Biotech Daily

Thursday June 26, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: IDT UP 11%, UNIVERSAL BIOSENSORS DOWN 9%**

*** MONASH UNI, PFIZER CENTRE FOR VICTORIA COMMERCIALIZATION**

*** NEUREN COMPLETES NNZ-2566 RETT SYNDROME ENROLMENT**

*** BENITEC: DSMB APPROVES CALIMMUNE 2nd ddRNAi HIV COHORT**

*** IMPEDIMED BEGINS L-DEX POST-APPROVAL TRIAL**

*** SOUTH AFRICAN APPROVAL FOR MEDICAL DEVELOPMENTS PETHROX**

*** ADMEDUS EXPECTS REVENUE UP 22% TO $9m**

MARKET REPORT

The Australian stock market climbed 1.15 percent on Thursday June 26, 2014 with the S&P ASX 200 up 62.3 points to 5,464.3 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and one was untraded. All three Big Caps were up.

IDT was the best, up two cents or 10.5 percent to 21 cents with 100,000 shares traded.

Optiscan climbed 9.1 percent; Alchemia was up 8.65 percent; Antisense rose 7.4 percent; Impedimed was up 5.7 percent; Mesoblast and Tissue Therapies were up more than three percent; Analytica, Cochlear and Genetic Technologies rose more than two percent; Medical Developments, Osprey, Psivida and Sirtex were up more than one percent; with Benitec, CSL and Resmed up by less that one percent.

Universal Biosensors led the falls, down two cents or 9.1 percent to 20 cents with 447,885 shares traded.

Avita lost 8.7 percent; Ellex was down 6.6 percent; Bionomics and Pharmaxis were down five percent or more; Circadian fell 4.55 percent; Acrux and Living Cell were down more than three percent; Anteo, Neuren, Phosphagenics and Prima shed more than two percent; Atcor and Nanosonics were down more than one percent; with GI Dynamics down 0.8 percent.

VICTORIA GOVERNMENT, MONASH UNIVERSITY, PFIZER

The Victoria Government says that Monash University will collaborate with Pfizer to create the Centre for Therapeutic Innovation to commercialize Victorian research.

The Victoria Minister for Technology Gordon Rich-Phillips said that the Centre for Therapeutic Innovation program was launched in 2010 and was "designed to bridge the gap between early scientific discovery and its translation into new medicines".

A Victoria Government media release said that the Centre would be based at Monash University in Clayton and managed by researchers from the Faculty of Medicine, Nursing and Health Sciences and joined four Centres in Boston, New York, San Diego, and San Francisco.

Mr Rich-Phillips said the new centre was a significant investment by Pfizer in Victoria's biotechnology capabilities and would see Monash and Pfizer strengthen existing research collaborations.

"Monash's research strengths in areas like cancer, regenerative medicine, structural biology, immunology and a focus on infection and immunity are providing a basis for translation into innovative clinical practices and, ultimately, better health for people worldwide," Mr Rich-Phillips said. "These collaborative projects are estimated to each represent an investment of between $12 to $14 million, while further strengthening Victoria's international reputation as a global leader in areas like infectious and chronic diseases, immunology and vaccines."

The media release said that the announcement was made at the BIO 2014 convention in San Diego, with Monash University research staff as part of a Victorian delegation led by the Governor of Victoria, Dr Alex Chernov.

NEUREN PHARMACEUTICALS

Neuren says it has enrolled all 54 subjects in its double-blind, placebo-controlled phase II trial of NNZ-2566 for Rett syndrome, with results expected by the end of 2014.

The company said that trial began in April 2013 and was the first commercial multi-site clinical trial in Rett syndrome, for which there was no approved therapy currently available (BD: Jan 20, Jun 5, 2013).

Neuren said the trial was supported by the International Rett Syndrome Foundation and would be featured at the IRSF Symposium in Washington DC June 24-26, 2014.

The company said that two dose levels of oral NNZ-2566 were being tested in female subjects aged 16 to 45 years, with the trial duration for each subject about 10 weeks.

The company said that 47 subjects had completed the trial, with seven more in progress.

Neuren said that as well as the primary endpoint of safety and tolerability, a number of measures would be analyzed for signs of clinical efficacy.

The company said that there had been four meetings of the independent drug safety monitoring committee and no safety concerns had been identified.

Neuren executive chairman Dr Richard Treagus said the company was pleased that the three clinical trial sites had completed the enrolment by June 30, as planned.

The company said that Rett syndrome was a post-natal neurological disorder which occurred almost exclusively in females following apparently normal development for the first six months of life.

Neuren said that many patients had recurrent seizures and a variety of motor problems including increased muscle tone, or spasticity, and abnormal movements; and were never able to provide for their own needs; with the disorder believed to be second only to Down syndrome as a genetically-determined cause of chronic neurological problems.

Neuren fell 0.2 cents or 2.4 percent to 8.2 cents with 2.2 million shares traded.

