Biotech Daily

Monday June 21, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 19%; IMMUTEP DOWN 12%**

*** IMMUTEP RAISES $60m, PLAN FOR $5m; TRIPLE COMBINATION TRIAL**

*** VICTORIA: MIPS, DOHERTY mRNA VACCINE TRIAL 'THIS YEAR'**

*** TELIX: EARLY DATA TAKES TLX101 TO 1st-LINE GLIOBLASTOMA TRIAL**

*** ORTHOCELL: 'CELGRO EARLY DATA SHOWS NERVE REGENERATION'**

*** STARPHARMA: UK SARS-COV-2 QUESTIONS HALT VIRALEZE SALES**

*** ST VINCENT'S INSTITUTE, PFIZER CANCER COLLABORATION**

*** ACTINOGEN APPOINTS 2 CROs, COGSTATE FOR XANAMIA**

*** EMVISION, MSH RESEARCH AND INNOVATION DEAL**

*** MAYNE LICENCES SOLARAZE, ACTKERALL; US NEXTSTELLIS LAUNCH**

*** PALLA APPOINTS ALLOGA UK PRE-WHOLESALE CO-CODAMOL SUPPLIER**

*** INCANNEX: VECTURA TO FORMULATE IHL-216A FOR TBI**

*** LITTLE GREEN REQUESTS 'ACQUISITION, CAPITAL RAISING' HALT**

*** UNISUPER BELOW 5% OF KAZIA**

*** CRYOSITE DIRECTOR ANDREW KROGER HOLDS 43.3%**

*** JOANNA JOHNSON REPLACES ACRUX CFO, CO SEC DEBORAH AMBROSINI**

*** EPSILON: LOUISA HO IN, PHILIP LEIGHFIELD OUT, NICHOLAS MARSHALL CFO**

MARKET REPORT

The Australian stock market fell 1.81 percent on Monday June 21, 2021, with the ASX200 down 133.6 points to 7,235.3 points. Just six of the Biotech Daily Top 40 stocks were up, 31 fell and three traded unchanged. All three Big Caps fell.

Actinogen was the best, up 2.5 cents or 19.2 percent to 15.5 cents, with 20.5 million shares traded. Patrys climbed 12.2 percent; Prescient was up 7.7 percent; Osprey rose 6.7 percent; Compumedics rose 4.1 percent; with Universal Biosensors up 1.35 percent.

Immutep led the falls, down 7.5 cents or 12.2 percent to 54 cents, with 9.1 million shares traded. Starpharma and Telix lost more than nine percent on bad news and good news, respectively; Opthea fell 7.6 percent; Amplia, Proteomics and Uscom retreated more than six percent; Mesoblast and Pharmaxis were down more than five percent; Antisense, Clinuvel, Dimerix, Imugene and Optiscan fell more than four percent; Medical Developments and Nova Eye were down more than three percent; Cyclopharm, Nanosonics, Next Science, Pro Medicus and Volpara shed more than two percent; Avita, Kazia, LBT, Oncosil, Paradigm, Polynovo, Resmed and Resonance were down more than one percent; with Cochlear, CSL, Genetic Signatures, Neuren and Orthocell down by less than one percent.

IMMUTEP

Immutep says it has raised $60 million in a placement at 52 cents a share and hopes to raise up to $5 million through a share plan to expand its clinical portfolio.
Immutep said the funds would go to a new phase I triple combination therapy of IMP321, an anti-programmed death-1 (PD-1) therapy and chemotherapy, a phase III metastatic breast cancer trial, other trials, manufacturing and validation, regulatory processes, an autoimmune program for IMP761 and to strengthen its team and research projects.
Immutep said the new Insight-003, up-to 20 patients, phase I, triple combination therapy trial for solid tumors would be conducted at Krankenhaus Nordwest in Frankfurt, Germany.
The company said patients would receive 30mg doses of IMP321 every two weeks for 24 weeks with chemotherapy and an anti-PD-1 therapy to assess the safety, tolerability and initial efficacy of the combination.
Immutep said it the non-underwritten share plan hoped to raise $5 million and had a record date of June 18, the offer would open on June 28 and close on July 19, 2021.
Immutep fell 7.5 cents or 12.2 percent to 54 cents with 9.1 million shares traded.

