Biotech Daily

Tuesday June 27, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEUREN UP 9%, ATCOR DOWN 9.5%**

*** INNATE TUMBLES 93% ON MIS416 FAIL FOR MULTIPLE SCLEROSIS**

*** WEHI: INHIBIT MK2 TO IMPROVE SMAC MIMETICS FOR CANCER**

*** GORDAGEN, DR RIC DEGARIS LEGAL DISPUTE; WINDING UP CLAIM**

*** PHARMAUST HIRES BRI TO FIX MONEPANTEL (PPL-1) TASTE**

*** NEUREN REQUESTS CAPITAL RAISING TRADING HALT**

*** ANTEO PLEADS SCHULTZ, FUNDING TO ASX 32% FALL QUERY**

*** CRESO EGM FOR 6m DIRECTORS 'PERFORMANCE' SHARES**

*** MICHAEL SORENSEN, VIG INCREASE, DILUTED TO 17% OF BIOXYNE**

*** BIO-MELBOURNE 'US REGULATORY LANDSCAPE' BRIEFING**

MARKET REPORT

The Australian stock market slipped 0.1 percent on Tuesday June 27, 2017 with the ASX200 down 6.0 points to 5,714.2 points. Seven of the Biotech Daily Top 40 stocks were up, 25 fell, six traded unchanged and two were untraded.

Neuren was the best for the second day in a row, up 0.6 cents or 8.6 percent to 7.6 cents with 3.8 million shares traded.

Benitec climbed 8.3 percent; Cellmid was up four percent; Prima and Viralytics were up more than three percent; Starpharma rose 2.1 percent; with ITL up 1.05 percent.

Atcor led the falls, down 0.4 cents or 9.5 percent to 3.8 cents with 139,400 shares traded.

Compumedics, Genetic Signatures and Polynovo lost five percent or more; Ellex, Impedimed, Living Cell, Pharmaxis and Universal Biosensors fell four percent or more; Opthea was down 3.93 percent; Airxpanders, LBT, Medical Developments, Nanosonics, Oncosil and Prana shed more than two percent; Actinogen, Admedus, Avita, CSL, Factor Therapeutics, Mesoblast, Orthocell, Pro Medicus and Resmed were down more than one percent; with Acrux, Cochlear and Sirtex down by less than one percent.

INNATE IMMUNOTHERAPEUTICS

Innate fell 93 percent on news its trial of MIS416 for secondary progressive multiple sclerosis showed no “clinically meaningful or statistically significant” efficacy.

Innate said the 12-month, 93-patient, phase IIb, randomized, double-blind, placebo-controlled trial of weekly injections “did not show clinically meaningful or statistically significant differences in measures of neuromuscular function or patient reported outcomes”.

Innate chief executive officer Simon Wilkinson told a teleconference that he was “extremely disappointed for secondary progressive multiple sclerosis patients for whom there are no treatment alternatives”.

“These results were a shock and not what we expected,” Mr Wilkinson said. “The results don’t align with reports from patients in the compassionate use program.”

Mr Wilkinson said that on all efficacy measures including brain volume changes, cranial magnetic resonance imaging and patient reporting there was no significant difference between the 62-patient MIS416 group and the 31 placebo group.

Innate said that 17 MIS416 patients and four placebo patients prematurely discontinued treatment, which Mr Wilkinson said was “a little on the high side but not greatly so” for the severely disabled cohort.

The company said that measures of neuromuscular function included measures of upper extremity function and strength, walking speed and distance, visual acuity, and two measures of cognitive processing speed and the analysis showed “no overall clinically meaningful or statistically significant differences across the multiple measures of neuromuscular function assessed during the trial”.

Innate said that patient-reported outcome questionnaires comprising the Multiple Sclerosis Impact Scale, as well as fatigue and pain measures showed no overall clinically meaningful or statistically significant differences and the expanded disability status scale (EDSS) score showed no change between the two groups.