BENITEC BIOPHARMA

Benitec says that licencee Calimmune has received approval to treat the second patient cohort of its phase I/II clinical trial of Cal-1 for HIV (BD Mar 5, 2012; Jul 10, 2013).
Benitec said that a review of trial data from the first cohort of patients by the data safety monitoring board confirmed that none of the four participants experienced any serious adverse events or side effects from the therapy.
The company said that the Los Angeles, California-based Calimmune's Cal-1 was a DNA-directed RNA interference (ddRNAi) therapy targetting the gene for CCR5, a molecule that is critical for HIV binding to the body's T cells.
Benitec said that silencing the gene for CCR5 in the patient's blood stem cells with the ddRNAi DNA construct was designed to provide the cells with resistance to HIV infection, as well as helping to retain immune system function.
Benitec said that all patients previously had been on anti-retroviral drugs but had discontinued taking them because of side effects or treatment fatigue.
Calimmune chief executive officer Louis Breton said the board recommendation was "an important step in bringing this potential one-time therapy to the patients, and takes us closer to our ultimate goal of eradicating AIDS".
Benitec chief executive officer Dr Peter French said the approval "provides important early validation of the safety of this ddRNAi approach for human therapeutic applications".
"Cal-1 is potentially a one-shot curative approach for HIV/AIDS," Dr French said.
"This trial, along with our trial of ddRNAi for hepatitis C, demonstrates that the use of Benitec's gene silencing technology clinically is gaining momentum," Dr French said.
Benitec was up half a cent or 0.4 percent to $1.145.

IMPEDIMED

Impedimed says it has enrolled the first patient in its post-approval clinical trial of L-Dex for the early detection of lymphoedema six months ahead of schedule.
Impedimed said that the randomized control trial would enrol 1,100 patients and was led by the Nashville Tennessee-based Vanderbilt University School of Nursing's Prof Sheila Ridner as principal investigator and would be completed in about two years and conducted in at least five sites in the US and Australia.
Impedimed chief executive officer Richard Carreon said that data from the trial would "provide unique insights into patient outcomes following early detection of lymphoedema and we believe will lead to improved approaches in preventing progression of this often incapacitating, long-neglected condition".
"The post-approval trial is a defining event for the company and adds to growing body of evidence highlighting the benefits of early detection of lymphoedema using L-Dex," Mr Carreon said.
"There is an opportunity to make a difference for these patients," Prof Ridner said.
"I am fully committed to conducting rigorous research that will meet the aims of the study," Prof Ridney said.
Impedimed said the start of the trial was a new phase in the commercial rollout of L-Dex, with interim data from the trial to be used as the company sought coverage from private health insurers in the US.
The company said that the inclusion of major cancer centres in the trial would also drive market adoption as the current procedural terminology (CPT) category 1 code for Government reimbursement, would come into effect on January 1, 2015.
Impedimed was up one cent or 5.7 percent to 18.5 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says the South African Medicines Control Council has approved the Penthrox methoxyflurane inhaled analgesic' for trauma and surgical pain.
Medical Developments said that the approval gave its South African partner Link Healthcare, through its wholly-owned subsidiary Equity Pharmaceuticals, the right to sell Penthrox, marketed as Penthrop in South Africa.
The company said the market for prescription-only analgesics in South Africa was $90 million and the approval opened the regulatory pathway for approvals in Namibia, Botswana, Lesotho, Swaziland, Angola, Malawi, Mozambique and Zambia.
Medical Developments said that Link advised that the approval process in those countries would take less than 12 months because South African regulators have registered Penthrox for sale.
Medical Developments chief executive officer John Sharman said the approval was "a great opportunity for our company and could open the door to Africa".
Medical Developments was up two cents or 1.6 percent to $1.25.

ADEMEDUS (FOREMERLY ALLIED HEALTH)

Admedus says that total income, including revenue grants and other income, for the year to June 30, 2014 is expected to be up by more than 22 percent to $9 million.
In 2013, Admedus, then Allied Health, had revenue for the year to June 30, 2013 of $7,415,000 reducing net loss after tax to $1,892,000 (BD: Aug 30, 2013).
Today, Admedus chief executive officer Lee Rodne said that "the past 12 months have been extremely successful, with European and US marketing clearance for our lead regenerative tissue product Cardiocel and the completion of the HSV-2 vaccine phase I study".
"The initial target is to get Cardiocel into 15 key centres in Europe and in the US and as we scale up our manufacturing we will increase the number of new centres coming on-stream and continue to grow our revenue," Mr Rodne said.
Admedus said it had 12 key centres in Europe using the bovine cardiac tissue and had received orders from US centres earlier than scheduled.
Admedus said it was seeking Cardiocel marketing approvals in other jurisdictions and expansion of use for Cardiocel, not only for additional cardiovascular applications, but also for other areas of surgical repair.
The company said that Cardiocel was used in Australia under the Authorised Prescriber Scheme with more than 200 patients successfully implanted to date.
Admedus said it acquired a state-of-the-art manufacturing site in Western Australia earlier this years and expected production of Cardiocel for the US market to begin in July, 2014.
The company said that the in the next 12 months it hoped to have Cardiocel in 15 European and 15 US centers, obtain Asian market approval, begin market expansion studies and progress Cardiocel with cellular therapies, as well as expand the regenerative tissue portfolio, complete preclinical human papillomavirus therapeutic vaccine program, begin the herpes simplex virus-2 phase II clinical study and increase revenues.
Admedus was unchanged at 13.5 cents with 3.3 million shares traded.