Biotech Daily

Thursday February 7, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 13%; TELIX DOWN 6%**

*** CELLMID: 'MIDKINE ANTIBODIES FOR HEART INFLAMMATION'**

*** KOLIGO $7m IPO FOR KYSLECEL FOR PANCREATITIS, PIPELINE**

*** ANATARA 'GARP' FOR IRRITABLE GUT PROOF-OF-CONCEPT**

*** USCOM APPOINTS KONESKA SPIROSONIC US DISTRIBUTOR**

*** ELIXINOL BUYS $2.6m, 60-ACRE NSW PROPERTY FOR MARIJUANA**

*** E-SENSE TO SUPPLY MARIJUANA E-JUICE TO VAPORSPEC**

*** SPILL CALL PURA VIDA, FRESHERO TAKE 15% OF FACTOR**

*** FIL REDUCES TO 5% OF IMPEDIMED**

*** RESPIRI APPOINTS MICHAEL CLARKE WHEEZO AMBASSADOR**

MARKET REPORT

The Australian stock market was up 1.1 percent on Thursday February 7, 2019, with the ASX200 up 66.4 points to 6,092.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and one was untraded.

Patrys was the best, up 0.3 cents or 13.0 percent to 2.6 cents with 1.8 million shares traded.

Impedimed climbed 11.4 percent; Genetic Signatures improved 10.5 percent; Neuren was up 7.95 percent; Prescient rose 6.9 percent; Clinuvel and Uscom were up more than four percent; Airxpanders and Dimerix climbed more than three percent; CSL, Kazia and Medical Developments rose two percent or more; with Cynata, Opthea, Pro Medicus, Proteomics and Resmed up more than one percent.

Telix led the falls, down four cents or 5.6 percent to 68 cents, with 107,749 shares traded.

Cyclopharm and Ellex fell more than four percent; Avita and Oncosil lost more than three percent; Antisense, Nanosonics, Prana and Universal Biosensors shed two percent or more; LBT, Optiscan and Paradigm were down more than one percent; with Cochlear and Starpharma down by less than one percent.

CELLMID

Cellmid says pre-clinical studies show that its midkine antibodies prevent heart muscle damage and preserved function in chronic inflammatory heart disease.

Cellmid said that it planned to validate the findings using its antibodies for autoimmune myocarditis triggered by checkpoint inhibitors used as cancer treatments.

The company said midkine promoted cardiac muscle inflammation associated with the occasionally fatal autoimmune disease, myocarditis and its midkine antibodies prevented cardiac muscle damage due to inflammation, thereby reducing fibrosis and preserving cardiac function.

Cellmid said that in 14 patients with myocarditis confirmed by endomyocardial biopsy (EMB) and reduced cardiac function assessed by echocardiographic left ventricular ejection fraction, neutrophil extracellular traps (NETs) were detected in the biopsies of two patients with evidence of parvovirus infection and eight patients with evidence of parvovirus, with poly-morpho-nuclear neutrophils in all 14 biopsies.

The company said that an experimental mouse model of myocarditis was used to obtain further evidence for the presence of NETs in inflamed cardiac tissue.

Cellmid said the mice were treated with reagents to block NET formation and showed that NETs were “required for cardiac inflammation and remodeling”.

The research, titled ‘Midkine drives cardiac inflammation by promoting neutrophil trafficking and NETosis in myocarditis’ was published in the Journal of Experimental Medicine and an abstract is at: https://www.ncbi.nlm.nih.gov/pubmed/30647120.

Cellmid said that blocking midkine with one of its antibodies that recognized the midkine protein “dramatically reduced the number of neutrophils from 768/mm2 to 158/mm2 ($p < 0.001$) in heart muscle, together with a 5-fold decrease in the percentage of neutrophils that co-localized with NETs ($p<0.001$), demonstrating that midkine contributes to both formation of NETs as well as enhancing neutrophil recruitment.

Cellmid chief executive officer Maria Halasz told Biotech Daily that midkine increased inflammation and an anti-midkine antibody could reduce fibrosis.

Ms Halasz said that the company could “add autoimmune myocarditis to our midkine program” or consider partnering the technology for checkpoint inhibitor-induced autoimmune myocarditis with companies developing cancer treatments

Ms Halasz said the next steps would begin with investigate pre-clinical mouse model of myocarditis.

Cellmid said the data further validated its patent application covering the use of midkine antibodies for the treatment of myocarditis.

The company said its antibodies against midkine had shown “considerable promise in other inflammatory and autoimmune disorders including chronic kidney disease and a model of multiple sclerosis called experimental autoimmune encephalitis”.

“The common feature of these studies is that blocking midkine modifies the behavior of immune and inflammatory cells that perpetuate the destructive tissue injury and organ dysfunction associated with several chronic diseases,” Cellmid said.

Lead author and Cellmid collaborator Dr Ludwig Weckbach said that “to date, there is no established therapy for patients with chronic inflammatory cardiomyopathy other than non-specific immunosuppression with limited benefit and severe side effects”.

“Blocking midkine or NETs could represent novel and promising therapeutic options for patients with myocarditis,” Dr Wechbach said.

Cellmid head of research Dr Graham Robertson said the potential of midkine antibodies to alleviate the heart failure in cancer patients might lead to using the midkine assets “as an adjunct therapy in oncology to work alongside immuno-oncology drugs”.

Cellmid fell one cent or 4.2 percent to 23 cents.

KOLIGO THERAPEUTICS

Koligo says it hopes to raise $6 million to $7 million in an initial public offer on the ASX to commericialize its Kyslecel autologous pancreatic islets for pancreatitis.

Koligo chief executive officer Matthew Lehman told Biotech Daily that the Louisville, Kentucky-based company first began work on saving islets of Langerhans for re-infusion in 1977 and the Kyslecel product was approved by the US Food and Drug Administration in November 2017.

