Biotech Daily

Tuesday March 7, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: MESOBLAST UP 10%, USCOM DOWN 11%**

*** METABLOQ, CENTENARY DRUG TO 'BLOCK CANCER METABOLISM'**

*** BURNET RE-ENGINEERS HEPATITIS C PROTEIN FOR VACCINE**

*** GBS: 'OTSUKA $329m+ DEAL FOR NEUROVANCE FOR ADHD'**

*** ANTEO, COOK DEVELOP COATINGS FOR IMPLANTABLE DEVICES**

*** PARADIGM PHASE II PPS TRIAL FOR ROSS RIVER VIRUS**

*** AVITA COMPLETES PIVOTAL US BURNS TRIAL TREATMENT**

*** MESOBLAST: FDA FAST-TRACK FOR MSC-100-IV FOR PAEDIATRIC GVHD**

*** IMPEDIMED SOZO PASSES TESTS, 1st INSTALLED AT SCRIPPS HEALTH**

*** PSIVIDA FEASIBILITY STUDY WITH UNNAMED COMPANY**

*** INNATE NAMES MIS416 FOR MS MECHANISM-OF-ACTION ABSTRACTS**

*** GBS REDUCES, DILUTED TO 17% OF AIRXPANDERS**

*** CRESO, DOMACO CANNIBINOIDS FOR HUMAN, PET FOOD ADDITIVES**

*** GI DYNAMICS: PROF CAREL LE ROUX, PROF JAN GREVE ADVISERS**

MARKET REPORT

The Australian stock market was up 0.26 percent on Tuesday March 7, 2017 with the ASX200 up 14.9 points to 5,761.4 points. Ten of the Biotech Daily Top 40 stocks were up, 15 fell, 14 traded unchanged and one was untraded.

Mesoblast was the best, up 17 cents or 9.6 percent to $1.94 with 1.4 million shares traded. Viralytics climbed 9.5 percent; Neuren was up 7.9 percent; Living Cell was up five percent; Avita improved 4.8 percent; Compumedics was up 3.1 percent; Cochlear, CSL, Impedimed, Nanosonics and Polynovo rose more than one percent; with Clinuvel up 0.15 percent.

Uscom led the falls, down 2.5 cents or 11.4 percent to 19.5 cents with 552,500 shares traded. IDT lost 6.45 percent; Benitec fell 5.9 percent; Ellex fell 4.2 percent; Cellmid, Prima and Psivida were down more than three percent; Airxpanders and Orthocell shed more than two percent; Atcor; Genetic Signatures and ITL were down more than one percent; with Resmed, Reva, Sirtex and Starpharma down by less than one percent.

METABLOQ PTY LTD, CENTENARY INSTITUTE

Metabloq says it has acquired and hopes to develop cancer metabolism-blocking technology from Sydney's Centenary Institute

Metabloq chief executive officer Dr Chris Burns told Biotech Daily that the intellectual property over cancer metabolism and how to block the metabolism was acquired from the Centenary Institute, with Metabloq financially supported by the Brandon Capital-managed Medical Research Commercialization Fund, Uniseed and the Commonwealth Scientific and Industrial Research Organisation.

A media release from the Centenary Institute said that the "potentially game-changing drugs block metabolic processes critical to cancer cells and are currently in the early stages of development" with clinical trials expected to begin "within three years".

The Centenary Institute said that its scientists had discovered links between cancer and its metabolism of nutrients and developed a method of starving cancer cells but not normal cells, essentially cutting the energy supply to the diseased cell.

The Institute said that a study led by Prof Jeff Holst discovered "an important role for a protein involved in the metabolism of certain cancer cells … vital for helping them survive and grow".

"If we are able to specifically block the supply of nutrients to cancer cells by inhibiting the function of this protein, we can essentially starve the cells and stop them from growing," Prof Jeff Holst said.

The media release did not identify the protein but said that a collaboration with University of Sydney researchers identified molecules that blocked the action of the unnamed protein and were being developed as possible new drugs.

Dr Burns said that the initial scientific discovery "would not have been possible without support for the basic research through the Centenary Institute, University of Sydney and [New South Wales] Ministry of Health".

Metabloq is a private company

THE BURNET INSTITUTE

The Burnet Institute says its researchers have re-engineered the major protein of the hepatitis C virus to develop a preventive vaccine.

The Institute said that re-engineering the protein would expose the virus more effectively to attack by the human immune system, an important step towards the development of a vaccine.

The Burnet said that the research, led by Prof Heidi Drummer and published in the journal Hepatology, demonstrated how to overcome hepatitis C's ability to trick the immune system into producing antibodies that hinder an effective immune response.

"What we've done is to redirect the immune response to the parts of the virus that you want the immune system to see, and those are the parts that generate broadly cross-reactive antibodies effective against all seven circulating genotypes of virus," Prof Drummer said.

