Biotech Daily

Tuesday October 4, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PARADIGM UP 20%; GENETIC SIGNATURES DOWN 5%**

*** IMPEDIMED, GENESISCARE US SOZO LYMPHOEDEMA SCREENING DEAL**

*** PARADIGM: PPS 'SIGNIFICANT PAIN IMPROVEMENT'**

*** EMVISION BRAIN SCANNER STUDY APPROVED**

*** IMMUTEP WINS FDA IMP321 FAST TRACK STATUS FOR 1st LINE NSCLC**

*** BIOTRON ENROLS BIT225 HIV TRIAL**

*** IMMURON, PHARMARON TRAVELAN DIARRHOEA TRIAL**

*** MAYNE COMPLETES $772m SALE OF METRIC TO CATALENT**

*** RADIOPHARM: LRRC15 'PROTECTS TUMOR CELLS, CAUSES GROWTH'**

*** GENETIC SIGNATURES TELLS ASX: 'RESULTS NOT MARKET SENSITIVE'**

*** CANN GROUP MILDURA MARIJUANA LICENCE EXTENDED**

*** ADALTA RECEIVES $1.6m FEDERAL R&D TAX INCENTIVE**

*** ARGENICA RECEIVES $1.4m FEDERAL R&D TAX INCENTIVE**

*** TDM TAKES 27% OF SOMNOMED**

*** M-D DR KAREN DUGGAN INCREASES, DILUTED TO 6.9% IN VECTUS**

*** IMUGENE APPOINTS DR GIOVANNI SELVAGGI CMO, PAUL WRIGHT CMC**

MARKET REPORT

The Australian stock market was up 3.75 percent on Tuesday October 4, with the ASX200 up 242.4 points to 6,699.3 points. Nineteen of the Biotech Daily Top 40 stocks were up, seven fell, 10 traded unchanged and four were untraded. All three Big Caps were up.

Paradigm was the best, up 25 cents or 19.8 percent to $1.51, with four million shares traded. Emvision climbed 16.8 percent; Polynovo was up 8.65 percent; Actinogen rose 7.2 percent; Immutep, Impedimed and Pharmaxis improved more than six percent; Orthocell and Starpharma were up five percent or more; Alcidion, Cynata and Telix improved more than four percent; Cochlear, Next Science and Pro Medicus were up more than three percent; Imugene and Resmed rose more than two percent; Clinuvel, CSL, Nanosonics and Volpara improved more than one percent; with Avita up by 0.9 percent.

Genetic Signatures led the falls, down five cents or 5.4 percent to 88 cents, with 93,045 shares traded. Patrys fell five percent; Micro-X was down 3.2 percent; with Antisense, Oncosil, Prescient and Universal Biosensors down by two percent or more.

IMPEDIMED

Impedimed says it has a commercial partnership with Genesiscare for lymphoedema screening services for breast cancer patients in the US.

Impedimed did not disclose the commercial terms but said the pilot program would consist of an initial rollout of five Sozo bioimpedance fluid volume systems to "establish lymphoedema screening services for breast cancer patients in centres across the US" by December 30, 2022.

The company said that Genesiscare had more than 300 locations across the US, Australia, Spain and the UK, and that upon completion of the pilot program, Genesiscare would evaluate a staged expansion to additional sites in the US and globally.

Impedimed interim chief executive officer David Anderson said "we are proud to partner with organizations like Genesiscare that are committed to bringing innovative technologies and solutions to their patients".

"Our team will work closely with the five pilot sites to ensure successful implementation of Sozo within their existing workflows," Mr Anderson said.

"These initial programs will create the template to bring lymphoedema prevention services to more cancer patients across the globe," Mr Anderson said.

Impedimed was up 0.4 cents or 6.25 percent to 6.8 cents with 2.1 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says patients receiving injectable pentosan polysulfate sodium (PPS) showed "statistically significant improvement" in pain and stiffness scores at day 56.

Paradigm said its 61-patient, randomized, phase II trial was evaluating the treatment effects of PPS on synovial fluid biomarkers associated with osteoarthritis-related pain, inflammation, and disease progression in humans.

