Biotech Daily

Wednesday April 12, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: EMVISION UP 7%; USCOM DOWN 11%**

*** IMMVIRX DOSES 1st IVX037 CANCER PATIENT**

*** PHARMAXIS, FDA ADD ARM TO PXS-5505 TRIAL; DROPS LIVER CANCER**

*** AROA WINS FDA 510(k) ENIVO SYSTEM APPROVAL**

*** CYNATA CYP-001 GvHD TRIAL AUSTRALIAN ETHICS APPROVAL**

*** ANTERIS US DURAVR HEART VALVE PATENT**

*** RECCE ANTI-INFECTIVES ISRAELI TRADE MARK APPROVAL**

*** MEDIBIO: CEO DR THOMAS YOUNG DIRECTOR, LOSES MELANIE LEYDIN;**
- STEPHEN BUCKLEY REPLACES CO SEC MATHEW WATKINS

*** RESPIRI APPOINTS WILLIAM SIGSBEE US CCO**

MARKET REPORT

The Australian stock market was up 0.47 percent on Wednesday April 12, 2023, with the ASX200 up 34.0 points to 7,343.9 points.

Nine of the Biotech Daily Top 40 stocks were up, 19 fell, 11 traded unchanged and one was untraded. All three Big Caps were up.

Emvision was the best, up 10 cents or 7.3 percent to $1.47, with 40,189 shares traded. Avita and Orthocell climbed five percent or more; Pharmaxis was up 4.3 percent; Clinuvel rose 2.3 percent; Neuren and Universal Biosensors were up more than one percent; with Cochlear, CSL, Pro Medicus, Resmed and Telix up by less than one percent.

Uscom led the falls, down 0.5 cents or 11.1 percent to four cents, with 226,695 shares traded. Actinogen lost 6.1 percent; Atomo and Paradigm were down five percent or more; Micro-X, Next Science and Opthea fell more than four percent; Compumedics, Impedimed, Nova Eye and Starpharma were down three percent or more; Antisense, Genetic Signatures, Immutep and Mesoblast shed more than two percent; with Medical Developments, Nanosonics, Polynovo and Proteomics down by one percent or more.

IMMVIRX PTY LTD

Immvirx says it has dosed the first of up-to 27 patients in its phase Ia trial of its “next generation oncolytic virus” IVX037 for colorectal, gastric and ovarian cancer.

Immvirx chief executive officer and co-founder Dr Malcolm McColl told Biotech Daily that the dose escalation and expansion phase Ia part of the trial was likely to take until April 2024, to be followed by an up-to 45-patient phase Ib trial to establish the dosing regimen when combined with an immune checkpoint inhibitor.

Dr McColl was the chief executive officer of Viralytics when the company was sold to Merck Inc (Merck Sharp and Dohme) for $502 million for its Cavatak oncolytic immunotherapy (BD: Feb 22, Jun 4, 2018).

Dr McColl said that the former Viralytics chief scientific officer Prof Darren Shafren was the Immvirx chief scientific officer.

Today, the Newcastle, New South Wales-based Immvirx said the first patient has been dosed in the two-part, first-in-human, phase I trial of intra-tumoral IVX037 for patients with late stage colorectal, gastric or ovarian cancer, “three of the most prevalent cancer types”.

The company said the phase Ia trial would begin with a dose frequency escalation period with nine to 12 patients, treated with one to three doses of IVX037, followed by a cohort expansion with a further 15 patients treated at the recommended dosing regimen.

Immvirx said that the phase Ia trial would evaluate safety, tolerability and preliminary markers of efficacy following intra-tumoral administration of IVX037.

The company said that phase Ib would assess the recommended dosing regimen of IVX037 in up-to 45 patients when combined with an immune checkpoint inhibitor.

Dr McColl said the start of the trial was “a key milestone for Immvirx”.

“IVX037 has been developed by our highly experienced team based in our facilities in the Hunter Medical Research Institute in Newcastle,” Dr McColl said.

“The agent has demonstrated safety and efficacy in pre-clinical studies,” Dr McColl said.

Immvirx said the trial was titled ‘CP-IVX001: A phase I open-label, non-randomized, multi-cohort clinical study of intra-tumoral IVX037 as monotherapy or in combination with an immune checkpoint inhibitor in patients with advanced or metastatic solid tumors’.

The company said that the study would be conducted in patients with colorectal, ovarian and gastric cancers which had progressed on, or were not suitable for, standard of care systemic therapies.

