Biotech Daily

Thursday August 8, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: RESONANCE UP 29%; LBT DOWN 5%**

*** TELIX TLX591-CDx TESTS ENZALUTAMIDE FOR PROSTATE CANCER**

*** NUHEARA SELLS PERU MINING INTERESTS FOR $369k**

*** INVITROCUE, SINGAPORE HOSPITAL WORK ON ONCO-PDO**

*** BIOSCIENCE MANAGERS $5.5m FOR CSIRO, PHARMAMARK INTENCAP**

*** PHYLOGICA ASX 63% QUERY: 'RESULTS PUBLISHED NEXT MORNING'**

*** IMMURON: IMM-124E FAILS ALCOHOLIC HEPATITIS STUDY**

*** SINGAPORE APPROVES POLYNOVO NOVOSORB WOUND TREATMENT**

*** STARPHARMA BEGINS DEP-IRINOTECAN SOLID TUMOR TRIAL**

*** RECCE EUROPEAN ANTIBIOTIC PATENT**

*** ADMEDUS LOSES ARCOMED DISTRIBUTION**

*** TOTAL BRAIN, EVERYDAY HEALTH PARTNER**

*** ELIXINOL $27m PET RELEAF MARIJUANA EXTRACT DEAL**

MARKET REPORT

The Australian stock market rose 0.75 percent on Thursday August 8, with the ASX200 up 48.6 points to 6,568.1 points. Twenty of the Biotech Daily Top 40 stocks were up, nine fell, 10 traded unchanged and one was untraded.

Resonance was the best on no news, up 2.7 cents or 29.0 percent to 12 cents, with four million shares traded. Opthea and Uscom climbed more than nine percent; Polynovo was up 8.8 percent; Antisense improved six percent; Avita was up 5.2 percent; Alterity, Impedimed, Oncosil, Prescient, Pro Medicus and Starpharma were up four percent or more; Mesoblast was up 3.2 percent; Nanosonics, Next Science and Telix rose more than two percent; CSL, Cynata, Genetic Signatures and Volpara were up more than one percent; with Paradigm and Resmed up by less than one percent.

LBT led the falls, down half a cent or 4.8 percent to 10 cents, with 398,708 shares traded. Patrys and Pharmaxis fell more than four percent; Clinuvel and Universal Biosensors shed more than two percent; Amplia, Ellex and Kazia were down more than one percent; with Cochlear and Neuren down by less than one percent.

TELIX PHARMACEUTICALS

Telix says that, with Genesiscare, a 40 patient, phase II trial will use its TLX591-CDx to image the application of enzalutamide for prostate cancer.

Last year, Telix said it had a strategic collaboration agreement with the Sydney-based Genesiscare Pty Ltd for oncology services in Australia and Europe, including its TLX101 glioblastoma program (BD: Oct 10, 2018).

Telix said at that time that Genesiscare was “the largest private provider of oncology services in Australia and Europe”.

Today, Telix chief executive officer Dr Christian Behrenbruch told Biotech Daily that “enzalutamide is a standard treatment for patients with metastatic prostate cancer”.

“We are imaging patients prior to treatment with enzalutamide in order to measure prostate specific membrane antigen expression at baseline, and then again post-treatment,” Dr Behrenbruch said.

“In doing so, we expect to quantitatively determine how enzalutamide boosts the expression of the PSMA receptor,” Dr Behrenbruch said.

“This, in turn, will inform us as to whether enzalutamide will sensitize prostate cancer cells to PSMA-targeting therapy with TLX591,” Dr Behrenbruch said.

Telix said that the single-centre prospective enzalutamide-enhanced imaging study or ‘Enhancing’ study, would enrol progressive metastatic prostate cancer patients about to receive second-line androgen-deprivation therapy with enzalutamide.

The company said it would recruit 20 men with metastatic prostate cancer with demonstrated castrate sensitivity, and 20 men with metastatic prostate cancer with demonstrated castrate resistance.

Telix said all would be imaged, treated and imaged again to evaluate if diagnostic sensitivity of 68Ga-PSMA, TLX591, positron emission tomography (PET) computed tomography (CT) imaging in patients with metastatic prostate cancer was enhanced by androgen blockade with enzalutamide, or any increase in number of lesions detected in an individual patient.

The company said that secondary outcomes included comparing the degree of enhanced diagnostic sensitivity of 68Ga- PSMA PET/CT imaging in metastatic castrate-resistant prostate cancer versus metastatic castrate sensitive prostate cancer, and report any incidental findings on 68Ga-PSMA PET/CT following androgen blockade with enzalutamide.

Telix said it would evaluate the impact of enzalutamide on prostate-specific membrane antigen (PSMA) expression, which it believed would be increased in some prostate cancer patients.

The company said it would compare the expression of PSMA before and after the treatment of enzalutamide, marketed as Xtandi, through the use of positron emission tomography scans.