The company said patients received either a subcutaneous injection of 2.0mg/kg PPS twice weekly, PPS once weekly and a placebo injection, or two placebo injections a week for six weeks.

Paradigm said that at day-56, the mean change from baseline in Western Ontario and McMaster Universities Osteoarthritis Index (Womac) pain scores was 50 percent compared to 30 percent ($p = 0.05$) for twice weekly PPS and placebo, respectively, as well as a 50 percent percentage change from baseline in Womac function scores compared to 25 percent ($p = 0.017$) for twice weekly PPS compared to placebo respectively.

Paradigm said the phase II trial was an exploratory study "not intended to be powered to obtain statistical significance".

Last week, the company said there were "no serious adverse events" in its 12-patient, phase II trial of PPS for muco-poly-saccharidosis type VI (BD: Sep 26, 2022).

Today, Paradigm chief medical officer Dr Donna Skerrett said the company was "very encouraged by the synovial fluid biomarker signals we see in this study".

"The observed changes indicate mechanistic effects through pain, inflammation, and chondroprotective pathways," Dr Skerrett said. "These changes are consistent with the clinical effects observed in this and prior studies of iPPS in osteoarthritis."

"Evidence of multimodal effects supports our understanding of the actions of iPPS," Dr Skerrett said. "These biomarker changes in the joint, following subcutaneous administration of iPPS, demonstrate local effects in the synovial fluid."

"These are meaningful signals that we will evaluate together with clinical and imaging outcomes in order to demonstrate disease modifying effects and to pursue regulatory authority guidance on a disease modifying pathway," Dr Skerrett said.

Paradigm was up 25 cents or 19.8 percent to $1.51 with four million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has trial approval for its portable brain scanner at Sydney's Liverpool Hospital, the Royal Melbourne Hospital and Brisbane's Princess Alexandra Hospital.
Emvision said the study protocol was yet to be announced, but the first two stages would enrol at least 180 participants, including acute stroke and stroke mimic patients, with endpoints of verification, safety and data to "enhance artificial intelligence algorithms".
The company said the validation phase would assess the safety, sensitivity and specificity of the brain scanner and that it expected to complete the study within 12 months.
Emvision said it had triggered a further $1.2 million milestone grant payment as part of its $8 million project agreement with Australian Stroke Alliance (BD: Sep 16, 2021).
Emvision chief executive officer Dr Ron Weinberger said the approval was "a significant milestone for Emvision on the journey to commercialize our first-generation product".
"Knowing that our device has gone through rigorous assessment and has been given a tick of approval to enter the clinical environment is a meaningful development," Dr Weinberger said. "This trial will provide us with significant information to learn about the range of capabilities of our technology to inform clinical decision making in stroke care."
Emvision was up 22 cents or 16.8 percent to $1.53.

IMMUTEP

Immutep says the US Food and Drug Administration has granted it fast track designation for IMP321 with pembrolizumab for first-line non-small cell lung cancer.
Immutep said IMP321, or eftilagimod alpha (efti), activated antigen-presenting cells to engage both the innate and adaptive immune system to target solid tumors.
In June, the company said its phase II trial of IMP321 with pembrolizumab, or Keytruda, showed "favorable efficacy in first-line non-small cell carcinoma" (BD: Jun 6, 2022).
Today, Immutep said that fast track designation was intended to expedite the review of drug candidates to treat serious conditions and fill an unmet medical need, and that it would have access to more frequent interactions with the FDA to discuss IMP321's development path and other relevant designations.
Immutep chief executive officer Marc Voigt said "Efti also offers a chemotherapy-free option for NSCLC patients in need of less toxic and more durable solutions".
Mr Voigt said that efti had fast track designation for both first-line non-small cell lung cancer and first-line head and neck squamous cell carcinomas, enabling the company to work more closely with the FDA to expedite bringing the treatment to cancer patients.
Immutep was up 1.5 cents or 6.25 percent to 25.5 cents with 1.7 million shares traded.

