Biotech Daily

Thursday December 15, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 9%;**
- IMMUTEP, RESONANCE DOWN 7.6%

*** VICTORIA $20m FOR START-UP FUND**

*** DIMERIX RECRUITS PART 1 OF DMX-200 PHASE III FSGS TRIAL**

*** ONCOSIL: 10 PANCREATIC CANCER PATIENTS TREATED IN SPAIN**

*** ISLAND, SYRACUSE UNI ISLA-101 DENGUE TRIAL OK; DRUG STABILITY**

*** KAZIA WORKS WITH QIMR ON PAXALISIB FOR SOLID TUMORS**

*** RHYTHM, BAKER COLLABORATE ON UNNAMED CANCER**

*** IMRICOR NORTHSTAR-MR 1st HUMAN A-F USE; V-T TRIAL**

*** MICRO-X: FIRB OKAYS VAREX $7.5m, ANDREW HARTMANN DIRECTOR**

*** ACRUX TERMINATES AMRING GENERIC DEAL, RETAINS OWNERSHIP**

*** RECCE ANTI-INFECTIVE UNIT AT MELBOURNE'S MCRI**

MARKET REPORT

The Australian stock market fell 0.64 percent on Thursday December 15, 2022, with the ASX200 down 46.5 points to 7,204.8 points. Eight of the Biotech Daily Top 40 stocks were up, 24 fell, five traded unchanged and three were untraded. All three Big Caps fell.

Oncosil was the best (see below), up 0.4 cents or 8.7 percent to five cents, with 195,400 shares traded. Actinogen climbed 6.1 percent; Genetic Signatures improved 4.65 percent; Dimerix and Paradigm were up more than three percent; Compumedics rose 2.6 percent; Avita was up 1.9 percent; with Clinuvel up by one cent or 0.05 percent to $21.50.

Immutep and Resonance led the falls, both down 7.6 percent to 30.5 cents and 4.9 cents, respectively, with 3.2 million shares and 310,003 shares traded, respectively. Prescient and Starpharma lost more than seven percent; Impedimed and Imugene were down more than five percent; Nanosonics fell 4.4 percent; Kazia, Next Science, Orthocell, Patrys, Polynovo, Proteomics and Volpara were down more than three percent; Antisense, Mesoblast and Universal Biosensors shed more than two percent; Amplia, Cochlear, Emvision, Medical Developments, Opthea and Resmed were down more than one percent; with CSL, Neuren, Pro Medicus and Telix down by less than one percent.

VICTORIAN GOVERNMENT

The Victorian Government has launched the $20 million 'Equity Investment Attraction Fund' for Victoria's start-up companies.

In a media released from Victoria's Treasurer and Minister for Trade and Investment Tim Pallas and Minister for Industry and Innovation Ben Carroll said that start-ups were "proven job creators … [driving] significant jobs growth in Victoria, with a 10.7 percent rise in employment year-on-year between 2018 and 2020".

The State Government said that the fund would invest between $1 million and $5 million into each venture, for a non-controlling minority stake.

The Government said the fund would co-invest with institutional investors and focus "on attracting the best and brightest early-stage start-ups from countries like Singapore, Israel, United Kingdom and United States to bolster Victoria's thriving start-up ecosystem".

The media release said companies had to be willing to "locate or invest large and critical parts of their operations in Victoria, have a strong lead investor and possess novel products and services with high commercial potential" and it would "prioritize investment proposals that create broader contributions to the economy".

The Government said the fund would have an advisory board of former GBS Ventures managing-director Brigitte Smith, Giant Leap partner Rachel Yang and Kerri Lee Sinclair.

Mr Pallas said the Victoria Government was "supporting start-ups from high-growth sectors to set up in Victoria as they seek to innovate, expand and create new jobs".

"The establishment of the fund sends a strong signal to creative and ambitious entrepreneurs who have solid business projects that Victoria is the place to be," Mr Pallas said.

For more information, go to: www.invest.vic.gov.au.

DIMERIX

Dimerix says it has recruited the 72 patients for part 1 of its 286-patient, phase III trial of DMX-200 for focal segmental glomerulosclerosis (FSGS) kidney disease.

In May, Dimerix said it had begun recruitment in the pivotal, multi-center, randomized, double-blind, placebo-controlled trial, titled 'Angiotensin II Type 1 Receptor & Chemokine Receptor 2 Targets for Inflammatory Nephrosis' (Action3),' to study the efficacy and safety of its DMX-200 in patients with FSGS (BD: May 31, 2022).

At that time, the company said that the trial had two interim analysis points designed to capture evidence of proteinuria and kidney function to generate sufficient evidence to support accelerated marketing approval.

