Biotech Daily

Tuesday April 19, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: COMPUMEDICS UP 5%, GENETIC TECH DOWN 9%**

*** TGA OKAYS DIMERIX DMX-200 SPECIAL ACCESS FOR KIDNEY DISEASE**

*** REDHILL TAKES RHB-105 TO 2nd PHASE III HELICOBACTER TRIAL**

*** VIRALYTICS UPDATES THREE CAVATAK TRIALS**

*** MEDIBIO TAKES HEARTLINK'S IP FOR $1.2m IN SCRIP**

*** IMMURON APPOINTS ALLOCATION TO SELL TRAVELAN IN THE US**

*** MGC PLEADS SCHULTZ, CANNABIS COSMETICS, LAW TO ASX 50% QUERY**

*** M&G REDUCES TO 11% OF GI DYNAMICS, TAKES $3m-$6m LOSS**

*** MESOBLAST TO RELEASE 15m ESCROW SHARES**

*** SIMAVITA TAKES CAPITAL RAISING, BOARD HALT TO SUSPENSION**

*** COGSTATE APPOINTS ABBY MOORE ACTING CO-SEC**

MARKET REPORT

The Australian stock market climbed 1.01 percent on Tuesday April 19, 2016 with the ASX200 up 51.7 points to 5,188.8 points. Ten of the Biotech Daily Top 40 were up, 15 fell, 11 traded unchanged and four were untraded.

Compumedics was the best, up two cents or 4.7 percent to 44.5 cents with 325,019 shares traded.

Starpharma climbed three percent; Actinogen, Impedimed, Prana and Prima rose more than two percent; Biotron and IDT were up more than one percent; with Airxpanders, CSL and Mesoblast up by less than one percent.

Genetic Technologies led the falls, down 0.2 cents or 8.7 percent to 2.1 cents with two million shares traded.

Nanosonics fell 4.7 percent; Living Cell, Oncosil, Pro Medicus and Universal Biosensors were down more than three percent; Anteo, Clinuvel, Neuren and Tissue Therapies shed more than two percent; Acrux, Medical Developments, Pharmaxis, Resmed and Sirtex were down more than one percent; with Ellex and Cochlear down by less than one percent.

DIMERIX

Dimerix says the Australian Therapeutic Goods Administration has approved the supply of propagermanium to participants in its 30-patients DMX-200 clinical trial.

Dimerix said that DMX-200 combined the chemokine receptor CCR2 blocker, propagermanium used for its anti-inflammatory properties and an angiotensin II type I receptor blocker, irbesartan, registered for treatment of hypertension.

The company said that propagermanium was not on the Australian Register of Therapeutic Goods, while irbesartan was on the register and the TGA special access scheme would allow the use of propagermanium.

Dimerix chief operating officer Kathy Harrison told Biotech Daily that the patients were receiving irbesartan as part of their standard-of-care and the addition of propagermanium was equivalent to receiving the DMX-200 combination drug.

Dimerix said that preclinical testing of DMX-200 in models relevant for kidney disease showed a significant reduction in proteinuria, strongly supporting the potential of DMX-200 to improve the same condition in patients.

The company said the TGA approval was on a case-by-case basis and related to the first two participants in the phase II study of DMX-200 in patients with chronic kidney disease, who were expected to complete the 24 weeks treatment period for the first part of the trial shortly and the special access scheme request was filed by the principal investigator.

Dimerix said the Melbourne trial aimed to demonstrate safety and reduction of proteinuria at 24 weeks of treatment in chronic kidney disease patients and that reducing proteinuria reduced the risk of chronic kidney disease progression and consequent progressive loss of renal function and the development and progression of cardiovascular disease.

Dimerix executive chairman Dr James Williams said that the special access scheme approval was significant and indicated “the investigators involved do not have any safety concerns and consider there is potential benefit for patients to continue on the treatment”.

Dimerix was up 0.1 cents or 14.3 percent to 0.8 cents with 1.5 million shares traded.

REDHILL BIOPHARMA

Redhill says it will begin a second confirmatory phase III trial of RHB-105, developed from Giaconda’s Heliconda, for Helicobacter pylori infection this year.

The company has told Biotech Daily that RHB-105 was based on Giaconda’s Heliconda for but it had further developed the drug (BD: Mar 31, 2016).

In August 2010, Giaconda sold its Myoconda, Heliconda and Picoconda patents to Israel’s Redhill Biopharma for $US500,000 plus seven percent of net sales that gave Redhill the charge over Giaconda’s 78,373,505 shares (BD: Aug 17, 2010).