VICTORIA GOVERNMENT
MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES, DOHERTY INSTITUTE

The Victoria Government says the state “has developed and will make Australia’s first local mRNA Covid-19 vaccine candidate to reach phase I clinical trials” this year.
A media release from Acting Premier James Merlino said Victoria would support the Monash Institute of Pharmaceutical Sciences, with the Doherty Institute, to manufacture doses of the mRNA vaccine for trials on about 150 people “due to start within months”.
The State Government said that an mRNA-based vaccine would enable a Victorian manufacturer to develop critical manufacturing capability of mRNA vaccines for clinical trials “a level of expertise currently unavailable in Australia”.
The Victoria Government said the $5 million came from the previously announced $50 million fund to develop the State’s mRNA manufacturing capability (BD: Apr 21, 2021).
Victoria said that the MIPS candidate was “Australia’s leading mRNA vaccine candidate” and previously received $3 million from the Federal Government’s Medical Research Future Fund to cover the costs of the phase I clinical trial.
“The development of mRNA capability is revolutionizing medical research globally and has the capacity for broad-based application in HIV, cancer and other treatments,” the Victoria Government said.
In January, the Doherty Institute said that the Federal Government had provided $1.5 million for trials of two severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) vaccines (BD: Jan 17, 2021).
In January, the Doherty said the vaccines were developed by researchers from the Doherty Institute and the Monash Institute of Pharmaceutical Sciences and used two different approaches focusing on the tip of the severe acute respiratory syndrome-Coronavirus-2 (Sars-Cov-2) spike protein, known as the receptor binding domain, which mediated the virus’s ability to attach and enter the cell.
In a media release in September 2020, the Doherty Institute said the two candidates were both focused on the “receptor binding domain” (RBD) of the Sar-Cov-2 “spike protein”.
The Institute said the first was an RBD protein acting against the tip of the spike in an isolated molecular form to focus the immune response on this critical region of the virus targeted by antibodies that neutralized viral infectivity; and the second was the RBD mRNA candidate acting on the virus genetic sequence that codes for the tip of the spike, which would lead to production of the RBD protein.

TELIX PHARMACEUTICALS

Telix says it has closed recruitment in its phase I/II trial of TLX101 for recurrent glioblastoma on positive data and will take the combination therapy to a first-line trial.

Telix said that having recruited 10 patients in the phase I section of the up-to 44 patients in the Ipax-1, phase I/II trial of in combination with external beam radiation therapy for recurrent glioblastoma multiforme, an interim analysis of safety and preliminary efficacy was "sufficiently encouraging to warrant study in front-line therapy, where radiation therapy is more extensively used".

Telix chief executive officer Dr Christian Behrenbruch told Biotech Daily that the first 10 patients "were a milestone that would have led to the decision to move to the phase II study as both single and fractionated dosing was evaluated".

"Instead of moving to the phase II in the recurrent, or second-line, patients we are going to move up the treatment cascade to first-line patients," Dr Behrenbruch said.

The company said TLX101 was a systemically administered molecularly-targeted radiation asset targeting the L-type amino acid transporter 1 (LAT-1), which was overexpressed in glioblastoma and had been granted orphan drug designation in the US and Europe.

Telix chief medical officer Dr Colin Hayward said the company was "highly encouraged by the safety profile of this single arm dose-escalation study, where different dosing regimens have been combined with external radiation therapy".

"Whilst a small study of 10 patients, promising overall survival and anti-tumor response observed from longitudinal imaging supports the decision to progress this candidate into an earlier line of therapy," Dr Hayward said.

Telix said it would release the safety and efficacy data on completion of the study report.

Dr Behrenbruch said Ipax-2 trial design was being developed and was likely to be a combination with chemotherapy, surgery and external beam radiation.

Dr Behrenbruch said that TLX101 had "a combination effect of both delivering targeted radiation to cancer cells, including behind the blood-brain barrier, and also increasing the sensitivity of external beam radiation".

Telix fell 64 cents or 10.0 percent to $5.77 with 1.6 million shares traded.

ORTHOCELL

Orthocell says it interim data from its Celgro shows that 25 of 33 nerve repairs following injury consistently restored arm and hand function.

Orthocell said the 12-month data was for 16 of the 19 patients in the trial who had nerve injuries following motor vehicle, sporting or work-related incidents, received one or more nerve repairs augmented with Celgro in one or both upper limbs.

The company said recovery was assessed by grading the strength of target muscles closest to the site of the nerve repair with 25 of 33 (75.8%) of repairs resulting in functional recovery of muscles controlled by the repaired nerve.

Orthocell said 17 of 33 nerve repairs were in five quadriplegic patients with 13 of 17 (76.5%) repairs resulting in "the best-case clinical outcome" at 12 months post treatment.

Orthocell said it was preparing for talks with the US Food and Drug Administration, insurance companies and opinion leaders on registration and reimbursement pathways.

Orthocell managing director Paul Anderson said that "consistently returning function to paralyzed upper limbs is the primary goal in this study".

"I am delighted by the 12-month follow up results, our most complete data set to date, demonstrating higher quality outcomes, improved predictability, and consistency of return of muscle function following Celgro nerve regeneration treatment," Mr Anderson said.

Orthocell fell half a cent or 0.8 percent to 60 cents with 4.5 million shares traded.