The company said that a separate analysis of possible treatment effect was underway on the per-protocol population of patients who followed the trial protocol and completed at least 75 percent of the required study visits.

“There is nothing to suggest at this time that this analysis will result in a favourable conclusion,” Innate said.

The company said there was “at least one treatment-related adverse event in 60 of the 63 patients in the MIS416 group and 23 of the 31 placebo group patients, with at least one treatment related serious adverse event in 16 MIS416 patients and five in the placebo group, which was expected to show that the higher incidence in the MIS416 group could be associated with the previously observed fever, chills, muscle weakness response to initial MIS416 dosing, with ongoing further analysis of the findings.

Innate said that as there were no dose limiting safety concerns, it had advice that there was no immediate need to halt the compassionate use program.

Mr Wilkinson said that the company’s priority was “to decide if there was any clinical future for MIS416” and the company would review the results to see if there was any sub-group that had a response and whether there was any biomarker for responders.

Mr Wilkinson said that the review would take about six weeks.

In 2013, Innate raised $10 million at 20.1 cents a share to list on the ASX and hit a high of $1.83 in January 2017 on news that Republicans close to US President Donald Trump including Health Secretary Dr Tom Price were shareholders, with New York Congressman Chris Collins a founding director (BD: Dec 18, 2013; Jan 22, 27, 31, Mar 31, 2017).

Innate closed down 59.1 cents or 92.3 percent to 4.9 cents with 128.1 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that inhibitors of the protein MK2 can improve the anti-cancer effect of Smac mimetics.

WEHI said that its team discovered how the MK2 protein helped keep cancer cells alive, making them resistant to the anti-cancer effects of Smac mimetics.

The Institute said that the findings provides a rationale for combining inhibitors of MK2 with Smac mimetics as a combination therapy for cancers with few treatment options, such as acute myeloid leukaemia.

The research article, entitled 'MK2 Phosphorylates RIPK1 to Prevent TNF-Induced Cell Death' was published in Molecular Cell and the full article is available at: http://www.cell.com/molecular-cell/fulltext/S1097-2765(17)30316-7.

A 2015 article in Clinical Cancer Research by Frankfurt, Germany based Goethe-University Prof Simone Fulda said that second mitochondrial activator of caspases (Smac) mimetics were small-molecule inhibitors that mimicked Smac, an endogenous antagonist of inhibitor of apoptosis proteins, which blocked programed cell death and were expressed at high levels in some human cancers, making them targets for cancer drug development.

"Preclinical studies have shown that Smac mimetics can directly trigger cancer cell death or, even more importantly, sensitize tumor cells for various cytotoxic therapies, including conventional chemotherapy, radiotherapy, or novel agents," Prof Fulda wrote.

Prof Fulda said that several Smac mimetics were being evaluation.

Her article, entitled 'Promises and Challenges of Smac Mimetics as Cancer Therapeutics', is available at: http://clincancerres.aacrjournals.org/content/21/22/5030.

Today, WEHI said that the research was the outcome of a collaboration between its Dr Najoua Lalaoui, Prof John Silke and colleagues, and staff from the University of London's Institute of Cancer Research and Germany's University of Cologne.

Dr Lalaoui said the research helped advance her team's previous discovery that combining the Smac mimetic agent birinapant with another new class of anti-cancer agents, called p38 inhibitors, could offer a new approach to treating acute myeloid leukaemia.

"We knew these two agents could be combined, but didn't fully understand the how they worked together at the molecular level," Dr Lalaoui said.

"This latest study has pinpointed the MK2 protein as critical for the combination of Smac mimetics and p38 inhibitors to have a potent anti-cancer effect," Dr Lalaoui said.

"As well as understanding our previous discovery better, it also highlights MK2 as an exciting new target for anti-cancer therapies, particularly in combination with Smac mimetics," Dr Lalaoui said.