Telix said the study would assess the potential of combining enzalutamide and PSMA-targeting radiopharmaceuticals such as TLX591 to treat prostate cancer.

Telix was up three cents or 2.1 percent to $1.44.

NUHEARA

Nuheara says it will sell its southern Peruvian mining concessions to Auryn Resources subsidiary Corisur Peru SAC for $US250,000 ($A369,075).

Nuheara said it was selling its mining assets to focus on its hearing technologies, help develop Iqbuds Max and market its other assets.

Nuheara was unchanged at 3.5 cents with 1.2 million shares traded.

INVITROCUE

Invitrocue says it will collaborate with Singapore's National University Hospital for a validation study of its patient cancer-derived organoid screening assay.
Invitrocue said it would test chemotherapy agents on patient derived organoids (PDOs) grown from patients' refractory solid tumor cells, using its Onco-PDO screening assay.
The company said screening would allow it to select chemotherapy drugs with the highest response rate for individual breast, ovarian, colorectal or head and neck cancer patients.
Invitrocue said it hoped to offer the Onco-PDO test to National University Hospital on completion of the study.
Invitrocue executive chairman Dr Steven Fang said the study was "a key step" to enable Onco-PDO to help more patients have access to personalized cancer treatment.
Invitrocue fell half a cent or 7.7 percent to six cents.

BIOSCIENCE MANAGERS, PHARMAMARK NUTRITION PTY LTD COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Bioscience Managers says it has invested $5.5 million in Pharmamark Nutrition to develop CSIRO micro-encapsulation technology for food and beverage applications.
Bioscience Managers said the funds would go towards the Sydney-based nutrition technology company Pharmamark to develop Commonwealth Scientific and Industrial Research Organisation invented microencapsulation technology with the initial target the $US62.5 billion ($A89.3 billion) global baby milk formula market, and the completion of the company's spray dryer facility in Thailand.
The company said that the Intencap technology was "an innovative technology for lipid and bioactive nutrition, by which bio-active ingredients from marine and algal oils and vegetable and fungal oils are micro-encapsulated for food and beverage applications".
Bioscience Managers said the Intencap technology used a flexible protein and carbohydrate base, on which the specific nutrients were loaded, with an emulsion film then applied as a protective barrier, following which the micro-encapsulated nutrients are incorporated into a spray-dried powder.
The company said that a range of different types of nutrients could be loaded into shelf-stable powder products suitable for infant formula and a range of human food formulations, with a high degree of customization possible.
Bioscience Managers said Pharmamark's primary focus was the omega-3 docosahexaenoic acid (DHA) infant formula market in Asia and Oceania.
The company said that docosahexaenoic acid was a type of omega-3 fat, known to support brain function and eye health.
Pharmamark is a private company.

PHYLOGICA

Phylogica has told the ASX that it received laboratory results in an email at 6.11pm on Monday August 5 and published the news at 9.41 am on Tuesday August 6, 2019.
The ASX said the company's share price climbed 1.7 cents or 63.0 percent from 2.7 cents on July 26 to 4.4 cents on August 6, 2019 and noted "a significant increase" in the volume of securities traded.
Phylogica said the information "concerning the ability of … [its] cell penetrating peptide (CPP) technology to deliver an antisense oligonucleotide (ASO) drug cargo into human retinal pigment epithelial cells" would be considered material.
Phylogica fell 0.4 cents or 10.8 percent to 3.3 cents with 5.9 million shares traded.

IMMURON

Immuron says top line results of IMM-124E showed no statistical significance in a 57-patient safety and efficacy study for severe alcoholic hepatitis.

In 2015, Immuron said it had begun a 66-patient, US National Institutes of Health-sponsored phase II trial of IMM-124E for alcoholic steatohepatitis (BD: Jan 18, 2015).

Today, the company said the Treat-003 study by the Treat Consortium and funded by the National Institute of Alcohol Abuse and Alcoholism (NIAAA) was held at three US clinical sites was a proof-of-concept in human subjects for the mechanism of action in steroid-treated, severe alcoholic hepatitis patients.

Immuron said it enrolled 57 severe alcoholic hepatitis patients with a model for end stage liver disease (MELD) score of between 21 and 28 and treated patients with either 2,400mg a day or 4,800mg a day of IMM-124E or a placebo for 28 days.

Immuron said IMM-124E was safe for severe alcoholic hepatitis patients, but did not reduce circulating lipopolysaccharide levels, mortality or have an impact on MELD scores.

The company said no suspected unexpected serious adverse reactions were reported, no serious adverse events were observed and both doses were well tolerated.

Immuron said endotoxin levels were variable but statistically similar to baseline at day-7 and day-30 and nine deaths were reported with no difference between study groups.

The company said patient MELD scores were improved especially at day 30 onwards, but it was not statistically significant.

Richmond, Virginia-based Commonwealth University professor of gastroenterology and hepatology and lead principle investigator Prof Arun Sanyal said the study's major objective "was to determine if orally administered IMM-124E could reduce endotoxemia in patients with severe alcoholic hepatitis being treated with steroids".

