Biotech Daily

Monday November 7, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AIRXPANDERS UP 13%, CELLMID DOWN 9%**

*** INNATE: 'MOST MS PATIENTS WANT MIS416 OPEN ACCESS TREATMENT'**

*** ITL SELLS 1m DONORCARE NEEDLE GUARD 2 IN 1st MONTH**

*** FDA REMOVES FACTOR THERAPEUTICS VF-001 HOLD, TRIAL OK**

*** SIRTEX CEO GILMAN WONG: 'I SOLD SHARES TO PAY TAX ON RIGHTS'**

*** IMUGENE STARTS HER-VAXX ASIA GASTRIC CANCER TRIAL**

*** MEDLAB PREPARES NANABIS CANNABIS CANCER PAIN TRIAL**

*** MGC STARTS EURO CANNABIDIOL SKIN TREATMENT REGISTRATION**

*** CRESO, GREVELING, A&H MARIJUANA DEAL FOR PET HEALTH**

*** PLATINUM TAKES 9% OF IMUGENE**

*** DIMERIX APPOINTS G-M KATHY HARRISON CEO**

MARKET REPORT

The Australian stock market recovered 1.35 percent on Monday November 7, 2016 with the ASX200 up 70.0 points to 5,250.8 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and two were untraded. All Big Caps rose.

Airxpanders was the best, up 15 cents or 12.8 percent to $1.32 with 330,661 shares traded. Factor Therapeutics climbed 9.2 percent; Acrux, Actinogen and Oncosil improved more than four percent; Atcor, Benitec and Genetic Signatures were up more than three percent; Bionomics, Compumedics, Ellex, Nanosonics and Resmed rose more than two percent; Cochlear, CSL and Pharmaxis were up more than one percent; with Cyclopharm, Impedimed, Mesoblast and Sirtex up by less than one percent.

Cellmid led the falls, down 0.3 cents or 9.4 percent to 2.9 cents with 3.4 million shares traded.

Clinuvel lost 5.6 percent; Pro Medicus and Universal Biosensors fell more than four percent; Avita and Opthea were down more than three percent; Orthocell and Osprey shed more than two percent; Admedus and Starpharma were down more than one percent; with Medical Developments and Viralytics down by less than one percent.

INNATE IMMUNOTHERAPEUTICS

Innate says that more than 90 percent of secondary progressive multiple sclerosis patients who completed its MIS416 phase IIb trial have requested open-label access.
Innate said that the 12-month randomized, placebo-controlled, double-blind trial completed enrolment of 93 patients in April (BD: Apr 13, May 24, 2016).
Today, the company said that the last patient was expected to complete all study related visits in early May 2017 with the trial report expected about four months later.
Innate said that to date it had received requests from 44 patients wanting access to MIS416 having completed or about to complete the trial.
The company said that as part of gaining ethics approvals for the trial, it undertook to make MIS416 available to all patients who completed the study and who, with the support of their doctor, wanted access to the unapproved drug.
Innate chief executive officer Simon Wilkinson said “the strong interest from almost all the patients who have completed the trial so far is very encouraging indeed”.
“Liaising with the patients, the trial sites, the patient's doctors and the regulators is generating a lot of work for our small team but is extremely rewarding at the same time,” Mr Wilkinson said.
Innate said that in Australia, post-trial open-label access was under the Therapeutic Goods Authority’s special access scheme and in New Zealand was under the Medicines Act.
The company said that to help monitor the risks and benefits of the continued use of an unapproved medicine, it would be collecting the results of on-going blood sample safety analysis together with three-monthly patient-reported efficacy-related outcomes.
Innate said that the patient-reported outcomes comprised the Short Form Health Survey; the MS Impact Scale; the Neurological Fatigue Index for MS; and the Brief Pain Inventory, which were also used in assessing the phase IIb trial.
The company said that patients accessing MIS416 after their completion of the phase IIb trial would join 18 patients in New Zealand who had been using MIS416 on compassionate use grounds for up to eight years.
Innate said that 70 percent of the New Zealand patients reported a significant improvement in their activities of daily living which they attributed to MIS416 treatment.
Innate was up seven cents or 12.5 percent to 63 cents.