Formerly a Prima (now Immutep) chief executive officer, Mr Lehman said that from its launch in the last week of November 2017 to December 31, 2018, the company had $1.3 million in revenue from the re-implanted cells.

Mr Lehman said that pancreatitis patients had their pancreas removed and the surgeons saved the islets of Langerhans which were then treated and reinfused into the patient's liver via the portal vein, where they continued their function of producing insulin to break down glucose.

Mr Lehman said that the company had a pre-clinical pipeline of products and indications, including the use of the cells for type 1 diabetes.

He said the Australian company would have Peter James as its chairman with Ariel Sivikofsky as chief financial officer.

Mr Lehman said there was a potential $300 million US market for Kyslecel and the treatment would be reimbursable by US health insurers and Government agencies.

He said that the company expected to complete the initial public offer by the end of February or early March and list on the ASX under the code KOL.

Mr Lehman said that following the listing he expected the company to have a market capitalization of about $20 million.

ANATARA LIFESCIENCES

Anatara says it has in-vitro proof-of-concept for its gastro-intestinal reprogramming dietary supplements for irritable bowel syndrome and inflammatory bowel disease.

Anatara said it used in-vitro gut models to assess its dietary supplements, based on its bromelain pineapple stem Detach of pig diarrhoea, which it licenced to Zoetis last year for $US8.8 million ($A12.4 million) plus royalties (BD: Jul 18, 2018).

Today, the company said the laboratory in-vitro model reduced the production of pro-inflammatory proteins by gut and inflammatory cells by more than 85 percent, reduced the attachment and invasion of irritable bowel syndrome and inflammatory bowel disease pro-inflammatory bacteria in health gut cells by more than 95 percent and "protected and maintained gut integrity".

Anatara said it expected to complete mouse studies by the end of July andwas planning a human clinical study for irritable bowel syndrome to begin recruitment by the end of 2019.

The company said that irritable bowel syndrome affected about 11 percent of the global population and inflammatory bowel disease affected up to five million people worldwide.

Anatara has given the human variant of Detach the name 'Garp', standing for gastro-intestinal reprogramming, and previously told Biotech Daily that it was unrelated to John Irving's best-selling novel of the same name.

Anatara chief executive officer Steven Lydeamore said "the results we've seen from these data and the feedback from gastroenterologists to date have been very positive and indicate that Garp may be a breakthrough dietary product".

"This is a major milestone for Anatara's Garp development program bringing us closer to partnering," Mr Lydeamore said.

Anatara was untraded at 50 cents.

USCOM

Uscom says it has signed a two-year distribution deal with New York-based electronic health provider Koneksa Health for its Spirosonic device to measure lung capacity.
Uscom said the manufacture and delivery of its first order had begun, with an estimated revenue of $140,000.
Uscom was up half a cent or 4.35 percent to 12 cents.

ELIXINOL GLOBAL

Elixinol says it has paid $2.6 million for a 60-acre (24.28 hectare) Northern Rivers District, New South Wales property for marijuana cultivation and manufacturing.
Elixinol said the first stage of development would be a 5,000 square metre (53,820 square foot) facility on a 4.9-acre block within the 60-acre property.
The company said it had renamed Elixinol Australia as Nunyara Pharma, which the company said was an indigenous word meaning “to be made well again”.
Elixinol said the purchase was conditional on receiving Federal Office of Drug Control permits and local government approvals, but said it was “commercially prudent to waive the conditions and to secure [the] asset”.
Elixinol fell 18 cents or 5.5 percent to $3.11 with 535,065 shares traded.

ESENSE-LAB

E-sense says it will supply up to five million 10ml bottles a year of marijuana-infused vaporizing juice to Vaporspec for the US and Canada.
E-sense said the three-year agreement with the Costa Mesa, California-based Vaporspec required minimum quantities of 450,000 bottles in the first year to five million in the third year.
The company said its “electronic juice” would be used for vaporizing or ‘vaping’, as “a safer alternative to smoking”.
E-sense was up 0.4 cents or 14.3 percent to 3.2 cents with 136.1 million shares traded.

FACTOR THERAPEUTICS

Dissident investors say they have increased their Factor holding from 100,078,397 shares (11.99%) to 155,078,397 shares (14.87%).
On Tuesday, Factor said it received a board spill request to replace chair Dr Cherrell Hirst and directors Tim Hughes and John Michailidis with Bruce Lane and David Sanders (BD: Feb 5, 2019)
A substantial shareholder notice signed by David Grant Sanders as “director of substantial shareholders” the Abu Dhabi-based Steven Scott Day and the Perth, Western Australia based Pura Vida, Freshero, and Canadian Nickel Corp said they had become substantial shareholders in Factor.
Today, the group added three more Perth-based names, Alitime Nominees Pty Ltd for the Honeyham Family account, David Charles Neesham and Pamela Christine Neesham, saying the three groups acquired five million shares each for $15,000, but did not disclose the other 40 million shares as required under the Corporations Act 2001.
Factor was unchanged at 0.3 cents.

IMPEDIMED

FIL Limited says it has reduced its substantial shareholding in Impedimed from 24,443,264 shares (6.45%) to 20,567,815 shares (5.43%).
The substantial shareholder notice said that FIL sold 3,875,449 shares between January 3 and February 4, 2019 at prices ranging from 19.00 cents a share to 23.97 cents a share.
Impedimed was up 2.5 cents or 11.4 percent to 24.5 cents with 2.1 million shares traded.

RESPIRI

Respiri says it has appointed former Australian cricket captain, Michael Clarke as the first "ambassador" for its Wheezo asthma detecting technology.
Respiri fell 0.2 cents or 2.3 percent to 8.6 cents.