Biotech Daily

Thursday June 14, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PRANA UP 14%; AIRXPANDERS DOWN 19%**

*** US APPROVES MDGH MOXIDECTIN FOR RIVER BLINDNESS; CERTARA**

*** PHARMAXIS LOXL2 FIBROSIS DRUGS 'POTENTIAL PARTNER BRIEFINGS'**

*** PRANA STARTS PHASE I PBT434 PARKINSON'S TRIAL**

*** ANTISENSE HAS ATL1103 FOR 12 ACROMEGALY PATIENTS**

*** PAINCHEK NATIONAL ROLLOUT**

*** ORTHOCELL: '88% OF ORTHO-ATI PATIENTS RETURN TO WORK'**

*** MERCHANT BELOW 5% IN POLYNOVO**

*** CVC, STINOC REDUCES TO 12% OF CYCLOPHARM**

*** INVESTMENT ADMINISTRATION SERVICES TAKES 5% OF SIENNA**

*** MMJ INVESTS $510k IN BEVCANNA MARIJUANA DRINK MANUFACTURER**

*** CRESO APPOINTS JOHN GRIESE COO FOR THE AMERICAS**

*** CLUNIES ROSS AWARD FOR WEHI'S VENETOCLAX RESEARCHERS**

*** RESPIRI APPOINTS MARK ZIIRSEN CHAIRMAN**

MARKET REPORT

The Australian stock market fell 0.11 percent on Thursday June 14, 2018 with the ASX200 down 6.9 points to 6,016.6 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and three were untraded. All three Big Caps fell.

Prana was the best, up 0.6 cents or 13.95 percent to 4.9 cents with 364,228 shares traded. Pharmaxis climbed 8.1 percent; Clinuvel and Dimerix improved five percent or more; Immutep, Opthea and Osprey were up three percent or more; Admedus, Compumedics, LBT, Nanosonics and Optiscan rose two percent or more; Polynovo was up 1.8 percent; with Medical Developments, Pro Medicus, Sirtex and Volpara up by less than one percent.

Airxpanders led the falls, down three cents or 19.35 percent to 12.5 cents with 2.3 million shares traded. Impedimed lost 8.9 percent; Cochlear and Universal Biosensors fell more than four percent; Avita, Imugene and ITL were down more than three percent; Cynata, Factor Therapeutics and Oncosil shed more than two percent; with CSL, Ellex, Mesoblast, Neuren and Starpharma down more than one percent.

MEDICINES DEVELOPMENT FOR GLOBAL HEALTH, CERTARA D3

Medicines Development for Global Health (MDGH) says it has US approval for oral moxidectin 8mg for river blindness or onchocerciasis in patients aged 12 years and older.

Biotech Daily believes this is the first time an Australian entity has taken a drug all the way to US Food and Drug Administration approval, apart from the Chemgenex drug Omapro, which was acquired by Cepahlon-Teva, who completed the filings (BD: Dec 5, 2012).

MDGH said the FDA had awarded it a priority review voucher for the drug.

Last year, the Melbourne-based Certara D3 president Dr Craig Rayner told Biotech Daily that his group supported the work undertaken by the Melbourne-based not-for-profit MDGH (BD: Dec 21, 2017).

Certara said at that time that river blindness was a debilitating tropical disease and the FDA granted MDGH priority review for moxidectin on December 16, shortening its review timeline from 10 months to six, triggering a tropical disease priority review voucher, should the submission be approved.

Today, MDGH said that it worked with the World Health Organisation Special Programme for Research and Training in Tropical Diseases for the US application.

MDGH said that the approval was based on data from two randomized, double blind, active controlled clinical studies and both met their respective primary endpoints, showing a statistically significant superiority of moxidectin over the current standard of care, ivermectin, in suppressing the presence of the microfilariae in skin.

MDGH said the full results from the phase III study were published in the Lancet in January 2018.

Medicines Development for Global Health founder and managing director Mark Sullivan said that FDA approval was “a momentous achievement for any biopharmaceutical company, but it is a particularly rare and exciting event in the neglected diseases setting”.

“It takes a broad community to develop a new medicine,” Mr Sullivan said.

“FDA approval represents decades of work by thousands of scientists, disease control specialists, expert advisors, community health workers, funders and study participants,” Mr Sullivan said.