ITL

ITL says that since the mid-October launch, it has sold more than one million Donorcare Needle Guard 2 packs.
ITL said that its biomedical division had launched its innovative and patented Donorcare Needle Guard 2 in the US and Canada, with additional customer evaluations being carried out in other geographic regions.
The company said that it had sold more than 200 million packs of its first generation Donorcare Needle Guard in more than 50 countries over 15 years.
ITL said that the Donorcare Needle Guard 2 had “robust functionality with enhanced features including visual confirmation that the needle is safely locked in place, along with an audible click”.
ITL chairman Bill Mobbs said it was “a great achievement by the team to have made such significant sales in important jurisdictions in such a short period of time”.
ITL was up three cents or 13.0 percent to 26 cents.

IMUGENE

Imugene says it has begun its phase Ib/II clinical study of HER-Vaxx for gastric cancer (BD: Oct 23, 2013).

In February, Imugene chief operating officer Leslie Chong said Imugene was the only company in the world to develop the technology to activate B-cells which she described as "like antibody factories" to attack cancer cells, (BD: Feb 24, 2016).

Ms Chong said at that time that with the Medical University of Vienna, the technology had been optimized to incorporate three B-cell epitopes into a single peptide, delivery systems were changed and an adjuvant added, leading to a 10-fold increase in antibody response and a 10-patient, phase I trial in Vienna in 2009 showed responses in eight of the 10 patients with the technology developed significantly since Imugene acquired it (BD: Oct 23, 2013; Jan 25, 2016).

Today the company said that gastric cancer patients would be screened and enrolled at eight key sites in Asia, including Hong Kong, Thailand and Taiwan.

Imugene said that the up to 18-patient phase Ib trial was an open-label, multicentre, dose-escalation study, designed to assess the safety, tolerability and immunogenicity, which would show how well the vaccine was directing production of HER2 antibodies in patients.

The company said the combination HER-Vaxx and chemotherapy trial would interrogate three dose levels and evaluate the booster schedule to help determine the optimal recommended dosing for the phase II study.

Imugene said that the 68-patient, open-label phase II study would recruit patients with metastatic gastric cancer overexpressing HER2 with patients randomized to either HER-Vaxx plus chemotherapy or chemotherapy alone.

Ms Chong said the trial start was "a significant milestone for Imugene and gastric cancer patients, especially across South East Asia".

Imugene said gastric cancer was a leading cause of cancer death worldwide, representing 10.1 percent of male cases and its incidence was substantially higher in Asia.

"We are confident that HER-Vaxx could fill a significant unmet medical need in gastric cancer, particularly in Asia," Ms Chong said.

Imugene fell 0.1 cents or 10.0 percent to 0.9 cents with eight million shares traded.

FACTOR THERAPEUTICS

Factor Therapeutics says the US Food and Drug Administration has removed the clinical hold on VF-001 for wound treatment, following a submission review (BD: Oct 10, 2016).

Factor said the clinical hold removal meant that it was permitted to proceed with its 168-patient, phase II trial of VF-001 for venous leg ulcers as planned (BD: Jul 25, 2016).

Factor chief executive officer Nigel Johnson said the FDA notice was "a major turning point for the company … and paves the way for us to commence patient recruitment in the US for our phase II trial of VF-001 in venous leg ulcers in the very near future".

Factor was up 0.6 cents or 9.2 percent to 7.1 cents with 2.2 million shares traded.

SIRTEX MEDICAL

Sirtex chief executive officer Gilman Wong says he sold 74,968 of his 274,968 shares that "to cover the tax incurred in relation to the recently vested tranche of rights".

"This was in line with my normal practice of the past three years," Mr Wong said.

The Sirtex annual general meeting approved the issue of 62,881 'performance' rights issuable and exercisable at no cost (BD: Sep 21, 2016).

Sirtex was up 16 cents or 0.6 percent to $27.11 with 189,458 shares traded.