Today, Redhill said that it had “a positive type B meeting” with the US Food and Drug Administration to discuss the results of the first phase III RHB-105 study which showed 89.4 percent efficacy in eradicating Helicobacter pylori infection.

The company said that it would complete the design of the planned confirmatory phase III randomized, double-blind, active comparator, two-arm clinical study, comparing RHB-105 against a high dose amoxicillin and omeprazole regimen.

Redhill said that Helicobacter pylori bacterial infection was “a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa-associated lymphoid tissue lymphoma”, and RHB-105 had been granted qualifying infectious disease product designation by the FDA, providing a fast-track development pathway, as well as priority review status.

Last night on the Nasdaq, Redhill climbed 84 US cents or 6.49 percent to $US13.79 ($A17.73) with 59,450 shares traded.

VIRALYTICS

Viralytics has reported updates on three trials, the phase II Calm extension clinical study, the phase Ib Mitci trial and a checkpoint inhibitor combination mouse study.

Viralytics released the updates in posters and presentations to the American Association for Cancer Research meeting in New Orleans, Louisiana yesterday.

The company said that Cavatak in late-stage melanoma (Calm) trial was designed to assess changes in tumor tissue following the administration of Cavatak in patients with advanced melanoma and in the 13-patient extension study, biopsies were taken from melanoma lesions following the intra-tumoral delivery of Cavatak and then monitored for evidence of Cavatak-induced changes in the tumour micro-environment.

Viralytics said that the results showed that Cavatak was able to influence the dynamics of the tumor micro-environment by inducing anti-cancer immune activity in the tumor tissue, as evidenced by the infiltration of immune cells, such as killer T-cells, and the up-regulation of key immune checkpoint molecules on cancer cells.

Principal investigator Dr Robert Andtbacka said the changes in the tumor micro-environment were “evident within lesions displaying stable disease or response and thus may provide some early predictive marker of a future tumor response”.

Viralytics said that Cavatak-induced changes signalled the potential for combination with other immunotherapies such as checkpoint inhibitors, as indicated by initial results from the phase Ib melanoma intra-tumoral Cavatak and ipilimumab (Mitci) study combination trial, in which the preliminary overall response rates for the combination were higher than published response rates for either Cavatak or ipilimumab, marketed as Yervoy, alone.

Viralytics said the US Mitci study had enrolled 11 advanced melanoma patients to date, with six patients evaluable for tumor assessment, and objective responses confirmed in four patients, including two complete responses and two partial responses, with one additional patient showing stable disease at day-106.

Lead investigator Dr Brendan Curti said the preliminary finding that, “of five patients not previously treated with Yervoy, four had clinically meaningful tumor regressions in sites injected with Cavatak as well as visceral, lymph node and subcutaneous sites that were not injected is notable in light of published objective response rates for monotherapy (Cavatak: 28.1%; Yervoy: 11%) in patients with advanced melanoma”.

“These preliminary findings help to confirm that systemic immunity against melanoma can be achieved with this combination,” Dr Curti said.

Viralytics said there had been no dose-limiting toxicities, and no Cavatak-related grade 3 or higher adverse events reported.

Viralytics said that non-small cell lung cancer and melanoma mouse studies assessing the combination of intravenous Cavatak with checkpoint inhibitor, anti-PD-1 or anti-CTLA-4, antibodies “resulted in notable survival benefits over single agents alone”.

The company said that a significant survival benefit was seen at day-47, with five of eight mice alive after treatment with the combination of Cavatak and the anti-PD-1 antibody, compared to one of eight mice surviving in groups treated with either anti-PD-1 antibody or Cavatak alone; and in the melanoma model, the combination of Cavatak with each checkpoint inhibitor produced superior anti-tumor activity and offered increased survival benefits, compared to the use of either agent alone.

Viralytics chief scientific officer Dr Darren Shafren said that “the significant anti-tumor activity resulting from the combination of Cavatak with these leading checkpoint inhibitors in mouse models of lung cancer and melanoma strongly supports Viralytics’ current clinical trial evaluations of such immunotherapeutic treatment regimens in patients with these cancer types”.

Viralytics was unchanged at 69 cents.

