Biotech Daily

Tuesday August 13, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CYCLOPHARM UP 4%; USCOM DOWN 12.5%**

*** MDGH: NOVO NORDISK BUYS MOXIDECTIN RIVER BLINDNESS VOUCHER**

*** FEDERAL $1m FOR EMERGENCY STROKE TREATMENT**

*** KAZIA COMPLETES PHASE I PART B CANTRIXIL RECRUITMENT**

*** RACE GRANTED 3rd US BISANTRENE PATENT**

*** REGENEUS REDUCES STAFF, PAY, COSTS BY 50%**

*** MGC: '100 CANNEPIL MARIJUANA PATIENTS'; TETRA DEAL**

MARKET REPORT

The Australian stock market fell 0.33 percent on Tuesday August 13, with the ASX200 down 21.8 points to 6,568.5 points.

Seven of the Biotech Daily Top 40 stocks were up, 19 fell, 13 traded unchanged and one was untraded.

Cyclopharm was the best, up six cents or 4.4 percent to $1.42, with 2,130 shares traded.

Ellex and Pro Medicus climbed more than one percent; with Compumedics, Genetic Signatures, Neuren, Polynovo and Resmed up by less than one percent.

Uscom led the falls, down 1.5 cents or 12.5 percent to 10.5 cents, with 269,211 shares traded.

Alterity (Prana) lost 7.1 percent; Antisense, Next Science, Opthea, Osprey and Proteomics were down more than six percent; Oncosil was down 5.9 percent; LBT fell four percent; Cochlear was down 3.4 percent; Amplia, Avita, Cynata, Nanosonics and Volpara shed more than two percent; CSL, Medical Developments and Starpharma were down more than one percent; with Clinuvel, Paradigm and Telix down by less than one percent.

MEDICINES DEVELOPMENT FOR GLOBAL HEALTH

Medicines Development for Global Health says the Copenhagen-based Novo Nordisk has bought its priority review voucher, but did not disclose the price.

The website www.priorityreviewvoucher.org, maintained by voucher co-developer David Ridley, said that vouchers had been sold at prices ranging from $US68 million to $US350 million with the most recent recorded sale for $US105 million.

Medicines Development for Global Health (MDGH) said the priority review voucher would allow Novo Nordisk to receive priority review designation on a new drug application with the US Food and Drug Administration, which would provide an accelerated six-month review timeline.

Last year, the company said it had FDA approval for oral moxidectin 8mg for river blindness, or onchocerciasis, in patients aged 12 years and older, which was believed to be the first time an Australian entity had taken a drug all the way to FDA approval, apart from the Chemgenex drug Omapro (BD: Jun 14, 2018, Dec 5, 2012).

Following the approval, MDGH said the FDA had awarded the company a priority review voucher for the drug, and it had received a $US13 million ($A17.29 million) investment from the Global Health Investment Fund (BD: Jun 14, 2018).

Today, the company said that moxidectin was the first new FDA-approved treatment for onchocerciasis in more than 20 years and the $US13 million of financing required for the final stages of development was enabled entirely as a result of the priority review voucher incentive program.

MDGH said that, with its financing partners at Global Health Investment Fund, it planned to apply a significant portion of the priority review voucher sale proceeds toward additional research on moxidectin and further development in underserved markets where almost 200 million people are at risk of river blindness.

The company said the balance would be returned to the investors at the Global Health Investment Fund who financed moxidectin's FDA approval.

MDGH said the priority review voucher sale was "a flagship example of the innovative investment model pioneered at Global Health Investment Fund".

The company said the sale was "an excellent case study for the [priority review voucher] program operating as it was originally intended: bringing new medicines for neglected diseases to market and providing the financial resources necessary to make those innovations accessible to those who need them most".

MDGH said that many of the initial investors would reinvest their returns in GHIF's second fund, rebranded as Adjuvant, to support innovation for neglected public health challenges.

Medicines Development for Global Health managing-director Mark Sullivan said moxidectin was "a medicine that would have been left on the shelf without the [priority review voucher] funding mechanism enabling a bold group of impact investors to finance the development of this asset".

"We are all doing this for the communities affected by river blindness and other neglected diseases and we look forward to working towards further development and delivery of this medicine," Mr Sullivan said.

"We particularly acknowledge our partnership with … the Special Program for Research and Training in Tropical Diseases in gaining the FDA approval that resulted in the [priority review voucher] award, the US government for putting the [priority review voucher] mechanism in place, and the US FDA for administering it," Mr Sullivan said.