Immvirx said that phase Ia would enrol 24 to 27 patients in a single-arm, open-label study to identify the optimal dosing regimen for phase Ib, which would subsequently assess the safety and efficacy of IVX037 in combination with an immune checkpoint inhibitor in up to 45 patients.

The company said the phase Ia trial would be conducted at four Australian clinical centres.

Immvirx said that oncolytic immunotherapy “harnesses the power of viruses to preferentially infect and kill cancer cells and induce local and systemic anti-tumor-immune responses.

The company said that its bio-selection platform enabled the development of RNA viruses targeting specific receptor proteins highly expressed on a range of cancer cell types, allowing them to selectively enter, replicate in, and destroy tumor cells while creating beneficial changes in the tumor micro-environment, potentially leading to the generation of specific innate and adaptive immune responses against cancer cells.

Immvirx said that the viral candidates were intended to increase the effectiveness of current immunotherapies, primarily immune checkpoint inhibitors and chimeric antigen receptor (Car) T-cell therapies, in fighting cancers of high unmet need including colorectal, gastric, ovarian and liver cancer.

Immvirx is a private company.

PHARMAXIS

Pharmaxis says that following discussions with the US Food and Drug Administration it will add a combination arm to its phase II trial of PXS-5505 for myelofibrosis.

Pharmaxis said it held a type C meeting with the FDA which examined safety and efficacy data from the monotherapy trial and provided guidance on the number of patients, treatment dose, duration and endpoints for a study in combination with a JAK inhibitor.

The company said that the trial would be “widened to include myelofibrosis patients already receiving a JAK inhibitor as standard-of-care in combination with PXS-5505”.

Pharmaxis said it previously reported interim data for PXS-5505 as a monotherapy showing “a well-tolerated drug that leads to stable or improved symptoms, haematological cell counts and fibrosis grades”.

Last year, the company said that interim data from its phase II trial of PXS-5505 for myelofibrosis suggested an “excellent safety profile with encouraging signs of clinical activity” and the 24-patient trial aimed to show that PXS-5505 was safe and effective as a monotherapy in myelofibrosis patients who were intolerant, unresponsive or ineligible for treatment with approved janus kinase (JAK) inhibitor drugs (BD: Oct 19, 2022).

Today, Pharmaxis said the trial had recruited 21 of the targeted 24 patients on monotherapy with 20 sites active worldwide and it would submit a protocol amendment to regulators that would add an arm to the existing study and use its existing trial sites.

The company said that “based on the FDA feedback, it is anticipated that the trial design can be streamlined to initiate the combination arm at the same dose currently used in the monotherapy arm and commence later this year”.

Pharmaxis chief executive officer Gary Phillips said that “the agreement with the FDA to expand the patient population in the ongoing phase II study to include those patients currently on a JAK inhibitor is an important step forward in realizing the benefits of lysyl oxidase inhibition for all myelofibrosis patients and in maximizing the commercial opportunity for PXS-5505”.

“We are already in discussion with the existing trial site investigators who have welcomed the opportunity to extend the patient population for the study and anticipate significantly accelerated recruitment,” Mr Phillips said.

Pharmaxis said that it had reported interim data from the MF-101 myelofibrosis trial, two poster presentations at the American Society of Hematology and the publication of “ground-breaking” pre-clinical data in myelodysplastic syndrome for PXS-5505.

The company said that following a review of its development strategy it had decided to focus its resources on these haematological malignancies and will not at this point be progressing the previously planned study in hepatocellular carcinoma, or liver cancer, in an investigator-initiated trial by the University of Rochester.

In 2021, Pharmaxis said that the FDA had cleared an investigational new drug application for a phase II trial of PXS-5505 with chemotherapy for unresectable hepatocellular carcinoma patients, submitted by the New York State’s University of Rochester Medical Center and followed positive pre-clinical results (BD: Nov 9, 2021)

Earlier that year, the company said that PXS-5505 with chemotherapy improved survival, delayed tumor growth, and reduced intra-tumoral pressure in mice with cholangiocarcinoma (BD: Aug 5, 2021).

Today Mr Phillips said the collaboration with the research team at University of Rochester “remains highly valued and their work is continuing with further pre-clinical evaluation of our pipeline assets but for now we have decided not to pursue [liver cancer] given the timelines for recruitment and the need to focus our resources”.

Pharmaxis said it expected further regulator feedback on the MF-101 trial by July 2023.