Prof Silke said the research was part of a growing trend in the field, taking rational approaches to treating cancer better, particularly through selecting combinations of anti-cancer agents.

"By understanding precisely which molecules are helping cancer cells to survive and evade treatment, we can develop smarter ways to kill these cells," Prof Silke said.

"In the first place, the rational development of combination therapies has the potential to provide new treatments for cancers, such as [acute myeloid leukaemia], that have previously had poor outcomes," Prof Silke said.

Prof Silke said that a potential benefit of combined anti-cancer therapies could be using each agent at lower doses.

"With a combined approach, the agents could still kill the cancer cell but with fewer harmful side effects on healthy tissues," Prof Silke said.

"Our goal is to develop cancer treatments that are both safer and more powerful than are currently available," Prof Silke said.

GORDAGEN PHARMACEUTICALS

Supreme Court of Victoria documents disclose legal action between Gordagen and former chief operating officer Dr Ric DeGaris.

One document filed by Dr DeGaris, entitled 'Affidavit in support of application for winding up in insolvency affidavit of Ric DeGaris' said that at March 1, 2017 he was owed $120,223 for outstanding salary payments and a short term incentive payment for 2015 and said "the sum demanded remains due and payable by the defendant to me".

A second document from Dr DeGaris' lawyers Piper Alderman said he claimed "an order that the defendant be wound up in insolvency under the Corporations Act 2001 … [and] such further or other orders as the Court considers just and necessary".

Gordagen told Biotech Daily that it applied to the Supreme Court of Victoria seeking to set aside the demand, but the application was dismissed by Associate Justice Rodney Randall in a hearing on May 23, 2017.

A Supreme Court order said that the originating process dated April 3, 2017 was dismissed, the compliance of the statutory demand was extended to May 30, 2017 and ordered the plaintiff, Gordagen, pay the defendant's costs including reserved costs.

Gordagen said it had lodged an application with the Court of Appeal seeking leave to appeal against the ruling and lodged a Notice of Appeal on June 20, 2017.

Gordagen said it "strenuously and vigorously disputes the purported claims made in the creditor's statutory demand and the winding up application".

No hearing date had been set at the time of publication.

Gordagen is a private company.

PHARMAUST

Pharmaust says it has appointed the Vancouver, British Columbia-based BRI Biopharmaceutical Research to reformulate monepantel for its clinical trials.

Pharmaust said that BRI would evaluate a range of platforms to determine the optimal formulation for oral delivery of monepantel, formerly PPL-1, with the primary objective to mask the unpleasant taste to address compliance issues with previous formulations.

The company said the work would build on efforts from the Nottingham, England-based Juniper Pharma Services who reformulated liquid monepantel in the form of Zolvix into capsules (BD: Jul 11, 2016).

Pharmaust said the Juniper capsules were being used in an on-going trial treating dogs diagnosed with lymphoma (BD: May 19, 2017).

The company said that the current capsule formulation was not suitable for more advanced clinical trials due to the unpalatability of Zolvix even when encapsulated.

Pharmaust said that BRI would prepare a fully-optimized monepantel formulation that met the requirements for scaled manufacture, late-stage clinical trials and registration.

The company said that other aims included increasing the dose of monepantel in each tablet or capsule to reduce overall pill burden, maximizing the amount of drug delivered into the blood stream and ensuring the drug was stable when stored.

Pharmaust fell 0.1 cents or 1.5 percent to 6.4 cents.

NEUREN

Neuren has requested a trading halt "pending an announcement regarding a raising transaction".

Trading will resume on June 29, 2017 or on an earlier announcement.

Neuren last traded up 0.6 cents or 8.6 percent to 7.6 cents with 3.8 million shares traded.

