Biotech Daily

Monday May 9, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRESCIENT UP 28%; IMPEDIMED DOWN 14%**

*** DIMERIX: US FDA APPROVES PHASE III DMX-200 FSGS TRIAL**

*** AMPLIA: FDA WANTS MORE AMP945 DATA FOR CANCER TRIAL**

*** ARTRYA, HUNTSVILLE HEART CENTRE FOR US SALIX STUDY**

*** PRESCIENT PTX-200 AML REMISSION EXPANDS COHORT**

*** MAYNE RECEIVES UP TO $4.8m FEDERAL MANUFACTURING GRANT**

*** IMUGENE TELLS ASX QUERY NOT AWARE UNTIL MAY 2**

*** IMMURON: TRAVELAN FOR US STUDY MANUFACTURED**

*** ZELIRA LAUNCHES ITURA MARIJUANA CREAM IN THE US**

*** NUHEARA APPOINTS JOHN LUNA US CEO, ROTH CAPITAL ADVISER**

*** MICROBA APPOINTS PATRICK MOELK FOR NORTH AMERICA SALES**

MARKET REPORT

The Australian stock market fell 1.18 percent on Monday May 9, 2022, with the ASX200 down 84.9 points to 7,120.7 points. Six of the Biotech Daily Top 40 stocks were up, 29 fell, four traded unchanged and one was untraded.

Prescient was the best, up 3.5 cents or 28.0 percent to 16 cents, with 18.4 million shares traded. Polynovo climbed 3.3 percent; Opthea and Paradigm rose two percent or more; Cyclopharm and Kazia were up more than one percent; with CSL up 0.8 percent.

Impedimed led the falls, down 1.5 cents or 13.6 percent to 9.5 cents, with 2.9 million shares traded. Compumedics and Nova Eye lost 12 percent or more; Actinogen and Imugene were down more than 11 percent; Micro-X was down 8.1 percent; Orthocell and Telix lost more than seven percent; Starpharma and Universal Biosensors shed more than six percent; Avita, Nanosonics and Resonance retreated more than five percent; Antisense, Cynata, Emvision, Medical Developments, Pro Medicus and Volpara fell four percent or more; Alcidion, Dimerix, Neuren and Next Science were down more than three percent; Clinuvel and Immutep shed more than two percent; Cochlear, Genetic Signatures, Mesoblast, Oncosil and Resmed were down more than one percent; with Proteomics Telix down by 0.5 percent.

DIMERIX

Dimerix says the US Food and Drug Administration has approved its phase III 'Action3' study of DMX-200 in up to 286-patients with focal segmental glomerulosclerosis.

Dimerix said the phase III trial, titled 'Angiotensin II Type 1 Receptor & Chemokine Receptor 2 Targets for Inflammatory Nephrosis' (Action3), was a pivotal, multi-centre, randomized, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) who were receiving a stable dose of an angiotensin II receptor blocker.

The company said that once the angiotensin II receptor blocker dose was stable, patients would be randomized to receive either DMX-200 (120mg capsule twice daily) or placebo.

Dimerix said that the investigational new drug application for the study was active and allowed for patient recruitment in the US.

Dimerix said that the trial was being conducted at 75 locations in 12 countries, with 19 sites in the US and it expected the first interim analysis by July 2023.

In October, the company said that it had the first approval to start its up-to 250-patient, phase III trial of DMX- 200 for FSGS kidney disease and in February, it said it had Danish Medicines Agency approval (BD: Oct 21, 2021; Feb 1, 2022).

Today, Dimerix managing-director Dr Nina Webster said the FDA approval of the investigational new drug for the phase III FSGS study was "an important milestone, as it includes regulatory review of all manufacturing, non-clinical and clinical data that we have generated for the DMX-200 program to date".

Dimerix fell half a cent or 3.85 percent to 12.5 cents with 1.5 million shares traded.

AMPLIA THERAPEUTICS

Amplia says the US Food and Drug Administration has requested further information before allowing a study of AMP945 for pancreatic cancer, but won't delay the trial.

Amplia said that the FDA advised that the design of its planned study of investigational focal adhesion kinase inhibitor AMP945 was generally acceptable but recommended "some further pharmaco-kinetic sampling to more thoroughly interrogate patient exposures to AMP945, gemcitabine and nab-paclitaxel".