BIOTRON

Biotron says it has completed recruitment in its Australian phase II trial of BIT225 for human immunodeficiency virus-1 (HIV-1)
In 2021, Biotron said it had begun a 27-patient, Thailand phase II trial and a 20-patient, Sydney phase II trial of BIT225 in HIV-1-positive populations (BD: Nov 1, 2021).
Today, Biotron said the study would determine immune activation, inflammation and viral markers with the addition of 200mg BIT225 to stable, suppressive anti-retroviral treatment administered daily for 12 consecutive weeks.
Biotron managing-director Dr Michelle Miller said the company was "very pleased" to complete patient enrolment as the Covid-19 pandemic made trials an "extraordinarily challenging environment" and said she expected to report the results by July 2023.
Biotron was up 0.3 cents or 6.5 percent to 4.9 cents.

IMMURON

Immuron says it has a clinical trial agreement with the Baltimore, Maryland-based Pharmaron CPC Inc for a 60-patient, phase II trial of its Travelan for diarrhoea.
Immuron said the trial would be funded in part by the $6.2 million award from the US Department of Defense for the development of a military dosing regimen of Travelan for diarrhoea (BD: Jan 16, 2022).
The company said the study would enrol up to 60 volunteers who would be randomly assigned to receive either a once-daily dose of 1200mg of Travelan or placebo to evaluate the efficacy of a single dose regimen of Travelan in a controlled human infection model using the enterotoxigenic Escherichia coli strain H10407.
Immuron said that the dosing regimen for Travelan in the study was “more suited for use by the US military, it was “on track” to submit an investigational new drug application to the US Food and Drug Administration by the end of 2022 and would be the sponsor of a study planned for 2023, subject to approval.
Immuron was unchanged at eight cents.

MAYNE PHARMA

Mayne says it has completed the sale of Metric Contract Services to Catalent Pharma Solutions Inc for $US475 million (about $A772 million).
In August, Mayne said the Somerset, New Jersey-based Catalent would pay $US475 million ($A679 million) for its Metrics Contract Services development and manufacturing company (BD: Aug 10, 2022).
Today, Mayne said that following completion, it would “repay the syndicated debt facility and return a significant portion of excess funds to shareholders” and that further details regarding the nature and timing of these initiatives would be provided in the coming weeks, pending relevant shareholder approvals.
Mayne chair Frank Condella said “the divestment of Metrics Contract Services is a key part of the board’s transformation agenda to reposition Mayne Pharma for growth and unlocks significant value for Mayne Pharma’s shareholders”.
Mayne was up 1.5 cents or 5.6 percent to 28.5 cents with 7.2 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says a published article shows LRRC15 proteins on cancer associated fibroblasts protect tumor cells from the immune system causing tumor growth, in mice.
A Radiopharm executive told Biotech Daily that its DUNP19 was a monoclonal antibody which targeted LRRC15 expression in tumor cells and surrounding stroma.
The executive said that the independent research reported the critical role of LRRC15.
The research article, titled ‘LRRC15+ myofibroblasts dictate the stromal setpoint to suppress tumour immunity’, was published in Nature and the full article was available at: www.nature.com/articles/s41586-022-05272-1
In April, the company said it had licenced the LRRC15-targeting DUNP19 antibody from the University of California Los Angeles for solid tumors (BD: Apr 4, 2022).
Today, Radiopharm said it planned to replicate the study with its DUNP19 against LRRC15, which was hoped to “kill the tumor cells directly, and perhaps as importantly, the surrounding cells in the tumor micro-environment that protects the cancer from being attacked by the immune system”.
Radiopharm was unchanged at 17 cents.

GENETIC SIGNATURES

Genetic Signatures has told the ASX it marked an announcement regarding the results of a study of its Easyscreen detection kit as market sensitive “in error”.

Last week, Genetic Signatures said that an in-vitro trial published in Diagnostics showed that its Easyscreen detection kit had “excellent sensitivity and specificity” for detection of antibiotic resistance (BD: Sep 29, 2022).