STARPHARMA

Starpharma says it has withdrawn its Viraleze anti-microbial nasal spray from sale in the UK following questions from the regulator on claims about Sars-Cov-2 and Covid-19.

Last week, Starpharma said the SPL7013 active ingredient, the same as in its Vivagel for bacterial vaginosis and condom coatings, was more than 99.9 percent effective against all strains of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) the cause of Covid-19, in-vitro (BD: Jun 18, 2021)

Today, the company said its UK distributor Lloyds Pharmacy received correspondence from the UK Medicines and Healthcare Products Regulatory Agency "in relation to specific promotional claims made for Viraleze antiviral nasal spray".

Starpharma said the correspondence related to "promotional claims, including references to Sars-Cov-2 and Covid-19, and the inter-relationship between these product claims and its categorization", but did not question or relate to the safety or quality of Viraleze.

The company said it was engaging with the MHRA to resolve the matter as quickly as possible and while it disagreed with the MHRA, it would "temporarily pause sales of Viraleze in the UK during this time".

Starpharma said it had "extensive data, including published data, in relation to the broad-spectrum anti-viral activity and the mechanism of action for Viraleze supporting the product and its promotional claims" and prior to the launch, it obtained regulatory advice and input from a European Union regulatory body in relation to the product and its claims.

Starpharma said that "the temporary pause in promotion and sales is specific to the UK and does not impact other markets, including in Europe and India where the product is registered for sale".

The company said Viraleze was available in multiple countries but not Australia.

Starpharma fell 16 cents or 9.4 percent to $1.54 with 1.9 million shares traded.

ST VINCENT'S INSTITUTE OF MEDICAL RESEARCH

Melbourne's St Vincent's Institute says it has a cancer research collaboration with Pfizer's Centers for Therapeutic Innovation.

The St Vincent's Institute said that the early-stage research collaboration aimed "to identify potential new small molecules that target the DNA damage response … common to most cancers".

The Institute said that the small molecules mighty provide the basis for future cancer treatments that targeted specific vulnerabilities of cancers based on their genetics, "treatments that could be more effective and less toxic than traditional chemotherapies".

St Vincent's said the research would be led by Prof Wayne Crismani and evolved from "many years of research" undertaken by his DNA Repair and Recombination Laboratory and the Institute's Genome Stability Unit, led by Prof Andrew Deans.

"Our vision is to develop personalized cancer treatments by translating decades of fundamental knowledge from research on rare diseases and DNA repair pathways," Prof Crismani said.

"By exploiting the mechanisms that cause DNA damage, the very thing that starts cancer in the first place, our team hopes to be able to find new potential treatments," Prof Crismani said.

Prof Crismani said the Institute would combine its knowledge with Pfizer's drug discovery, research and translation expertise.

St Vincent's Institute director Prof Tom Kay said that "uniting our scientists' drive to understand fundamental mechanisms of human health with Pfizer's leadership in oncology research has the potential to transform cancer treatment".

ACTINOGEN MEDICAL

Actinogen says it has appointed two clinical research organisations and Cogstate to assist in the conduct, management, and recruitment of the Xanamia part-A study.
Earlier this month, Actinogen said it had ethics approval for its 100-healthy older volunteer, part-A Xanamia dosing study of Xanamem for cognition (BD: Jun 2, 2021).
Today, the company said that Sydney's Paratus Clinical and Adelaide's Avance Clinical would assist the study, costing a total of about $2.1 million.
Actinogen said it had an agreement with Cogstate for $US300,000 ($A399,474) to use its cognition tests.
The company said the dose ranging Xanamia study would be conducted at four Paratus Clinics enrolling 105 healthy volunteers aged 50 years and above, to confirm the minimum effective dose, while Avance would manage the study.
Actinogen was up 2.5 cents or 19.2 percent to 15.5 cents with 20.5 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has a clinical expertise, research and innovation collaboration with Metro South Health to advance its electromagnetic imaging into products.
Emvision said the Brisbane-based Metro South Health provided public health care would provide access to neurology, radiology and critical care expertise, assistance with expanded clinical study design and development, access to simulation rooms and hospital infrastructure, advancement of bedside processes and input into technology development.
The company said it would contribute $215,500 in research funding during the one-year term and would retain any intellectual property developed during the collaboration.
Emvision chief executive officer Dr Ron Weinberger said that Metro South Health had "state-of-the-art facilities and clinical expertise".
"Collaboration of this kind for emerging medical device companies is a best practice model in countries with world leading health technology advances but is less prevalent in Australia," Dr Weinberger said.
"Metro South Health is following this best practice path while allowing Emvision exceptional access to a very large pool of clinical expertise that is unusual for a company of our size," Dr Weinberger said.
Emvision was up two cents or 0.7 percent to $3.03.