Dimerix said the first part of the trial would conclude once 72 patients completed 35 weeks of treatment, expected in the first half of 2023, with the second part continuing after patients showed a minimum of six weeks stable dosing of an angiotensin receptor blocker prior to randomization and dosing with 120mg DMX-200 twice daily or placebo.

Today, the company said it had recruited patients at 70 sites in 11 countries.

Dimerix managing-director Dr Nina Webster said that the recruitment of the first 72 patients was a "significant and exciting milestone" with several hundred patients pre-screened to enrol the 72 patients.

"We are delighted that the time from first patient recruited to the 72nd patient was only seven months and we now eagerly await the results of the interim analysis once these patients have been dosed," Dr Webster said.

"We also look forward to the strong recruitment momentum achieved to date continuing into part two of the trial," Dr Webster said.

Dimerix was up half a cent or 3.3 percent to 15.5 cents.

ONCOSIL MEDICAL

Oncosil says 10 patients have been treated with its radiotherapy device for pancreatic cancer in Spain.
In April, Oncosil said a hospital in Madrid has completed the first commercial use of its Oncosil device (BD: Apr 13, 2022).
Today, the company said that four hospitals had installed the device "resulting in the first 10 patients being treated within Spain".
Oncosil managing-director Nigel Lange said the company was "proud of having achieved this significant milestone in the Spanish market and provide hope to patients who otherwise have a poor prognosis".
Mr Lange said the company would extend into other areas in Spain, the EU and UK.
Oncosil was up 0.4 cents or 8.7 percent to five cents.

ISLAND PHARMACEUTICALS

Island says it has ethics approval for a 46-patient phase IIa study of ISLA-101 for Dengue fever at New York's Syracuse University, and that ISLA-101 had achieved "stability".
Island said it had conditional approval for the randomized, double-blind, controlled study of its ISLA-101 anti-viral drug in a Dengue challenge model, pending clearance of its investigation new drug application to the US Food and Drug Administration.
Island chair Dr Paul MacLeman told Biotech Daily that the trial would treat four cohorts of four participants each, with a further 30 control participants already completed.
In October, Island said its US investigational new drug application was expected to be filed this year, with manufacture of ISLA-101 awaiting final testing (BD: Oct 28, 2022).
Today, Island said that ISLA-101 had passed "its critical accelerated stability milestone," which enabled the finalization of its investigation new drug application, which was "on track to be submitted to the US Food and Drug Administration in December 2022".
Island was unchanged at 17 cents.

KAZIA THERAPEUTICS

Kazia says it has a pre-clinical collaboration agreement with Brisbane's Queensland Institute of Medical Research Berghofer to explore the use of paxalisib in solid tumors.
Kazia did not disclose the commercial terms of the collaboration but said that the research project would be led by Prof Sudha Rao and "build on initial research … of paxalisib as an immune modulator in the treatment of diseases such as breast cancer".
The company said that paxalisib was a PI3K inhibitor, and PI3K inhibitors had shown anti-cancer effects, with five therapies approved by the US Food and Drug Administration.
Kazia said that Prof Rao's research had identified a "separate effect of PI3K inhibition: as a modulator of the immune microenvironment within and around the tumor".
Kazia said the use of PI3K inhibitors at different doses and frequencies, appeared to activate the immune system in the tumor "making it more susceptive to immunotherapy".
The company said that results of the research would be published by July 2023, with potential for clinical trials in 2023.
Prof Rao said that "in treatment-resistant pre-clinical models of breast cancer, paxalisib has shown encouraging results in inhibiting both the primary tumor burden and metastasis by reinvigorating the immune system within the tumor micro-environment".
Kazia chief executive officer Dr James Garner said the company had expanded "its field of opportunity outside of cancers of the brain".
Kazia fell 0.3 cents or 3.4 percent to 8.6 cents.

RHYTHM BIOSCIENCES

Rhythm says it has appointed Melbourne's Baker Institute for a proof-of-concept study for a second unnamed cancer program using its cancer diagnostic platform.

Last year, Rhythm said it would invest $750,000 to assess whether its test had promise for breast, cervical, lung, gastric and pancreatic cancers (BD: Dec 14, 2021).

In July, the company said the lead biomarker in its Colostat bowel cancer test would be used to expand its diagnostic platform to breast, lung, cervical, pancreatic and gastric cancers (BD: Jul 19, 2022).

At that time, Rhythm said that it would focus on the next stage of feasibility, testing and validation of the bio-markers of interest, and it had hired Adelaide's Agilex Biolabs to assess and develop one initial cancer target, allowing it to continue developing Colostat for colorectal cancer.

Today, Rhythm managing-director Glenn Gilbert said his company was "in a great position being on the cusp of initial market entry for its colorectal cancer blood test, and in parallel assessing options on how to leverage the technology platform into other cancers".