ANTEO DIAGNOSTICS

Anteo has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price fell 0.7 cents or 31.8 percent from 2.2 cents on June 15 to 1.5 cents on June 26, 2017, and noted an increase in trading volume.
Anteo said that it told the market in April that merger partner Diasource had agreed to a EUR4,322,000 ($A6,091,780) earn-out and the Diasource vendors had agreed to an extension of the payment to July 11, 2017, the same timing at the next vendor finance payment (BD: Apr 18, 2017).
The company said it was "working on a number of financing options, including corporate transactions at the parent company level or the possible divestment of Diasource, to meet these financial obligations, however at this stage these options are incomplete and therefore unable to be disclosed".
Earlier in April, Anteo said it had raised funds to terminate its draw-down equity facility with New York's Bergen Global Opportunity Fund (BD: Mar 3, 2016; Apr 12, 2017).
On April 6, Anteo said had secured $1,005,000 in short term loans from shareholders, directors and chief executive officer Dr Jef Vangenechten and secured an extension of the earn out liability to the Diasource vendors to June 2017.
Anteo was up 0.4 cents or 25 percent to two cents with 2.2 million shares traded.

CRESO PHARMA

Creso will vote to four directors and a consultant 6,100,000 "performance" shares, pending collaborations, joint ventures acquisitions and remaining with the company.
Creso said it proposed to issue 1,600,000 performance shares to executive chairman Boaz Wachtel, 2,500,000 shares to chief executive officer Miri Halperin Wernli, 1,500,000 shares to director Adam Blumenthal, 200,000 shares to director Dr James Ellingford and 300,000 shares to consultant and Ms Halperin Wernli's husband, Jorge Wernli.
The company said that the conditions varied with the issue, with the collaboration, joint venture and acquisition conditions applying to Mr Wachtel's shares, with Ms Halperin Wernli's shares dependent on selling animal and human cannabis derived products, Mr Blumenthal's shares dependent on medical cannabis industry transactions and Dr Ellingford's dependent on staying with the company for one and two years.
Creso said the meeting would vote to ratify the prior issue of shares and the issue of 100,000 advisor options to Asenna Wealth Solutions Pty Ltd, exercisable at 60 cents within three years.
The meeting will be held at Everblu Capital, Level 39, 88 Phillip Street, Sydney on July 27, 2017 at 9am (AEST).
Creso was up one cent or 1.9 percent to 52.5 cents.

BIOXYNE

Michael Sorensen and Vig Limited say they have increased and been diluted from 39,818,277 shares (19.9%) to 85,188,117 shares (16.78%).
Last year Michael Sorensen, Vig Limited and 'Custodian Nominee Co' said they had acquired 39,868,277 shares (19.9%) in Bioxyne (BD: Sep 12, 2016).
Today, the Auckland, New Zealand-based Mr Sorensen said that 39,818,277 shares were acquired in the rights issue at one cent a share on May 30, 2017.
Bioxyne was up 0.2 cents or 12.5 percent to 1.8 cents with 1.6 million shares traded.

BIO-MELBOURNE NETWORK, VICTORIA GOVERNMENT

The Bio-Melbourne Network says four North American specialists will assist early-stage medical technology companies with their plans for export.

The Network said that a program supported by the Victoria Government called 'The Export Ready for North America Program' would begin with the first module in July, with further modules in August, September and November.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said "this program will give actionable insights to help companies with their export market strategy".

"The State Government of Victoria is assisting us to bring in experts with deep domain knowledge and experience for each module so that attendees can hear directly from those with decades of experience in the North America," Dr Evans said.

Dr Evans said the program was oversubscribed but the Network was offering all organizations with an interest in global expansion access to the visiting specialists through a bio-briefing associated with each module.

The Network said the first bio-briefing, entitled 'US Regulatory Landscape: Hills and Valleys at FDA' would be presented by Regulatory and Clinical Research Institute regulatory affairs and quality systems advisor Dr Mary Beth Henderson.

The Network said that the -briefing would be held at the offices of Davies Collison Cave on July 10, 2017, with registration from 3:45pm for a 4pm start and would be followed by a networking session until 6pm.

To register go to: https://tinyurl.com/usexport1.