The company said that the recommendations could be "readily applied without delaying the trial" and that it intended to implement them "in full".

Amplia said that its trial design included selection of first-line patient population and a proposed dose-escalation followed by a 'Simon two-stage design' and was expected to begin recruitment by July 2022.

The company said that the FDA commented that "the available and planned pre-clinical data appear to support both the trial and a future marketing application in the proposed indication".

Amplia said that the FDA reviewed the proposed drug substance and drug product specifications and advised that "these appear reasonable".

The company said that the FDA had granted AMP945 orphan drug designation for pancreatic cancer, providing it seven years of exclusivity and a waiver of FDA fees.

Amplia managing-director Dr John Lambert said the company was "very pleased to receive FDA's timely and helpful feedback".

"This [pre-investigational new drug] advice provides early insight into FDA's priorities and equips us to address these proactively," Dr Lambert said.

"It also allows us to enter our planned clinical study reassured that our intent to bring first-line patients into the trial is reasonable and acceptable," Dr Lambert said.

Amplia was unchanged at 12 cents with 1.05 million shares traded.

ARTRYA

Artrya says the Huntsville Heart Center in Alabama will study the efficacy of its Salix computed tomography scan analysis software.

Artrya said that the Huntsville Center would conduct a study of its Salix coronary anatomy artificial intelligence-based technology, which analyzes cardiac computed tomography (CT) scans to report a unique combination of coronary disease biomarkers, including components of high-risk plaque.

The company said that the study would use CT scans previously obtained for clinical purposes, which would be anonymized and uploaded to the internet cloud-based Salix technology for interpretation.

Artrya said that this interpretation would then be compared with the interpretation of multiple 'expert' readers.

Artrya co-chief executive officers, Jory Tremblay and Ted Schwab said it was the company's first clinical partnership in the US, and were "pleased that such a well-regarded heart centre has joined in our mission to create better detection of the world's leading killer, heart disease".

The company said that it expected the clinical trial to be completed by October 2020.

Artrya was unchanged at 70 cents.

PRESCIENT THERAPEUTICS

Prescient says it will expand the PTX-200 45mg/m^2 cohort in its phase Ib study of PTX-200 and cytarabine, following a "complete remission" and no dose limiting toxicities.

Last year, Prescient said the 35mg/m^2 second cohort of its combination trial for acute myeloid leukaemia (AML) showed no "dose limiting toxicities" (BD: Apr 23, 2021).

Today, the company said three patients received cytarabine with 45mg/m^2 PTX-200, with no dose limiting toxicities reported and one patient achieving a complete remission of disease with neutrophils and/or platelets yet to recover to normal levels.

Prescient said the study at the Tampa, Florida-based H Lee Moffitt Cancer Center under principal investigator Prof Jeffrey Lancet had four complete remissions and one patient in the 35mg/m^2 cohort had a partial response.

Prof Jeffrey Lancet said that "it is believed that 45mg/m^2 may be a biologically effective dose of PTX-200, therefore we will recruit an additional three patients at this dose level to further investigate safety and efficacy in this fragile patient population".

Prescient managing-director Steven Yatomi-Clarke said that it was "very satisfying to see another patient with remission in a disease that is so aggressive and fatal".

Prescient was up 3.5 cents or 28.0 percent to 16 cents with 18.4 million shares traded.

MAYNE PHARMA GROUP

Mayne says it has received up to $4.8 million from the Federal Government Modern Manufacturing Initiative to "expand its advanced manufacturing capability and capacity".

Mayne chief executive officer Scott Richards said the grant would allow the company "to expand its advanced manufacturing capability and capacity and ensure the Salisbury site remains one of Australia's leading solid oral dose manufacturing facilities".

"The project seeks to more than double the encapsulation and blister packaging capacity and introduce new technologies such as serialization to support the export of select solid oral dose products," Mr Richards said.

Mayne was unchanged at 28.5 cents with 3.2 million shares traded.