In its aware query, the ASX said that the company marked the announcement as market sensitive and as a result asked why did it not announce the study results on September 14, when they were first published?

Today, Genetic Signatures said that it did not consider the announcement would have “a material effect on the price or value of its securities” and that the trading of its shares on September 29 after it released its announcement, “supports this conclusion”.

Genetic Signatures said that the announcement was marked market sensitive in error with the wrong field being inadvertently selected and it “regrets the error”.

The company said that it “first became aware of the publication late on September 23, 2022 via a third party”.

Genetic Signatures said it had “reinforced the importance to its relevant officers of correctly applying the ‘market sensitive’ field on only those ASX announcements which the board has determined to in fact be market sensitive (which it did not determine with respect to the information)”.

Genetic Signatures fell five cents or 5.4 percent to 88 cents.

CANN GROUP

Cann Group says the good manufacturing practice licence for its Mildura Marijuana factory has been extended to cover “additional manufacturing capabilities”.

In July, Cann said the Australian Therapeutic Goods Administration had granted its Mildura factory a good manufacturing practice (GMP) licence to produce active pharmaceutical ingredients at the factory, manufacture Satipharm capsules, conduct chemical, physical and microbiological tests and distribute its products through the TGA’s approved access pathways (BD: Jul 1, 2022).

Today, the company said the licence extension allowed the Mildura factory to manufacture and release finished dried flower products for patient use.

Cann said that cultivation, manufacturing, testing, and packaging were being offered as a service to commercial clients.

Cann Group was up half a cent or 1.9 percent to 26.5 cents.

ADALTA

Adalta says it has received a $1,582,473 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Adalta said the rebate related to research and development expenditure for the year to June 30, 2022.

The company said it had lodged an overseas finding application with the Federal Government’s Ausindustry to determine if overseas expenditure was eligible for a tax incentive, and if approved would be worth about $495,454, taking the total to $2,077,927.

Adalta fell 0.4 cents or 8.3 percent to 4.4 cents.

ARGENICA THERAPEUTICS

Argenica says it has received $1,377,917 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Argenica said the rebate related to research and development expenditure for the year to June 30, 2022.
Argenica was up 1.5 cents or 3.4 percent to 45.5 cents.

SOMNOMED

TDM Growth Partners Pty Ltd says it has increased its substantial holding in Somnomed from 22,181,065 shares (26.80%) to 22,311,159 shares (26.96%).
The Sydney-based TDM said that on September 23, 2022 it bought 130,094 shares for $179,530 or $1.38 a share.
Somnomed was up seven cents or 4.5 percent to $1.63.

VECTUS BIOSYSTEMS

Vectus managing-director Dr Karen Duggan says she has increased and been diluted from 3,201,500 shares (13.64%) to 3,278,500 shares (6.94%).
The Sydney-based Ms Duggan said that on December 5, 2016 she received 2,000 shares through the exercise of options, and that on January 21, 2020 she received 75,000 shares from “deferred chief executive officer share awards”.
Ms Duggan did not disclose how her holding had diluted.
Vectus was untraded at 68 cents.

IMUGENE

Imugene says it has appointed Dr Giovanni Selvaggi chief medical officer and Paul Wright as head of chemistry, manufacturing and controls, effective from October 1, 2022.
Imugene said that Dr Selvaggi had more than 10 years of experience in the pharmaceutical industry, most recently working for Xcovery Holdings as chief executive and medical officer and previously working for Glaxosmithkline, Novartis Oncology, Oncolytics Biotech and Bristol Myers Squibb.
The company said Dr Selvaggi held A Doctor of Medicine from the University of Torino in Italy.
Imugene said Mr Wright had more than 25 years of experience in protein and virus products, most recently working at Pfizer for 21 years in its manufacturing and vaccine research and development organizations.
Imugene said Mr Wright held a Bachelor of Science from Anglia Ruskin University in Cambridge, England.
Imugene was up half a cent or 2.7 percent to 19 cents with 27.5 million shares traded.