MDGH said the Global Health Investment Fund was founded by the Bill & Melinda Gates Foundation and JP Morgan in 2012 and its investors include the International Finance Corp, the Children's Investment Fund Foundation and Germany's Federal Ministry for Economic Cooperation and Development.

FEDERAL GOVERNMENT

The Federal Government says it will provide $1 million to development and implement portable brain imaging tools in emergency vehicles for stroke treatment.
A media release from Federal Health Minister Greg Hunt said a University of Melbourne and Royal Melbourne Hospital-based team of researchers based led by Prof Geoffrey Donnan and Prof Stephen Davis were the recipients of the grant and would "target the crucial first hour after stroke onset, known as the golden hour, to give patients the best chance of survival".
The release said researchers would "spend a year developing a detailed implementation plan for lightweight, mobile, brain-imaging equipment and a telehealth stroke network to transform diagnosis and care for stroke patients".
The Government said that the brain imaging tools would be developed for use in air and road ambulances and would "better equip first responders and have the potential to transform access to emergency stroke treatment for people in rural and regional areas".
The media release said that "point-of-care diagnosis would be a breakthrough for stroke victims around Australia and around the world, reducing deaths and reducing disability for stroke survivors".
Mr Hunt's release said that the grant came through the Medical Research Future Fund Frontiers initiative.
The media release said that there were more than 56,000 strokes each year in Australia, with about 500,000 Australians living with the effects of stroke.
The Government said that the research program would be a collaboration of more than 30 Australian health and academic institutes and charities.

KAZIA THERAPEUTICS

Kazia says it has completed recruitment for its 12-patient, part B of its phase I trial of Cantrixil 5.0mg/kg for ovarian cancer.
In April, Kazia said one of nine-patients in the dose-escalation part A of the study had a partial response when co-administered with chemotherapy, with five patients achieving "stable disease after two cycles of Cantrixil monotherapy" (BD: Apr 1, 2019).
Today, the company said part B would seek preliminary signals of potential efficacy for Cantrixil at the maximum tolerated dose of 5.0 mg/kg, established in part A.
Kazia said initial data from part B was expected by January 1, 2020 with the completion of the study expected in 2020.
Kazia was unchanged at 38 cents.

RACE ONCOLOGY

Race says it has been granted a third US patent for use of Bisantrene in combination with other cancer drugs to treat acute myeloid leukaemia and breast cancer.
Race chief executive officer Peter Molloy told Biotech said that the patent, titled 'Combinatorial Methods To Improve The Therapeutic Benefit Of Bisantrene And Analogs And Derivatives Thereof' and would provide intellectual property protection until 2034.
In a media release, Mr Molloy said that "given that most cancer treatments employ combination regimens, we believe these new claims significantly bolster the attractiveness of Bisantrene to commercial partners".
Race was unchanged at 6.5 cents.

REGENEUS

Regeneus says it has restructured operations to reduce its monthly operating costs by up to $250,000, or 50 percent, through remuneration and employee cutbacks.
Regeneus said chief executive officer Leo Lee would reduce his yearly compensation by $650,000 to $290,000 a year, but would receive equity to offset the cash reduction, subject to board and shareholder approval
The company said director and chief scientific officer Prof Graham Vesey had agreed to reduce his executive role and reduce his remuneration to $140,000 a year, with chief financial officer and chief operating officer John Bird agreeing to reduce his role and salary.
Regeneus said the executive pay changes would deliver a total of $605,000 or 50 percent saving to the company.
The company said that it would reduce the “headcount of employees”, replacing in-house resources with partnerships with universities and research organizations.
Regeneus said it would relocate to a smaller officer which would deliver further savings.
Mr Lee said the cost reductions would allow the company to bring Progenza to market in Japan for osteoarthritis by 2023.
“The resulting 50 percent reduction in costs from these initiatives and the restructuring of the business is expected to provide us with sufficient runway to finalize our Japanese commercialization deal and commercially launch Progenza to this timeline,” Mr Lee said.
Regeneus was unchanged at 8.6 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTCALS

MGC says 100 patients have been prescribed its Cannepil for epilspsy, and has a distribution agreement with the Sydney-based Tetra Health.
Last year, MGC said the Australian Therapeutic Goods Administration had made Cannepil available through the authorized prescriber scheme for drug-resistant epilepsy (BD: Oct 11, 2018).
Today, the company said that Tetra would buy its products from distributor Health House International for its network of pharmacies, physicians and partnered clinics.
MGC said there were “no specified minimum contract amounts or volumes under this agreement”.
MGC fell 0.1 cents or 1.9 percent to 5.2 cents with 4.1 million shares traded.