IMUGENE

Imugene has responded to an ASX aware query saying it was first aware of the termination of the supply agreement with Merck & Co on May 2, 2022.
The ASX said a webpage on the US National Library of Medicine website outlined the phase II trial, had amendments published on April 19, 2022 which removed Merck as collaborator and asked if Imugene was aware of the termination prior to its announcement.
Imugene said that the changes to the website were “an administrative matter” and were “not related to the information or the termination that occurred on May 2, 2022”.
Last week, Imugene said that the pembrolizumab, or Keytruda, supply agreement with the Kenilworth, New Jersey-based Merck & Co Merck & Co has been terminated, but the phase II gastric cancer trial would continue unchanged (BD: May 2, 2022).
In March, Imugene said it would sponsor the phase II trial of HER-Vaxx with an anti-programmed death 1 therapy for human epidermal growth factor 2 (HER-2) positive gastric cancer study, while Merck & Co would provide Keytruda (BD: Mar 15, 2022).
Imugene executive chair Paul Hopper told Biotech Daily last week the company would source pembrolizumab elsewhere but the trial was “still full speed ahead”.
In its aware query, the ASX noted that following the release of the termination announcement on May 2, the share price dropped 13.6 percent from the closing price of 22 cents a share at April 29, to the closing price of 19 cents a share at May 2.
Imugene fell two cents or 11.1 percent to 16 cents with 26.0 million shares traded.

IMMURON

Immuron says it has completed manufacture of Travelan for travelers’ diarrhoea for evaluation by the Bethesda, Maryland-based Uniformed Services University.
Immuron said that the US Department of Defense Uniformed Services University, the UK Ministry of Defense and the New York City Travel Clinic would conduct a randomized, double-blinded, placebo-controlled, multi-centre clinical trial of 1,336-patients to evaluate the efficacy of the prebiotic Bimuno, the probiotic Florastor and the cow colostrum-based IMM-124E, or Travelan, against a placebo, for prophylaxis during deployment or travel to a high-risk travelers’ diarrhoea region.
Immuron said the study was expected to begin recruitment in June 2022, with enrolment expected to conclude in about 18 months” and the protocol had extended the treatment period from 13 days to 22 days to cover the quarantine period still required by some countries with travelers at risk of diarrhoea symptoms during this period.
Immuron was up half a cent or 4.8 percent to 11 cents.

ZELIRA THERAPEUTICS

Zelira says Cardiovascular Solutions of Central Mississippi will sell its Itura marijuana-based cream for symptomatic relief of peripheral artery disease and diabetes.
Zelira said the Cleveland, Mississippi-based Cardiovascular Solutions launched Itura with an initial 10,000-unit order and would have exclusive marketing rights to the US market.
The company said Itura was a “relief cream formula using [cannabidiol] and ‘Hemp Spectra Technology’ that targeted numbness, tingling, muscle cramps, insensitivities and neuropathies including pain associated with peripheral artery disease and diabetes”.
Zelira said it would receive royalties on Itura sales in the US.
Zelira managing-director Dr Oludare Odumosu said that the launch of Itura was a “significant milestone”.
Zelira was up two cents or 1.6 percent to $1.30.

NUHEARA

Nuheara says it has appointed John Luna as its US-based chief executive officer and engaged Roth Capital Partners as its adviser for US listing alternatives.

Nuheara said that co-founder and former chief executive officer Justin Miller would remain as its managing-director.

The company said that Mr Luna joined Nuheara in May 2021 and previously was its chief revenue officer and head of Americas.

Nuheara said that Mr Luna had more than 30 years of experience, working previously as an executive of Ihear Medical, Eargo, Bernafon Demant and Insound Medical.

Nuheara fell half a cent or 2.8 percent to 17.5 cents.

MICROBA LIFE SCIENCES

Microba says it has appointed Patrick Moelk as head of sales for North America, effective from today.

Microba said that Mr Moelk had more than 15 years of experience in the diagnostics and medical sales industry in the US, previously working for Natera and Myriad Genetics.

Microba head of platform solutions Bernie Woodcroft said that “consumers and practitioners are becoming increasingly aware of the effectiveness of gut microbiome testing as part of health management”.

“With the appointment of Patrick, Microba will accelerate its rapid deployment of testing technology into new distribution partnerships throughout North America to capture this growing demand,’ Mr Woodcroft said.

Microba fell three cents or 8.1 percent to 34 cents.