“We particularly acknowledge the $US13 million investment from the Global Health Investment Fund as well as the extraordinary persistence and dedication of the team at [the WHO tropical diseases program],” Mr Sullivan said.

Mr Sullivan said the approval was “the result of a paradigm-changing approach to the development of new medicines for neglected diseases”.

“As neglected tropical diseases are endemic in low and middle-income countries, there are limited markets for medicines,” Mr Sullivan said.

“Therefore, finding investors willing to support development in these diseases is extremely difficult … [but], the introduction of the FDA's neglected diseases [priority review voucher] program has created a market around neglected diseases,” Mr Sullivan said.

Last year, Certara said that onchocerciasis was caused by the filarial worm Onchocerca volvulus which was transmitted through the bites of infected black flies and each adult female worm could live for up to 15 years in the human body, producing millions of microfilariae that migrate through the skin, eyes, and lymph nodes.

Certara said symptoms included severe skin inflammation, intense itching, enlarged lymph nodes and, in some patients, visual impairment that can ultimately lead to blindness.

The company said onchocerciasis infections occurred in tropical climates, with 99 percent of cases in 31 sub-Saharan African countries and more than 25 million people infected.

Certara is owned by Sweden’s EQT VII Fund.

Medicines Development for Global Health is a not for profit organization.

PHARMAXIS

Pharmaxis says it has “briefed potential partners” at Boston’s BIO18 on early phase I trial data of its anti-fibrotic lysyl oxidase like 2 (LOXL2) inhibitor program for fibrosis.

Pharmaxis said that the two compounds “demonstrated a best in class profile … [and] LOXL2 has been implicated as a key factor in various fibrotic diseases in organs such as the liver, lung, heart and kidney”.

The company said that it had two separate LOXL2 compounds in two separate trials which had completed the single ascending dose escalation phase in healthy volunteers and was ready to begin the multiple ascending dose escalation phase.

Pharmaxis said that there were no adverse safety findings in this first stage and both drugs delivered “high levels of inhibition for a full 24 hours from a single daily dose”.

The company said that full results from the trials were expected before the end of the year.

In 2015, Pharmaxis said it had a collaboration with the Southampton, England-based Synairgen PLC for the studies and last year said it was ready to begin its first human clinical trial (BD: Aug 5, 2015; Sept 6, 2017).

In December, the company said it had assumed “full scientific and commercial control” of the LOXL2 collaboration paying $8.75 million to Synairgen (BD: Dec 14, 2017).

Today, Pharmaxis said that in addition to studying the safety and pharmacokinetic profiles of the two LOXL2 inhibitors, the two studies were also investigating the degree to which the drugs could inhibit the target enzyme LOXL2.

The company said it had been able to show “a large and highly significant inhibition of this enzyme for a full 24 hours with a single oral dose”.

Pharmaxis chief executive officer Gary Phillips said “the data package being reviewed by several multinational pharmaceutical companies under confidentiality agreements is now maturing rapidly as we see the final data being generated by ongoing pre-clinical and clinical studies”.

“There are a number of key features which have contributed to an increase in the already strong interest amongst these companies,” Mr Phillips said.

“As research into predictive in-vivo animal models for anti-fibrotic diseases such as [non-alcoholic steato-hepatitis and idiopathic pulmonary fibrosis] and their biomarkers continue, our newly developed proprietary test to measure the levels of active LOXL2 in human blood has shown we have a best-in-class LOXL2 inhibitor,” Mr Phillips said.

“Other LOXL2 drug programs have either shown no enzyme inhibition in humans at all or only short-lived inhibition, however both our drugs deliver high levels of inhibition for a full 24 hours from a single daily dose,” Mr Phillips said.

“This finding plus the reassuring safety profile in phase I trials and toxicity studies are key to the overall positive engagement with [pharmaceutical companies] that we expect will lead to commercial partnering discussions later this year,” Mr Phillips said.

Pharmaxis said that its amine oxidase platform had generated small molecule enzyme inhibitors to a range of important disease targets that were at various stages of development.

The company said that the semicarbazide-sensitive amine oxidase (SSAO) inhibitor acquired by Boehringer Ingelheim was in a phase II trial and the LOXL2 inhibitors were in phase I trials.