"We're redirecting the focus of the immune response away from regions of the virus that generate antibodies that are not only ineffective, but which block the effectiveness of the desirable antibodies," Prof Drummer said.

"It's the first time this has been demonstrated in [hepatitis c] that you can actually re-engineer the surface protein to generate a profoundly different immune response that is now cross-reactive and blocks the virus from entering cells," Prof Drummer said.

"That gives us a lead that we can work with to produce a vaccine candidate that's going to be amenable for a clinical trial," Prof Drummer said.

GBS VENTURE PARTNERS

GBS Ventures says Otsuka will acquire Neurovance and its attention-deficit hyperactivity disorder drug for potentially more than $US250 million ($A329.2 million).

GBS managing partner Brigitte Smith told Biotech Daily that the Cambridge, Massachusetts-based Neurovance had developed centanafadine, formerly known as EB-1020, for attention-deficit hyperactivity disorder (ADHD).

Ms Smith said that Neurovance was established in 2011 as a spin-off from Euthymics Bioscience and GBS had invested about $9 million in the company and owned about 15 percent of Neurovance.

Ms Smith said that the Tokyo, Japan-based Otsuka Pharmaceutical Co would pay a $US100 million upfront fee, a further $US150 million in regulatory and development milestones with further payments contingent on sales.

Ms Smith said that centanafadine had “stimulant-like efficacy without being a stimulant”.

Ms Smith said that centanafadine was a triple reuptake inhibitor designed to modulate the activity of norepinephrine, dopamine and serotonin in a specific ratio to improve focus, attention and specific higher-level cognitive skills in patients with attention-deficit hyperactivity disorder.

She said that centanafadine showed improvements in symptoms in a phase IIb study in adults with ADHD similar to those seen in prior studies with stimulants.

“The drug showed rates of insomnia and loss of appetite less than typically seen with stimulants,” Ms Smith said.

Ms Smith said that Neurovance had raised about $US35 million from investors including GBS, Novartis Venture Fund, Venture Investors, Tekla Capital Management, the State of Wisconsin Investment Board and Timothy J Barberich.

ANTEO DIAGNOSTICS

Anteo says it has completed a feasibility with Cook Medical Australia to incorporate its Mix&Go technology in in-vivo medical devices (BD: Mar 25, 2015).

Anteo did not describe the device or devices but said “the study outcomes were compelling” and a verification study with the Australian division of the Bloomington, Indiana-based Cook Medical was due to begin by July 2017.

The company said that the study was “an important milestone in the commercialization approach taken to fast track the deployment of the technology to in-vivo medical devices”.

Anteo said it would undertake research and development, chemistry refinement and expansion of its intellectual property portfolio and had “embarked on an extensive internal program to re-formulate its chemistry with starting materials known to be safe for human use and compatible with in-vivo applications”.

Anteo chief executive officer Dr Jef Vangenechten said the “innovation arm has made significant progress in furthering work with partners on a number of medical device applications including implantable devices, in-vivo use medical devices and medical imaging”.

“The collaboration with Cook Medical Australia has been constructive to date and we welcome the opportunity to continue with the program of works planned”, Dr Vangenechten said.

Anteo said it wanted to provide functional nanometre-thin coatings and binders across multiple industries and applications and the medical coatings market was projected to reach $US13.23 billion by 2019.

Anteo was unchanged at 3.7 cents with 1.1 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it hopes to start a 24-patient phase II trial of pentosan polysulfate sodium for Ross River virus in Queensland and Victoria in June 2017.

Paradigm said that pentosan polysulfate sodium, or PPS, had both anti-coagulative and anti-inflammatory effects and had been in use since the 1940s to prevent the formation of platelets during pre-operative procedures, as well as to treat bladder pain.

The company said the potential for PPS to be used as a treatment for Ross River virus was discovered by the Brisbane-based Griffith University scientist Dr Lara Herrero, who had contracted the disease.

“For decades patients have suffered from the debilitating arthritic pain caused by [Ross River virus] infection, only to be told by their treating doctors that there is nothing that can be done,” Dr Herrero said.

Paradigm said that Dr Herrero’s research at Griffith University’s Institute for Glycomics showed promising results that PPS could halt the progress of Ross River virus-induced disease in mice, reducing the duration and severity of clinical signs and symptoms.

The company said the mouse model showed that PPS significantly decreased joint and muscle pathology and reduced the complications of viral arthritis such as chronic joint signs and cartilage breakdown.

The research paper, entitled ‘Pentosan Polysulfate: a Novel Glycosaminoglycan-Like Molecule for Effective Treatment of AlphavirusInduced Cartilage Destruction and Inflammatory Disease’ was published in the Journal of Virology in 2015, with an abstract available at: https://www.ncbi.nlm.nih.gov/pubmed/26018160.