MEDLAB CLINICAL

Medlab says it is “preparing to start Australia’s first clinical trial using cannabis for oncology patients suffering intractable pain”.
Medlab managing director Sean Hall, told shareholders that the trial with cannabis would take place at Royal North Shore Hospital in Sydney under the supervision of medical oncologist and palliative medicine specialist Prof Stephen Clarke.
The company said that the trial was subject to hospital ethics approval and granting of a clinical trial number from the Federal Health Department through the Therapeutic Goods Administration, both of which were expected “in coming months”.
Medlab said that the trial would use a formulation of the two most-known cannabis extracts cannabidiol and tetrahydrocannabinol, administered by the Nanocelle mouth spray delivery system.
Medlab said that its Nanabis cannabis formulation would be a Schedule 8 drug as a controlled substance, will be manufactured at a good manufacturing practice facility in Melbourne.
The company said that cancer pain was prevalent in 64 percent of patients with metastatic or advanced stage disease and that for one in two patients with cancer, pain was undertreated.
Medlab said that the cannabis-derived Nanabis was expected to be available within the next 12 months.
Medlab said that apart from its cannabis application, its initial Nanocelle work had been with statins, which were off-patent and do not require phased clinical trials.
The company said that it had conducted blood tests with Nanocelle showing superior absorption and utilisation of medicine by the body, with the next steps to test Nanocelle in bioequivalent studies.
Medlab said that Nanocelle was also being developed in prototype with 23 other active pharmaceutical ingredients, allowing for multiple commercialisation opportunities.
Medlab fell 0.5 cents or 0.8 percent to 59.5 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has begun European registration of its cannabidiol-based dermatological treatment products for acne, psoriasis and seborrhoea.
MGC said that registration was through the European Cosmetics Products Notification Portal and followed completion of the required safety assessments, including microbiology tests and a skin patch tests on 30 human volunteers, which showed no adverse dermatological symptoms.
The company said it would begin three-month clinical tests of its three cannabidiol-based products on human volunteers in Slovenia to determine the efficacy of the products for psoriasis, acne and seborrhoea,or oily skin, conditions.
MGC said it aimed to produce the dermatological products for consumers to purchase through its online shop, or retail outlets, as over-the-counter products.
MGC managing director Nativ Segev said the start of the European registration process was “a significant milestone”.
“Certification will then allow MGC Pharmaceuticals to immediately sell its [cannabidiol] dermatological skin care products throughout the European Union,” Mr Segev said.
“Simultaneously, we are pleased to be progressing to clinical tests of our [cannabidiol] dermatological products in order to demonstrate the efficacy of our formulations,” Mr Segev said.
MGC fell 0.1 cents or 2.2 percent to 4.5 cents with 1.05 million shares traded.

CRESO PHARMA

Creso says it has agreements with Greveling and Animal & Human Health AG to develop and commercialize hemp-derived food additives for pet care.
Creso says it has a binding letter of intent with the Zuid-Scharwoude, Netherlands-based veterinary product manufacturer and wholesaler Greveling Holding BV and the Baar, Switzerland-based Animal & Human Health AG "to develop and commercialize its cannabidiol-rich, hemp-derived nutraceutical products for the global pet care market".
Creso said its veterinary products would target conditions including behavioral disorders, "such as anxiety linked to separation, loud noise, travel, crowds, acute and chronic pain, inflammation, arthritis, allergic skin reactions and metabolic conditions such as diabetes".
The company said that treatment options for veterinarians was limited and available treatments were often human therapeutics poorly adapted to animals, while its marijuana-based products provided "a strong alternative to existing therapies and can target ailments such as anxiety and pain, seizures, arthritis and inflammation and contribute to improve the pet's quality of life and create better health".
Creso said that its products could be administered through veterinary delivery systems with Greveling assisting in developing products and as a commercialization partner in Europe and the Middle East, with Animal & Human Health AG the Swiss distributor.
Creso said that product development would take place in Europe.
Creso was up two cents or 9.1 percent to 24 cents with one million shares traded.

IMUGENE

Sydney's based Platinum Investment Management says it has increased its substantial shareholding in Imugene from 120,000,000 shares (6.02%) to 200,000,000 (9.24%).
Platinum said it acquired the 80,000,000 shares on November 3, 2016 for $600,000 or 0.75 cents a share in the $3.2 million placement (BD: Oct 21, 2016).

DIMERIX

Dimerix says that Kathy Harrison has been promoted to chief executive officer, from subsidiary Dimerix Biosciences Pty Ltd general-manager.
Dimerix chairman Dr James Williams said that Ms Harrison had driven "key strategic outcomes" from the recent pre-investigational new drug application meeting with the US Food and Drug Administration as well as administering patent prosecution and establishing the phase II clinical program targeting chronic kidney disease.
The company said that Ms Harrison had more than 20 years' experience in senior roles in the industry and listed companies with a focus on commercial development.
Dimerix said that Ms Harrison had worked for nine years in private practice as a patent and trade mark attorney and held a Bachelor of Applied Science from Melbourne's Swinburne University, a Masters of Science from Manchester University England and was a registered patent and trade mark attorney.
Dimerix said Ms Harrison's base salary would be $200,000 a year, plus superannuation and up to 25 percent of gross remuneration as a milestone dependant bonus.
Dimerix was unchanged at 0.9 cents with 4.2 million shares traded.