Pharmaxis said that a compound inhibiting both myelo-per-oxidase (MPO) and SSAO and another compound inhibiting all the lysyl oxidase (LOX) family of enzymes were both in the final stages of pre-clinical testing with phase I trials scheduled to begin in the next six to 12 months.

Pharmaxis was up 2.5 cents or 8.1 percent to 33.5 cents.

PRANA BIOTECHNOLOGY

Prana says it has begun recruitment for its up-to 75-patient, phase I trial to evaluate the safety and tolerability of PBT434 for Parkinson's disease in healthy volunteers.
Prana said that subjects in a single-ascending dose group would receive a single oral dose of PBT434 and have their safety and blood levels of the drug monitored for 72 hours after dosage.
The company said that patients in the repeated dose part of the study would receive PBT434 for eight days and have their safety and drug disposition monitored.
Prana said that secondary endpoints included "a range of pharmacokinetics measures to understand how PBT434 is absorbed and metabolized in the body".
The company said that PBT434 was the first of a new generation of small molecules designed to inhibit the aggregation of alpha synuclein and tau intracellular proteins that were implicated in neurodegenerative diseases, such as Parkinson's disease and atypical parkinsonism.
Prana chief medical officer Dr David Stamler said that following completion of the study "we aim to evaluate PBT434 in [multiple system atrophy and progressive supranuclear palsy] which are devastating neurodegenerative diseases with no approved therapies."
The company said the trial would be conducted by the Nucleus Network and would recruit healthy adult and elderly volunteers in Melbourne.
Prana was up 0.6 cents or 13.95 percent to 4.9 cents.

ANTISENSE THERAPEUTICS

Antisense says it has a sufficient ATL1103, or atesidorsen, to provide 12 acromegaly patients with 200mg doses twice a week for one year under an early access program.
Antisense said it was working with its Amsterdam, Netherlands-based partner Mytomorrows to work on the documentation required for the regulatory approvals to supply ATL1103 under the European Union's early access program and expected results from testing for the use of ATL1103 in humans by August.
The company said it initially planned to provide ATL1103 in the Netherlands, Germany and France.
Earlier this year, Antisense said that an unnamed US manufacturing facility would formulate injectable ATL1103 for acromegaly patients in Europe (BD: Feb 26, 2018).
Antisense was unchanged at 2.6 cents.

PAINCHEK (FORMERLY EPAT TECHNOLOGIES)

Painchek says its Painchek pain assessment system has been "rolled out nationwide" by Dementia Support Australia to its 150 consultants caring for 5,000 people a year.
Painchek said that since its national rollout in six Australian states in May, 2018, its Painchek system was "now a routine pain assessment tool embedded routinely within the workflow of [Dementia Support Australia] consultants.
The company said that from September 2017 to April 2018 it had conducted an initial rollout in South Australia and Western Australia to 118 patients aged 57 to 98 years with dementias or cognitive impairments and behavioral problems.
Painchek said that when pain in the patients was identified using its Painchek system "where subsequent pain-related recommendations were implemented, there was a significant improvement in [the patients'] behavioral scores at the time of discharge from the [Dementia Services Australia] service".
Painchek was up 0.3 cents or 5.4 percent to 5.9 cents with 1.9 million shares traded.

ORTHOCELL

Orthocell says that “88 percent” of 24 patients in its autologous tenocyte injection (Ortho-ATI) for lateral epicondylitis, or tennis elbow, trial returned to work after treatment.
The company did not provide specific patient numbers in the results.
Orthocell said that patients in the study worked in high dexterity professional roles, such as office administration.
The company said that before receiving treatment with Ortho-ATI patients in the study had experienced on-going pain and dysfunction as a result of their work-related injuries for an average of 23 months and had received between one and eight failed treatments.
Orthocell said the retrospective study was in collaboration with chief scientific officer Prof Ming Hao Zheng and orthopaedic surgeons Dr Jeff Hughes and Dr Alex O’Beirne.
Dr Hughes said that “these are difficult to treat patients who are impeded in their ability to work and to carry out their essential duties”.
“Ortho-ATI has been instrumental in helping my patients to recover from long-term lateral epicondylitis as a result of a work injury which has proved resistant to other modes of therapy including physiotherapy, corticosteroid and [platelet-rich plasma] injections and surgery,” Dr Hughes said.
“This new data helps to validate the durability or Ortho-ATI for chronic tendon injury,” Dr Hughes said.
Orthocell was unchanged at 35 cents.