Paradigm said that Ross River virus and chikungunya were alphavirus infections transmitted by mosquitoes that led to a range of debilitating symptoms and signs such as joint swelling, fatigue, fever and severe joint pain that could progress into chronic arthritis.

The company said that current treatment was anti-inflammatories and corticosteroids to provide symptomatic pain relief, which reversed when the medication stopped.

Paradigm chief executive officer Paul Rennie said that by repurposing and testing an existing drug, the company hoped to make an effective treatment for Ross River virus available much sooner than expected.

Paradigm was up half a cent or 1.3 percent to 40 cents.

AVITA MEDICAL

Avita says that long-term follow-up data has been collected on the last of 27 patients in its pivotal US Food and Drug Administration trial of Recell for burns.

Avita said that the 52-week follow-up marked the completion of the trial, which began in January 2015 and the company had the necessary clinical data to conduct the analyses for a pre-market approval application (BD: Jan 28, 2015).

The company said it had been given “updated guidance” by the FDA on preparation of materials for shelf-life stability testing, which would delay the application by three months.

Avita said that Recell shelf-life stability data was expected to be available in June 2017, with the application filed “soon after”.

The company said the FDA made decisions on 90 percent of submissions requiring advisory committee input within 320 days, with a decision expected by July 2018.

Avita said that 30 patients five years and older with burn injuries sufficiently deep to require auto-grafting were recruited, with 27 completing 52-weeks of follow-up.

Avita chief executive officer Adam Kelliher said “the most challenging part of the process is now behind us”.

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

MESOBLAST

Mesoblast says the US Food and Drug Administration has granted fast track designation for MSC-100-IV for paediatric graft versus host disease.
Mesoblast said that the designation had the potential to shorten the time to FDA approval of MSC-100-IV for this indication through priority review, shortening the review process from 10 to six months, and a streamlined rolling review process.
The company said that the mesenchymal stem cell product candidate's existing orphan designation might lead to potential commercial benefits following FDA approval.
Mesoblast said that its application for fast track status was supported by the clinical data in 241 paediatric patients with steroid refractory acute graft versus host disease (GVHD) who were treated on a single expanded access protocol with MSC-100-IV.
The company said that the overall response rate at day-28 in this group was 65 percent and day-100 survival was significantly improved in children who achieved an overall response at day-28.
Mesoblast said results from the expanded access protocol were used in discussions with the FDA that established the accelerated development pathway for MSC-100-IV as front-line therapy in children with steroid-refractory acute GVHD and the company believed that a single open-label phase III trial would be sufficient for conditional FDA approval.
Last year, Mesoblast said that the on-going 60-patient open label phase III registration trial of MSC-100-IV in children with steroid refractory acute GVHD was successful in a pre-specified interim futility analysis using the trial's primary endpoint of day-28 overall responses (BD: Nov 14, 2016).
Mesoblast said it was involved in exclusive negotiations with Mallinckrodt Pharmaceuticals for a commercial and development partnership to develop product candidates for paediatric and adult acute GVHD outside Japan and China (BD: Dec 23, 2016).
The company said that MSC-100-IV was marketed as Temcell HS for acute GVHD in children and adults in Japan by licensee, JCR Pharmaceuticals.
Mesoblast climbed 17 cents or 9.6 percent to $1.94 with 1.4 million shares traded.

IMPEDIMED

Impedimed says its Sozo bio-impedance spectroscopy device for measuring body fluid status has cleared safety and as system performance testing.
Impedimed said that the first Sozo unit had been placed at the San Diegao, California-based Scripps Health.
The company said that Scripps would use the Sozo in an initial study for monitoring patients with chronic heart failure in a clinical setting, to provide real-world data.
Impedimed said that the data was expected to be generated by mid-year and form the basis of the design of the larger scale trial expected to begin in mid-2017.
The company said that with the completion of safety and performance testing it expected to file its US Food and Drug Administration 510(k) clearance application in mid-2017, with Conformité Européenne (CE) mark expected "in the coming months" and a European launch by the end of 2017.
Impedimed chief executive officer Richard Carreon said that enrolment in the cardiac study would begin "shortly" and it was designed to use the Sozo to measure fluid levels in class III congestive heart failure patients and if successful, the Sozo would provide an early warning system for cardiac de-compensation with the potential to optimize patient care and significantly reduce hospital readmissions.
Impedimed was up one cent or 1.45 percent to 70 cents with 1.4 million shares traded.

