Biotech Daily

Tuesday May 16, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: FACTOR THERA UP 11%, IMPEDIMED DOWN 7%**

*** ACTINOGEN TREATS 1st XANAMEM ALZHEIMER'S PATIENT**

*** ARAVAX STARTS PHASE I PVX108 FOR PEANUT ALLERGY TRIAL**

*** CYNATA TREATS 1st CYP-001 STEM CELL GVHD PATIENT**

*** FIL, ASSOCIATES TAKE 5% OF FACTOR THERAPEUTICS**

*** LIVING CELL, AUCKLAND UNI NEURO-DEGENERATION COLLABORATION**

*** IMMURON, US DEFENSE COLLABORATE ON RESISTANT SHIGELLA**

*** ANTEO APPOINTS ALAN STUDLEY DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.21 percent on Tuesday May 16, 2017 with the ASX200 up 12.1 points to 5,850.5 points.

Nine of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and three were untraded.

Factor Therapeutics was the best, up 0.6 cents or 10.5 percent to 6.3 cents with 627,496 shares traded.

Neuren and Living Cell climbed more than four percent; Reva was up 3.4 percent; Opthea rose 2.35 percent; Bionomics, Cochlear and Compumedics were up more than one percent; with Ellex, Medical Developments and Resmed up by less than one percent.

Impedimed led the falls, down 4.5 cents or 7.4 percent to 56 cents with 1.6 million shares traded.

Actinogen, Benitec and Prana lost more than six percent; ITL and Mesoblast fell five percent or more; Sirtex shed 4.2 percent; Avita, Orthocell, Pro Medicus and Starpharma were down more than three percent; Universal Biosensors and Uscom shed more than two percent; Admedus, Clinuvel and Viralytics were down more than one percent; with CSL and Nanosonics down by less than one percent.

ACTINOGEN MEDICAL

Actinogen says it has treated the first patient in its 174-patient Xanadu phase II trial of Xanamem for Alzheimer's disease.

Actinogen said the first patient was treated at the East Gosford, New South Wales–based Central Coast Neurosciences Research site in a trial expected to enrol patients at 20 sites in Australia, the US and UK, with top-line results expected by April 2019.

The company said that the treatment was "a significant milestone" following more than a decade of research at Edinburgh University and at Actinogen to develop Xanamem for Alzheimer's disease".

Actinogen said Xanamem was designed to block excess cortisol production in the brain, a hormone produced in times of stress and with "a growing body of independent research that shows a strong association between excess cortisol and Alzheimer's disease".

The company said the Australian Imaging, Biomarker and Lifestyle (AIBL) ageing study showed "promising evidence for the potential of cortisol inhibition to prevent the cognitive decline of Alzheimer's disease".

Actinogen scientific advisory board member and AIBL co-author Prof Colin Masters said the study showed that raised cortisol was "strongly associated with the development of Alzheimer's disease" and Xanamem could be a major advance for Alzheimer's.

Macquarie University professor of neurobiology Prof Ralph Martins said the evidence linking raised cortisol and the development of Alzheimer's disease was "very compelling".

"If the results from Xanadu prove positive, Xanamem could be the blockbuster Alzheimer's drug that the world has been waiting for," Prof Martins said.

Actinogen fell half a cent or 6.25 percent to 7.5 cents with 2.4 million shares traded.

ARAVAX

Melbourne's Aravax says it has dosed the first two patients in its 48-patient, phase I, dose-escalation stage of PVX108 for peanut allergy.

Aravax said that the double-blinded and placebo-controlled trial began dosing last week, with the first group of subjects safely receiving the lowest dose of PVX108, which used selected fragments of peanut proteins to switch off allergic reactions.

The company said that the second stage of the trial would test PVX108 on 18 patients and it expected monthly injections would be sufficient to achieve a clinical benefit, with final results by the end of 2018.

Aravax said the trial was being conducted at Adelaide's CMax Clinical Research facility and at the Nucleus Network at Melbourne's Alfred Hospital and its technology was underpinned by more than 10 years of research led by the Alfred Health and Monash University team led by Prof Robyn O'Hehir.