POLYNOVO

Merchant Funds Management says it has ceased its substantial shareholding in Polynovo, selling 9,007,196 shares.
In May, Merchant said it held 38,999,960 Polynovo shares (5.93%) (BD: May 15, 2018).
Today, Merchant Funds Management said that between May 25 and June 12, 2018 it sold 9,007,196 shares for $4,999,911 or an average price of 55.5 cents a share.
Biotech Daily calculates that Merchant holds 29,992,764 shares or 4.56 percent of the company.
Polynovo was up one cent or 1.8 percent to 57 cents.

CYCLOPHARM

CVC Limited says it has reduced its substantial holding in Cyclopharm from 9,470,393 shares (13.80%) to 8,137,729 shares (11.92%).
In a substantial shareholder that listed Stinoc Pty Ltd as a registered holder, the Sydney-based CVC said that from April 17 to June 13, 2018 it bought 667,336 shares for $672,141 or an average of $1.07 a share and on June 8, 2018 it sold 2,000,000 shares for $1,989,749 or 99.5 cents a share.
Cyclopharm was untraded at $1.00.

SIENNA CANCER DIAGNOSTICS

Investment Administration Services (IAS) says it has become a substantial shareholder in Sienna with 9,105,829 shares or 5.05 percent of the company.
The Sydney-based IAS said the shares held by HSBC Nominees were acquired in a large number of on-market trades between August 4, 2017 and June 8, 2018 at prices from eight cents to 20 cents.
Sienna was untraded at 7.6 cents.

MMJ PHYTOTECH

MMJ says it has invested $C500,000 ($A509,745) for a 3.6 percent shareholding in the privately-held Vancouver-British Columbia based Bevcanna Enterprises Inc.
MMJ said that Bevcanna aimed to become a “premium-based…white label, end-to-end producer of [cannabidiol] and [tetrahydrocannabidiol] beverages”.
MMJ was up half a cent or 1.6 percent to 31 cents.

CRESO PHARMACEUTICALS

Creso says it has appointed John Griese as chief operating officer for the Americas.
Creso said Mr Griese would oversee the completion of the 1,858 square metres Mernova marijuana growing facility, the acquisition of Kunna Canada and Colombia’s Kunna SAS.
Creso was up one cent or 1.4 percent to 72 cents.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have won the 2018 Clunies Ross Knowledge Commercialisation Award for the development of venetoclax.
The Institute said the Australian Academy of Technology and Engineering award for the development of the anti-cancer drug was granted to Prof David Huang, Prof Peter Czabotar, Prof Guillaume Lessene and Prof Andrew Roberts for their roles in the collaboration with Roche’s Genentech and Abbvie.
WEHI said that venetoclax, marketed as Venclexta and Venclyxto, was approved for clinical use in Australia, North America and Europe for certain advanced forms of chronic lymphocytic leukaemia, “the most common type of leukaemia diagnosed in Australia”.
The Institute said that venetoclax had its foundation in a 1980s WEHI discovery that the BCL-2 protein could “make cancer cells immortal” by preventing programmed cell death.
Prof Huang said the team had a long-term goal of developing an anti-cancer treatment that killed cancer cells by inhibiting BCL-2 and Prof Czabotar said the research “benefited from the depth of structural biology expertise in the Institute, and from our access to the Australian Synchrotron”.
“By visualizing detailed structures of BCL-2 family proteins, we could see how medicines could be developed that were highly specific for BCL-2,” Prof Czabotar said.
WEHI director Prof Doug Hilton said the story of venetoclax was “an important example of Australian science having a global impact”.
“David, Andrew, Peter and Guillaume led the team that brought together skills in cancer research, structural biology, medicinal chemistry and clinical translation that, when combined with the strengths of our commercial partners Abbvie and Genentech, enabled us to see a laboratory discovery translated into a new medicine,” Dr Hilton said.

RESPIRI

Respiri says it has appointed Mark Ziirsen as chairman, effective from June 13, 2018.
Respiri said Mr Ziirsen was previously director of finance and information technology for the Asia Pacific region at Cochlear, chief financial officer at Admedus and director and chair of the audit committee at Smarttrans Holdings.
Respiri was untraded at 11 cents.