lowest MPC dose was least effective.

The company said the findings demonstrated that mesenchymal precursor cells were immuno-regulatory and concomitantly suppress the activation and proliferation of T-cells, monocytes and synoviocytes seen in active rheumatoid arthritis.

Mesoblast said that mechanistically, the data suggested that mesenchymal precursor cells inhibited the Th17 CD4 T cell subset, with the subsequent simultaneous reduction in the key cytokines, IL-17, IL-6, and TNF-alpha.

Mesoblast said it would be meeting the US Food and Drug Administration to discuss its phase II rheumatoid arthritis clinical program and subject to clearance, a randomized, placebo-controlled phase II trial was expected to begin by the end of 2012.

Prof Itescu said that rheumatoid arthritis was the second indication, after type 2 diabetes, "in a growing list of major market segments that will be targeted by Mesoblast's intravenous product formulation".

Mesoblast was up eight cents or 1.4 percent to $5.90.

SUNSHINE HEART

Sunshine Heart says it has completed 12-month follow-up, in its US C-Pulse heart assist system pilot trial as well as its first patient two-year follow-up.

The pilot trial completed enrolment in June 2011 and preliminary results were presented in November (BD: Nov 8, 2011).

Sunshine Heart said the six-month preliminary data of 20 patients suggested positive efficacy trends for C-Pulse with statistically significant results in New York Heart Association cardiac class reduction and Minnesota Living with Heart Failure quality of life, respectively.

The company said that two patients were disconnected permanently, given their level of improvement on the device.

Sunshine Heart said that at both six and 12 months, no neurological events or strokes occurred in subjects supported with the C-Pulse, which was most likely due to its non-blood contacting feature.

The company said that this was “one of the potential benefits over currently approved mechanical assist heart failure therapies”.

Sunshine Heart said that extended 12-month follow-up data included further positive trends in efficacy with continued improvements in New York Heart Association class reduction, quality of life score and six-minute hall walk.

The company said that at 12 months there were no additional patients with device related serious adverse events including exit site infections.

Sunshine Heart chief executive officer Dave Rosa said the company was “extremely encouraged to see the continued trends in positive efficacy and safety for our C-Pulse device”.

“We are especially pleased to see improvements in several efficacy endpoints without additional patients experiencing exit site infections over the 12-month follow-up period,” Mr Rosa said.

Cardiologist at St Luke’s Hospital Kansas City, Missouri Dr Andrew Kao said of the two-year follow up patient that he saw the patient “experience an amazing recovery of function”.

“The first time I met him, he could not walk or even say a few words without extreme perspiration and shortness of breath,” Dr Kao said.

“After C-Pulse implantation, he can do many more activities,” Dr Kao said. “He can walk around comfortably and also has improved self-confidence.”

“He and his family are extremely grateful for this amazing chance at a renewed life,” Dr Kao said.

Mr Rosa said Sunshine Heart was “proud of reaching a two-year milestone for the technology and … equally pleased to hear how the technology is positively impacting patient’s lives”.

“We believe our preliminary results continue to illustrate that C-Pulse has the potential to improve the longevity and quality of life for moderate to severe heart failure patients,” Mr Rosa said.

Sunshine Heart was up 0.7 cents or 17.1 percent to 4.8 cents with 2.1 million shares traded.

BIONICHE LIFE SCIENCES

Bioniche says a canine oncology product related to its Urocidin for human bladder cancer has been approved in the US and Canada.

Bioniche said the canine product Immunocidin was based on its mycobacterial cell wall technology, from which its phase III Urocidin for human bladder cancer was derived.

The company said Immunocidin was indicated as an immunotherapy for the intra-tumoral treatment of mixed mammary tumor and mammary adenocarcinoma in dogs.

Bioniche said the canine product was expected to be available in Canada in September, 2012, followed by a US launch by the end of 2012.

Bioniche Animal Health president Andrew Grant said that canine cancer was the leading disease-related cause of death in dogs, with about one in four dying of cancer.

“Human chemotherapies are commonly used for treatment, but this requires special handling and the side effects can vastly diminish the dog’s quality of life,” Mr Grant said.

Bioniche has previously said the development of Immunocidin and a second, as yet unnamed but related drug that restored white blood cells, erythrocytes and platelets, had implications for human cancer treatment (BD: May 2, 2012).

Bioniche said that in developing Urocidin for human bladder cancer, the mycobacterial cell wall technology “was extensively tested in a number of human cancer cell lines, including bladder, ovarian, colon, gastric and breast, as well as in canine cancer cell lines, including osteosarcoma and mammary, where it was shown to possess direct anticancer activity with apoptosis, programmed cell death, in cancer cells”.

The company said the technology had been demonstrated to be synergistic with chemotherapeutic agents and a large amount of toxicity work had been completed to ascertain the product’s safety for human use.

Bioniche said that one of the safety studies involved a number of dogs in an intravenous safety study, required to support the phase III Urocidin program and to support registration and despite the administration of large doses to the dogs, there were few side effects.

The company said that this work led to further analysis of an intra-venous therapy for canine cancer based on the same technology.

Bioniche said that chemotherapy commonly caused cytopenia, a deficiency in the number of cellular elements in the blood, including white blood cells as well as erythrocytes and platelets.

The company said that clinical studies showed that a single dose of the second Urocidin-related product following chemotherapy treatment in healthy dogs restored the number of white blood cells in the dog to normal levels within 24 to 48 hours with few side effects.

Bioniche said it was undertaking dose confirmation studies prior to conducting final licencing studies.

The company said it expected to complete the work in about nine months, after which regulatory approvals would be sought in North America, Australia and Europe.

Bioniche was untraded at 39.5 cents.

NUSEP

Director Andrew Goodall has increased his holding in Nusep from 19,000,000 shares (17.60%) to 22,230,000 shares (19.99%).

Mr Goodall said he acquired the 3,230,000 shares for $226,100 or seven cents through the conversion of part of a loan.

Nusep was unchanged at 4.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies has appointed former Impedimed chief executive officer Greg Brown as a non-executive director.

Genetic Technologies said Mr Brown had more than 25 years of business experience in the healthcare industry including overseeing product development and commercial launches based in Switzerland, England, Germany and the US.

The company said that Mr Brown was formerly Baxter Diagnostics sales and marketing director, Roche Molecular Systems senior marketing manager, Digene Corp head of strategic marketing and led sales, device management, marketing and managed care teams in Europe and the US.

Biotech Daily has reported extensively on Mr Brown's work in achieving US insurance coverage and reimbursement for Impedimed's L-Dex post-breast cancer lymphoedema detection system (BD: Jun 25, Aug 25, 2010; Dec 8, 2011; Mar 14, 2012.

Genetic Technologies markets the Brevagen genetic test for assessing non-familial breast cancer risk in the US (BD: Jun 20, 2011).

Mr Brown continues as an executive director of Impedimed.

Genetic Technologies was unchanged at 10 cents.