The company said that peanut allergy affected two percent of people worldwide and every year about 40 percent of peanut allergic individuals would have a serious adverse event from inadvertent exposure, including anaphylaxis which could lead to death.

Aravax said it was funded by $4.85 million from the Brandon Capital-managed Medical Research Commercialisation Fund, with support from the Food Allergy Foundation, the Alfred Hospital Trust and the National Health and Medical Research Council.

Aravax chief executive officer Dr Pascal Hickey said the company wanted "to help people around the world who suffer from peanut allergy to live stress-free lives without constantly fearing a major health event from accidental consumption".

"Our technology aims to alleviate that stress by reprogramming the immune system to tolerate peanuts," Dr Hickey said.

Aravax is a private company.

CYNATA THERAPEUTICS

Cynata says it has treated the first of up to 16 patients in its phase I trial of CYP-001 mesenchymal stem cells for steroid-resistant acute graft versus host disease.
Cynata said that patients at several major transplant centres in the UK and Australia would receive two infusions of CYP-001, with a week between doses.
The company said the first patient was treated at one of the UK centres and the start of the trial was “a milestone … and is the first time in the world that a patient has been treated with an allogeneic, induced pluripotent stem cell-derived therapeutic [mesenchymal stem cell] product” sourced from a single blood donation from one donor.
Cynata said that CYP-001 was manufactured in a scalable process using its Cymerus platform with induced pluripotent stem cells as the starting material, sourcing its stem cells from Fujifilm subsidiary, the Madison, Wisconsin-based Cellular Dynamics International.
The company said it had a strategic alliance with Tokyo’s Fujifilm.
Cynata said the stem cells “were derived from a single blood donation using a non-viral, non-integrating episomal reprogramming method, without genome modification” a process which overcame the need to source multiple donors and inherent variability in products.
The company said that graft versus host disease often followed a bone marrow transplant or similar procedure and occurred when the immune cells in the donor material, or the graft, attacked the recipient’s tissues, or the host, as foreign.
Cynata said that bone marrow transplants were used in for certain cancers including leukaemia, with corticosteroids the current treatment, but were often not effective, with steroid-resistant graft versus host disease mortality rates as high as 80 percent.
UK chief investigator and Manchester’s Christie Hospital consultant haematologist Dr Adrian Bloor said that treatment of steroid-resistant graft versus host disease was “one of the major challenges in management of patients undergoing bone marrow transplantation”.
“A number of previous studies have demonstrated that [mesenchymal stem cells] can be an effective treatment, but producing consistent [mesenchymal stem cells] in sufficient numbers for clinical use has been a major challenge until now,” Dr Bloor said.
Last year, Mesoblast launched its mesenchymal stem cell Temcell product for graft versus host disease, acquired from Osiris, in Japan (BD: Oct 11, 2013; Feb 4, 2016).
Today, Cynata chief executive officer Dr Ross Macdonald said the trial was “another major milestone and value catalyst for the company”.
“Our Cymerus technology eliminates the reliance upon multiple donors and the need to excessively expand [mesenchymal stem cells] derived from them,” Dr Macdonald said.
“Cynata is truly at the forefront of the industry with a sustainable and robust manufacturing process for therapeutic [mesenchymal stem cell] products,” Dr Macdonald said.
Cynata fell one cent or 1.75 percent to 56 cents.

FACTOR THERAPEUTICS

The Hong Kong-based FIL Investment Management says it has become a substantial shareholder in Factor Therapeutics with 37,583,718 shares or 5.15 percent.
The substantial shareholder notice said that the between February 8 and May 11, 2017, it bought 37,583,718 shares at prices ranging from 5.4 cents to 7.3 cents.
FIL said the custodians of the shares were Brown Bros Harrimen, Master Trust Bank of Japan and Clearstream Banking SA.
Factor Therapeutics was up 0.6 cents or 10.5 percent to 6.3 cents.