"Attracting two well-known bio-analytical partners to work with Rhythm on platform extension supports our scale ambitions and is designed to provide optional market opportunities to explore while we focus in the near term on deploying our cancer detection technology into unfortunately, growing colorectal cancer screening markets," Mr Gilbert said.

Rhythm was up two cents or 2.1 percent to 98 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says it has treated the first two atrial flutter patients and has ethics approval for a 64-patient, ventricular tachycardia ablation trial.

In September, Imricor said that it had filed its invasive cardiovascular magnetic resonance-guided (ICMR) ventricular tachycardia ablation clinical trial for approval in Europe (BD: Sep 19, 2022).

At that time, the company said the study, titled 'Vision-MR Ablation of VT' or Visabl-VT was a 64-patient, prospective, single-arm, multi-centre interventional investigation of the safety and efficacy of radio-frequency ablation of ventricular tachycardia associated with ischemic cardio-myopathy performed with its Vision-MR ablation catheter 2.0 in the invasive cardiovascular magnetic resonance environment.

Today, Imricor said that it had received ethics approval from the Leipzig Heart Centre in Germany, and was awaiting further approval from the German Federal Institute for Drugs and Medical Devices.

Imricor said that the Hague, Netherlands-based Haga Hospital had "successfully treated" two atrial flutter patients in the invasive cardiovascular magnetic resonance-guided "environment," and had simultaneously evaluated its prototype Northstar-MR three-dimensional (3D) mapping system in humans for the first time.

Imricor said that the Northstar-MR used Siemens magnetic resonance imaging scanners and removed "the reliance on others to develop 3D mapping systems needed for complex ablation procedure".

The company said that its goal was to apply Northstar-MR to magnetic resonance imaging (MRI) systems from GE Healthcare and Philips, "providing the same user experience for physicians no matter which MRI platform they utilize".

Imricor was up 1.5 cents or 3.9 percent to 40 cents.

MICRO-X

Micro-X says the Foreign Investment Review Board has approved the second tranche of its $7.5 million placement to Varex and it appointed Andrew Hartmann as director.
In September, the company said it had a $15 million collaboration with the Salt Lake City, Utah-based Varex Imaging Corporation to licence its Nex multi-beam x-ray tubes, and take a 9.9 percent holding in Micro-X (BD: Sep 19, 2022).
At that time, Micro-X said it would provide Varex an exclusive licence for its Nex multi-beam x-ray tubes for $US5 million ($A7.5 million), with Varex subscribing for 50,709,000 shares, or 9.9 percent of Micro-X, at 14.7 cents a share and Varex head of medical sales and marketing Mr Hartmann had been appointed as a non-executive director.
According to his Linkedin page, Mr Hartmann held a Certificate in Electrical and Electronics Engineering from North Sydney Technical College, an Associate diploma in Accounting from Sydney's Dover Heights College of Technical and Further Education and a Master of Business Administration from England's Ashridge Management College.
Micro-X was unchanged at 12.5 cents.

ACRUX

Acrux and Amring say they have mutually agreed to terminate the agreement for the development and commercialization of an undisclosed generic topical product.
In 2020, Acrux said that it had an agreement with the Berwyn, Pennsylvania-based Amring Pharmaceuticals Inc to develop and commercialize an unnamed generic product which had generated more than $400 million in US sales in the 12 months to March 31, 2020 (BD: Jun 18, 2020).
Today, the company said it retained ownership of all rights and intellectual property to the product which was at "an advanced stage of development" and was planning to submit an abbreviated new drug application to the US Food and Drug Administration "in late 2023".
Acrux said it hoped to appoint a licencing partner to launch the product after approval.
Acrux was untraded at 7.7 cents.

RECCE PHARMACEUTICALS, MURDOCH CHILDREN'S RESEARCH INSTITUTE

Recce says it has established an 'anti-infective research unit' with the Murdoch Children's Research Institute at Melbourne's Royal Children's Hospital.
The company did not disclose the commercial terms of the agreement with the Institute but said it had secured a dedicated research team of infectious disease experts, with a "fit-for-purpose laboratory space [with] access to a library of clinical isolates and drug-resistant pathogens" provided at no additional cost.
Recce said that the program would be led by the former head of the MCRI mucosal immunology division Dr Phil Sutton who was Recce's head of translational sciences, The company said that it would focus its research on its bacterial sinusitis program as well as its Mycobacterium abscessus program.
Dr Sutton said the company was "thrilled by this agreement with Murdoch Children's, as it will give Recce direct access to critical pre-clinical laboratory studies".
"Access to the facilities within one of the world's leading research institutes will also allow us to draw upon their impressive resources and clinical expertise," Dr Sutton said.
Recce was unchanged at 66.5 cents.