Prof Sanyal said that patients with established severe disease and very high endotoxin load had no statistically significant reduction of serum endotoxin levels or markers of liver injury in the treatment groups when compared to placebo.

"The possibility of using IMM-124E prior to development of severe disease and its ability to reduce endotoxin load in that setting remains unexplored," Prof Sanyal said.

"This is a disease with a high mortality rate, nine patients enrolled in the study died due to complications associated with the disease," Prof Sanyal said.

Immuron chief executive officer Dr Gary Jacob said the company pleased to support the initiative by the NIAAA to find potential new treatments for severe alcoholic hepatitis.

"The company remains focused on its own clinical development pipeline and pursuing the registration of Travelan with the [US Food and Drug Administration] as the only approved drug to prevent travelers diarrhoea, IMM-529 to prevent Clostridium difficile infection recurrence and expanding our anti-infective preclinical programs with the US Department of Defense," Dr Jacob said.

Immuron fell one cent or eight percent to 11.5 cents with 1.1 million shares traded.

POLYNOVO

Polynovo says the Singapore Health Sciences Authority has approved its Novosorb biodegradable temporizing matrix (BTM) wound treatment.

Polynovo said it would begin sales following appointment of a distributor.

Polynovo chief executive officer Paul Brennan said that Singapore was "a small but key strategic market for our [South East] Asian success".

Mr Brennan said the approval came "at a good time for our attendance and display at the Asia Burns conference in Singapore next week".

Polynovo was up 13 cents or 8.8 percent to $1.605 with 2.9 million shares traded.

STARPHARMA

Starpharma says it will conduct an up to 45-patient, phase I/II, open-label study of its dendrimer enhanced product (DEP) irinotecan for advanced solid tumors.
Starpharma said DEP-irinotecan was a nanoparticle formulation of SN-38 the active metabolite of irinotecan, marketed by Pfizer as Camptosar or Campto, which was used alone or in combination with other drugs to treat colorectal cancer.
The company said irinotecan was limited by US Food and Drug Administration Black Box warnings for both neutropenia and severe diarrhoea.
Starpharma said that the phase I part of the trial would administer DEP-irinotecan once every three weeks at escalating doses to establish the recommended phase II dose.
The company said it would assess anti-tumor efficacy of DEP-irinotecan in phase II and both phase I and II would characterise the safety, tolerability and pharmacokinetic profile of DEP-irinotecan.
Starpharma said it would initially enrol advanced solid tumor patients, including colorectal cancer patients, at UK cancer centres and recruit patients at additional trial sites in the UK and Australia and select the target tumor types.
Starpharma chief executive officer Dr Jackie Fairley CEO said that DEP-irinotecan was "the third internal DEP product developed using Starpharma's delivery platform to commence human trials".
"There are currently limited options available for colorectal cancer patients who do not respond to conventional therapy and clinicians are keen to get this trial underway," Dr Fairley said.
"In addition to our three internal DEP-products, we are also looking forward to Astrazeneca's first DEP product AZD0466 commencing clinical trials later this year," Dr Fairley said.
"The growing DEP clinical portfolio illustrates the optionality and commercial value created by Starpharma's DEP platform," Dr Fairley said.
Starpharma was up 5.5 cents or 4.5 percent to $1.285.

RECCE PHARMACEUTICALS

Recce says it has a European patent for its antibiotics, include its lead compound Recce 327, for a broad range of common human infections.
Recce said the patent, titled 'Copolymer for use in a method of treatment of a parenteral infection' would protect its intellectual property until November 2035.
Recce was unchanged at 22 cents.

ADMEDUS

Admedus says it has terminated its distribution agreement to supply Arcomed products in Australia and New Zealand.
In 2012, Admedus said it won a $2 million five-year contract to supply Arcomed's infusion management system to Mater Health Service North Queensland and distribute the platform in Australia (BD: Nov 7, 2012).
Today, the company said it would work with affected customers to ensure no impact to patient care.
Admedus was in an extended refinancing suspension and last traded at six cents.

TOTAL BRAIN

Total Brain says it has a partnership with the New York-based consumer health website Everyday Health.
Total Brain said Everyday Health would engage website visitors with Total Brain's mental health application and it would be paid for each registration to Everyday Health.
Total Brain was unchanged at 2.2 cents.

ELIXINOL GLOBAL

Elixinol says has a $US18 million ($A26.6 million) 18-month marijuana manufacturing and supply agreement with Altmed Pets to supply marijuana extract.
Elixinol said through its subsidiary Elixinol LLC, Altmed Pets, trading as Pet Releaf, would buy a minimum of $US18 million in cannabidiol (CBD) over 18-months, and pay a $US1.8 million ($A2.7 million) deposit in three equal payments.
The company said the contracts would be renewable annually for multiple years.
Elixinol was unchanged at $2.90 with 642,374 shares traded.