LIVING CELL TECHNOLOGIES

Living Cell says it has a research collaboration with the University of Auckland aiming to reverse human brain neuro-degenerative processes associated with pericytes.

Living Cell said the collaboration with the University's Centre for Brain Research would explore how its encapsulated pig cell products could reverse human brain neuro-degenerative processes associated with pericytes, which helped sustain the blood-brain barrier and other homeostatic and haemostatic functions in the brain.

The company said the agreement would extend the pipeline for its NTCell encapsulated pig choroid brain cells, currently in a trial for Parkinson's disease, by examining the effects of NTCell on human brain cell cultures with Alzheimer's disease and Huntington's disease.

Living Cell said the collaboration would identify other encapsulated cell therapies which might have potential to treat neuro-degenerative disorders by examining whether they could promote neuro-protective effects in the brain.

The company said that the research would be conducted by the University's commercial research company Auckland Uniservices, using its Neurovalida drug testing and drug target validation platform developed by the Centre for Brain Research's Prof Mike Dragunow, Prof Richard Faull and Prof Maurice Curtis to provide human brain-based neuroscience research collaborations, partnerships and services.

Living Cell chief executive officer Dr Ken Taylor said animal models were "of limited use" in discovering new treatments for neuro-degenerative diseases.

"The availability of human tissue cell cultures such as pericytes and other human brain cells eliminates that problem," Dr Taylor said.

Prof Faull said his group had been working with Living Cell "with the goal of defining a treatment-directed research project that brings together their expertize in the clinical development of cell-based therapies and our expertise in identifying targets from our knowledge and availability of human brain tissue".

Living Cell was up half a cent or 4.2 percent to 12.5 cents.

IMMURON

Immuron says it will expand its US Department of Defense agreement to include three fluoroquinolone-resistant Shigella-specific anti-microbial therapeutics.

Immuron said the development agreement was with the Silver Spring, Maryland-based, Walter Reed Army Institute of Research which would fund the evaluation of the anti-Shigella-specific activity of its antibodies, including assessing their protective capacity in established mouse and guinea pig models.

Shigella is a gram negative bacteria related to Escherichia coli.

The company said that the Bangkok, Thailand-based US Armed Forces Research Institute of Medical Sciences would fund and perform the evaluation of the three Shigella-specific therapeutics in non-human primate studies.

Immuron said that Shigella was a virulent organism that could cause disease in humans at low doses, with exposure to as little as 10 to 100 bacteria causing disease, and easily spread with infection characterized by the ability of Shigella to invade the mucosal epithelium, replicate intra-cellularly and spread inter-cellularly.

Immuron chief operating and scientific officer Dr Jerry Kanellos said the "rampant occurrence of antibiotic resistance in Shigella and the high incidence of this disease, underscores the need for the development of new non-antibiotic therapeutics".

The company said that fluoroquinolone-resistant Shigella caused about 165 million cases of severe dysentery globally every year, resulting in more than a million deaths each year.

Immuron was up two cents or 3.5 percent to 59 cents.

ANTEO DIAGNOSTICS

Anteo says it has appointed Alan Studley as an independent non-executive director.
Anteo said that Mr Studley had more than 30 years' experience in management and as a director of public, private and not-for-profit organisations across a range of industries, including public health, media and communications, superannuation, manufacturing and technology.
The company said that Mr Studley was the executive chairman of Revenue Clearing House Pty Ltd, Sausage Software chief operating officer, the executive director of the Women's and Children's Healthcare Network; Point Nepean Community Trust chief executive officer and HDM Mattingly Pty Ltd financial director.
Anteo said that Mr studley was currently a non-executive director of Access Health and the Australian and New Zealand Gastroenterological International Training Association and previously held directorships with Health Super, Victoria's Metropolitan Ambulance Service, Sausage Software and Methodist Ladies' College.
The company said that Mr Studley held a Masters of Business Administration.
Anteo was unchanged at three cents with 1.9 million shares traded.