MEDIBIO

Medibio says it has acquired all of Heartlink's intellectual property relating to a 'method for diagnosing psychiatric disorders' for $1.2 million in scrip.
Medibio said that the Perth-based Heartlink's patent covered the use of 24-hour heart rate data and circadian heart rate technology for the diagnosis of psychiatric conditions and the determination of the effectiveness of treatment.
The company said it would issue 4,000,000 shares at 30 cents each which would remain in escrow for 12 months, as the full consideration for the acquisition.
Medibio said the intellectual property included patents entitled 'Method for diagnosing psychiatric disorders' granted in Australia, Israel, New Zealand, the US and Canada.
Heartlink listed on the ASX in 2000 under the code HRK to develop what it described as "an ECG for mental health" but in 2011 changed direction to become a travel agency.
Today, Medibio said the acquisition was in line with its strategy of protecting a dominant position in the use of circadian heart rate technology for stress and mental health.
The company said it had completed the acquisition of all patents covering the use of 24-hour heart rate data for the diagnosis of psychiatric conditions and had filed two patent applications in the US in June 2015 entitled 'Method and System for Monitoring Stress Conditions' covering the use of the technology to assess the level and impact of stress and 'Method and System for assessing Mental State' extending the use of its technology for the diagnosis of depression and other mental health disorders.
Medibio said the second application covered discoveries made during the past 18 months and, if granted, extended the existing patents covering mental health diagnosis.
The company said that it intended filing Patent Cooperation Treaty applications for these two patents prior to June 30, 2016.
Medibio fell half a cent or 2.1 percent to 23 cents.

IMMURON

Immuron says it has appointed the Park Ridge, New Jersey-based Allocation Inc to sell Travelan in its healthcare distribution network.
Immuron said that the terms and conditions of the agreement were confidential.
The company said that Allocation supplied hospitals, clinics, universities, research institutions, healthcare providers and government agencies with product including generics and branded products, medical, surgical and over-the-counter products, with a staff of licenced pharmacists acting as a proxy sales force.
Immuron fell 1.5 cents or 4.55 percent to 31.5 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC 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 rose 50.0 percent from 4.2 cents on April 15 to 6.3 cents on April 18, 2016, and noted an increase in the trading volume.
MGC said it had "recently made announcements regarding its Australian strategy, the first distribution agreement for its MGC Derma cannabinoid cosmetics product line and the launch of the MGC Derma cosmetics online shop".
"We believe this recent news-flow, combined with the news last week that Victoria became the first state in Australia to legalise the use of medicinal cannabis for children with severe epilepsy, has led to the increased shareholder interest".
MGC fell 1.1 cents or 17.7 percent to 5.1 cents with 108.9 million shares traded.

GI DYNAMICS

M&G Investment Funds says it has further reduced its holding in GI Dynamics from 58,243,737 Chess depository instruments (12.24%) to 52,560,345 CDIs (11.05%).
In 2014, the London-based M&G group said it acquired 2,000,000 shares in a placement at 52 cents as well as 7,411,464 shares for an average of 54.2 cents a share between August 8 2013 and April 8, 2014 (BD: May 2, 12, 2014).
Today, M&G said that between April 6 and 15, 2016 it sold 5,683,392 CDIs for $111,800 or an average of 1.97 cents a share.
In 2011, GI Dynamics raised $80 million of a hoped-for $95 million in an initial public offer at $1.10 per CDI, implying that M&G lost between $2.5 million and $5.4 million in the recent sale (BD: Aug 30, 2011).
GI Dynamics was unchanged at 1.8 cents.

MESOBLAST

Mesoblast says that 15,298,837 shares held in voluntary escrow will be released on May 5, 2016.
A Mesoblast executive told Biotech Daily that following the release of the shares, the company would have 380,095,927 shares available for trading, with a further 1,277,210 shares held in escrow until February 23, 2017, when all 381,373,137 share would be available for trading.
Mesoblast was up one cent or 0.4 percent to $2.50 with 702,334 shares traded.

SIMAVITA

Simavita has requested a voluntary suspension to follow the trading halt requested on April 18, “to finalize arrangements around a potential capital raise and possible changes to the composition of the company's board of directors” (BD: Apr 18, 2016).
Simavita last traded at 4.5 cents.

COGSTATE

Cogstate says it has appointed Abby Moore as company secretary and acting finance manager, replacing Claire Newstead-Sinclair who is on maternity leave.
Cogstate said that Ms Moore held a Bachelor of Accounting from Monash University and had more than 15 years’ experience in accounting and finance and previously worked for Pitcher Partners and more recently was Ambulance Victoria’s operations business manager.
Cogstate was unchanged at 65 cents.