MAYNE PHARMA GROUP

Mayne Pharma says it has licenced Australian rights to Solaraze gel and Actikerall topical solution for actinic keratosis, and launched Nextstellis in the US.
Mayne Pharma said it had licenced Solaraze and Actikerall from Barcelona's Almirall
The company said it had acquired Fabior foam for acne from Glaxosmithkline and had filed an application to the Australian Therapeutic Goods Administration for approval.
The company said the full distribution rights of Solaraze gel had begun and was expected to be completed by July 1 while the transfer and launch planning of Actikerall had been completed.
Separately, the company said its drospirenone and oestetrol combination oral contraceptive Nextstellis had been launched in the US.
Last month, Mayne said the US Food and Drug Administration had granted Nextstellis five-year exclusivity as a new chemical entity (BD: May 27, 2021).
Mayne fell 1.5 cents or 4.3 percent to 33.5 cents with 5.6 million shares traded.

PALLA PHARMA

Palla says it has appointed the Weybridge Surrey, Enlgand Alloga UK as its exclusive provider of pre-wholesale supply chain services for its codeine-paracetamol in the UK.
Palla acting chief executive officer Brendan Middleton said the company was “able to access Alloga’s distribution network including six major UK wholesale groups which supply to70 percent of the UK Co-Codamol retail market”.
“In addition, Alloga’s international healthcare supply chain network offers a pan-European delivery capability, and the company will look to further leverage its partnership with Alloga as it launches products into other major European markets,” Mr Middleton said.
Palla fell 2.5 cents or 6.4 percent to 36.5 cents.

INCANNEX HEALTHCARE

Incannex says it has appointed the Chippenham, England-based Vectura to formulate its inhaled, marijuana-based IHL-216A for traumatic brain injuries.
Incannex said IHL-216A was a combination of cannabidiol with any volatile anaesthetic agent, including isoflurane, and was designed to be administered soon after head trauma to reduce secondary brain injuries that lead to neurological deficits.
The company said Vectura would undertake formulation screening studies, manufacturing process optimization studies, a stability assessment on the lead formulation, and manufacture a laboratory-scale batch of IHL-216A for toxicology studies.
Incannex said Vectura would provide support services for the regulatory process for the approval of IHL-216A and its inhalation delivery mechanism.
In March, Incannex said it had partnered with the Monash Trauma Group to study the protective effect of its cannabidiol and isoflurane-based IHL-216A for sports concussions in rats (BD: Mar 11, 2021).
Today, the company said it had appointed Vectura in parallel to the in-vivo study to ensure it had the specific formulation and delivery mechanism required to advance the pivotal clinical trials following the finalization of the study.
Incannex fell one cent or 3.85 percent to 25 cents with 5.6 million shares traded.

LITTLE GREEN PHARMA

Little Green has requested a trading halt pending an announcement “regarding a proposed acquisition and an associated capital raising”.
Trading will resume on June 23, 2021 or on an earlier announcement.
Little Green last traded at 65 cents.

KAZIA THERAPEUTICS

The Melbourne-based Unisuper says it has ceased its substantial share-holder in Kazia.
Last year, Unisuper said it had become a substantial shareholder in Kazia with 6,650,587 shares or 5.78 percent of the company. (BD: Oct 30, 2020)
Today, the company said it sold 698,630 shares for $946,644 or $1.355 a share and retained 5,951,957 shares, which Biotech Daily calculates to be 4.59 percent.
Kazia fell 2.5 cents or 1.85 percent to $1.325.

CRYOSITE

Cryosite director Andrew John Kroger says he has increased his substantial shareholding from 20,183,831 shares (43.07%) to 20,266,964 shares (43.25%).
The London-based Mr Kroger said that on June 17, he acquired 83,133 shares on market at 43 cents a share.
Cryosite was unchanged at 42 cents.

ACRUX

Acrux says it has appointed Joanna Johnson as its chief financial officer effective from June 21, replacing Deborah Ambrosini who retires on June 25, 2021.
In 2019, Acrux said Ms Ambrosini replaced Tim Bateman as its chief financial officer and company secretary (BD: Jun 7, 2019).
Last year, IDT said from March 2014 to June 2020 Ms Johnson was its chief financial officer and joint company secretary (BD: Jun 16, 2020).
Acrux was unchanged at 11.5 cents.

EPSILON HEALTHCARE

Epsilon says it has appointed Louisa Ho as company secretary effective from June 18, 2021 replacing Philip Leighfield following his resignation on June 18, 2021.
Last week, Cardiex said Nicholas Marshall would replace Philip Leighfield as joint company secretary (BD: Jun 18, 2021).
Today, Epsilon said it had appointed Nicholas Marshall as interim chief financial officer to support chief executive officer, Jarrod White, and chief operating officer, Sonny Didugu "through the completion of the corporate and strategic initiatives".
The company said Ms Ho would join Mr Didugu who continued as company secretary.
Epsilon fell half a cent or 3.3 percent to 14.5 cents.