PSIVIDA CORP

Psivida says it has a funded feasibility study agreement for its Durasert sustained release drug technology with an unnamed “bio-pharmaceutical company”.
Psivida said that in the first phase of the work plan Durasert would be formulated with “certain of the bio-pharmaceutical company’s proprietary molecules to determine potential pre-clinical benefits”.
The company said that pending results of the formulation research, the bio-pharmaceutical company might elect to proceed with the second phase of the pre-clinical work plan, which would involve combining Durasert with one or more of the proprietary molecules evaluated in the first phase.
Psivida fell seven cents or 3.1 percent to $2.21.

INNATE IMMUNOTHERAPEUTICS

Innate says that six abstracts relating to its MIS416 mechanism of action have been accepted for presentation at the American Academy of Neurologists meeting.
Innate said the abstracts from Australian, Canadian and Danish collaborators on MIS416’s mechanism of action, for patients with secondary progressive multiple sclerosis, would be presented at the meeting in Boston in late April, 2017.
Innate director Robert Peach said that the acceptance of the abstracts “indicates strong scientific interest in Innate’s understanding of the MIS416 mechanism of action”.
Innate said that the data demonstrated that MIS416 effectively engaged two distinct and complementary signalling pathways which were master controllers of immune system homeostasis.
Innate chief scientific officer Gill Webster said the data identified that engagement of both these pathways was central to the MIS416 treatment effect in neuro-inflammation which was “a unique feature of MIS416 compared to other immune modulators previously trialled in progressive multiple sclerosis”.
The company said that the abstracts were entitled: ‘Kynurenine pathway profiling in phase IIa trial secondary progressive multiple Sclerosis patients treated with a myeloid directed innate immune modulator MIS416’; ‘Evaluation of neurological improvements in secondary progressive multiple sclerosis patients treated with myeloid targeted immune modulator MIS416’; ‘MIS416, a myeloid targeted immune modulator for the treatment of secondary progressive multiple sclerosis acts directly within the CNS to induce Type I IFN and suppress neuroinflammation’; ‘Neuroprotective/Neuroreparative activity of MIS416, a myeloid-directed innate immune therapeutic in Phase 2B trial for the treatment of secondary progressive multiple sclerosis’; and ‘Modulation of post-traumatic epilepsy by MIS416, a novel innate immune modulator for the treatment of neuroinflammation’.
Innate fell 2.5 cents or 3.9 percent to 61 cents.

AIRXPANDERS

GBS Venture Partners says it has reduced its holding in Airxpanders and has been diluted through a placement from 20.33 percent to 16.85 percent
GBS said it previously held the equivalent of 48,306,735 Chess depository instruments (CDIs) and had reduced to the equivalent to 44,804,359 CDIs.
In January, Airxpanders said it would raise $45 million in a private placement at 92 cents per CDIs (BD: 27, 2017).
Today, GBS did not state the sale price of the stock.
Airxpanders fell two cents or 2.4 percent to 82 cents.

CRESO PHARMA

Creso says it has a binding letter of intent with the Lengnau, Switzerland-based Domaco Dr med Aufdermaur AG for cannabinoid food additives.
Creso said that Domaco was a European producer for companies such as Blackmores, Bayer, Danone and Angelini and was a manufacturer specializing in buccal, or mouth, delivery technologies.
The company said that the agreement covered the development, manufacture and commercialization of two cannabinoid food additives for humans and the agreement included development of an animal health food additive for pets.
Creso said that the human food additives targetted anxiety, stress and bone metabolism disorders, specifically osteoporosis and osteoarthritis, while the pet product would target conditions including behavior disorders, chronic pain, inflammation, arthritis and metabolic conditions such as diabetes.
Creso climbed eight cents or 20.8 percent to 46.5 cents with 6.9 million shares traded.

GI DYNAMICS

GI Dynamics says it has appointed Prof Carel Le Roux and Prof Jan Willem Greve as the first two members of its scientific advisory board.
GI Dynamics said that Prof Le Roux was an endocrinologist and was a primary investigator on two trials of the company's Endobarrier duodenal implant for obesity and type 2 diabetes.
The company said that Prof Le Roux was experienced bariatric and metabolic surgeon and was the head of pathology at University College Dublin, Ireland.
GI Dynamics said that Prof Le Roux held a Bachelor of Medicine and Bachelor of Surgery from the University of Pretoria, South Africa and a Doctorate of Philosophy from Imperial College London.
The company said that Prof Greve serves was the medical director of the Dutch Obesity Clinics South and chair of the metabolic and bariatric surgery unit at the Zuyderland Medical Center in the Netherlands.
GI Dynamics said that Prof Greve held a Doctorate of Philosophy from the Maastricht, Netherlands-based Academic Hospital and had authored more than 185 peer-reviewed papers and numerous book chapters on intensive care medicine, nutrition and bariatric and metabolic surgery.
GI Dynamics fell 0.4 cents or 8.9 percent to 4.1 cents with 4.8 million cents.