Pharmaxis was up 0.2 cents or 4.3 percent to 4.9 cents.

AROA BIOSURGERY

Aroa said its Enivo pump and catheter product has received US Food and Drug Administration 510(k) clearance.

The company said the product was part of tis Enivo Tissue Apposition Platform that used material derived from sheep forestomach to help reduce surgical and bodily fluid build-up in closed wounds for hematoma and seroma prophylaxis.

Aroa said that the pump and catheter device applied “negative pressure to a surgical site, helping to reduce fluid accumulation following surgery”.

“It has been cleared for use in the removal of surgical and bodily fluids from a closed wound for haematoma and seroma prophylaxis following plastic surgery or other general surgeries where large flaps are formed,” The company said.

“Currently, surgeons use surgical drains, adhesives, and quilting sutures to manage dead-space and prevent fluid accumulation, but these techniques are unreliable,” Aroa said.

Aroa chief executive Dr Brian Ward said the approval simplified future clinical studies and early commercialization activities and was “a key milestone in establishing our second technology platform”.

“We expect to develop a portfolio of products based on this technology platform for a range of soft tissue reconstruction procedures,” Dr Ward said.

Aroa fell 1.5 cents or 1.4 percent to $1.045.

CYNATA THERAPEUTICS

Cynata says it has Australian ethics approval for its 60-patient, phase II trial of CYP-001 mesenchymal stem cells for acute graft versus host disease.

Last year, Cynata said the US Food and Drug Administration has cleared its investigative new drug application for the trial, titled ‘A Multicenter, Randomized, Double-blind, Placebo-Controlled Phase II Study to Investigate the Efficacy and Safety of CYP-001 in Combination with Corticosteroids vs Corticosteroids Alone for the Treatment of High-Risk Acute Graft Versus Host Disease’ (BD: May 26, 2022).

Today, the company said it was finalizing contractual and logistical arrangements with individual sites in Australia to prepare for patient recruitment.

Cynata chief medical officer Dr Jolanta Airey said the trial was expected to begin patient recruitment by June 30, 2023 and complete primary data evaluation in 2024.

“The proposed clinical trial has a strong foundation given the very promising results achieved in our phase I clinical trial of CYP-001 in steroid resistant [acute graft-versus-host disease],” Dr Airey said.

Cynata was unchanged at 22 cents.

ANTERIS TECHNOLOGIES

Anteris says the US Patent and Trademark Office has granted a patent for its Duravr transcatheter bio-mimetic heart valve, designed to mimic a healthy human heart valve.

According to the USPTO website the patent was titled ‘Prosthetic Heart Valves’ and the company said it would protect their Duravr product until September 30, 2042.

The company said it had developed “a differentiated heart valve technology through its innovative single-piece, shaped-tissue design”.

Anteris chief executive officer Wayne Paterson said the patent signified “the extraordinary work by our team of engineers around the world responsible for the design of Duravr [transcatheter heart valve]”.

Anteris was up 68 cents or three percent to $23.18.

RECCE PHARMACEUTICALS

Recce says its name ‘RECCE’ has been registered as a trademark by the Israeli Patent Office, Trademarks Department.
Recce said the class 5 trademark was for its antibiotics, antibiotics for human use and pharmaceutical preparations, namely mixed antibiotic preparations.
The company said the trademark strengthened its intellectual property portfolio with those already registered in Australia, US, Europe, Japan, China and Hong Kong.
Recce chief executive officer James Graham said the trademark was a “welcomed advance in supporting the company’s Israeli opportunities over the time ahead”.
Recce was up 1.5 cents or 2.6 percent to 60 cents.

MEDIBIO

Medibio says it has appointed chief executive officer Dr Thomas Young as an executive director and non-executive director Melanie Leydin has retired.
Medibio said that Stephen Buckley would replace Mathew Watkins as company secretary, effective April 17 2023.
The company extended “its appreciation to Melanie and Mathew’s leadership and guidance throughout their respective tenures”.
Medibio was unchanged at 0.1 cents with 5.1 million shares traded.

RESPIRI

Respiri says it has appointed William Sigsbee as its US chief commercial officer.
The company said Mr Sigsbee had more than 30 years of experience in the healthcare experience and medical devices industry and was previously Medicom Health Interactive chief executive officer and a consultant for remote patient monitoring and telehealth companies.
Respiri was up 0.2 cents or 3.45 percent to six cents.