Biotech Daily

Monday November 6, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: KAZIA UP 22%; NEXT SCIENCE DOWN 8%**

*** NSW UNI ARTERY STENT 'BEATS BALLOON ANGIOPLASTY'**

*** QUEENSLAND UNI mRNA VACCINE, THERAPY FACTORY**

*** PRESCIENT INTERIM PTX-100 T-CELL LYMPHOMA DATA 'VERY PROMISING'**

*** IMUGENE 'POSITIVE' VAXINIA SOLID TUMOR RESULTS**

*** CLEO 1st OVARIAN CANCER TRIAGE TEST: '95% SENSITIVITY, SPECIFICITY'**

*** CYNATA CLOSES CYP-004 OSTEOARTHRITIS TRIAL RECRUITMENT EARLY**

*** IMMUTEP OPENS PHASE II EFTI COMBO BREAST CANCER TRIAL**

*** PYC, FDA AGREE ON PYC-001 ADOA TRIAL PATHWAY**

*** TRUSCREEN $276k ZIMBABWE SENSOR ORDER**

*** LBT, SOUTH AUSTRALIA LOAN RESTRUCTURE**

*** ADVANZ PAYS DIMERIX $10.7m FOR DMX-200 FSGS RIGHTS**

*** BCAL PATENT APPLICATION FOR BREASTEST BIOMARKERS**

*** MAYNE PHARMA WINS US NEXTSELLIS PATENT**

*** GLOBAL CR REDUCES TO 7.9% IN BIOXYNE**

*** L1 CAPITAL TAKES 14.6% OF ANTERIS**

*** RESPIRI LOSES 5-MONTH DIRECTOR BRIAN LEEDMAN**

MARKET REPORT

The Australian stock market was up 0.28 percent on Monday November 6, 2023, with the ASX200 up 19.2 points to 6,997.4 points. Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell and eight traded unchanged.

Kazia was the best on no news, up 1.2 cents or 21.8 percent to 6.7 cents, with 1.8 million shares traded. Impedimed improved 16.7 percent; Imugene was up 8.3 percent; Actinogen climbed 5.6 percent; Neuren was up 4.3 percent; Micro-X, Nanosonics, Resmed and Resonance were up more than three percent; Avita, Compumedics, Emvision, Orthocell and Polynovo rose more than two percent; Alcidion, CSL, Immutep, Medical Developments and Opthea were up more than one percent; with Clinuvel up by 0.8 percent.

Friday's 26.5 percent best, Next Science, led the falls, down 2.5 cents or 8.1 percent to 28.5 cents, with 377,174 shares traded. Genetic Signatures lost 5.05 percent; Amplia and Atomo fell more than four percent; Cynata and Prescient were down more than three percent; Dimerix, Nova Eye and Paradigm shed more than two percent; 4D Medical, Cyclopharm and Proteomics down by more than one percent; with Cochlear, Pro Medicus and Volpara down by less than one percent.

UNIVERSITY OF NEW SOUTH WALES

The University of New South Wales says its Esprit BTK dissolvable artery stent for peripheral artery disease was 32 percent “more effective” than balloon angioplasty.

The University said that a 261-patients, phase III, randomized, controlled multi-site trial showed patients blocked lower leg arteries were “more likely to remain open” when treated with its Esprit BTK (below the knee) stent compared to the current standard-of-care balloon angioplasty, reducing the need for limb amputation.

The University of New South Wales said one-year after treatment, the study showed about 75 percent of the Esprit BTK group’s arteries remained open, compared to 44 percent of the balloon angioplasty group.

The University said “there was little difference between the two treatments” in terms of patient safety in the study, with serious adverse events occurring in three percent of balloon angioplasty patients and two percent of the Esprit BTK group.

The University said peripheral artery disease involved the build-up of plaque in the peripheral arteries and caused narrowing which in severe cases lead to chronic limb-threatening ischaemia and affected 200 million people around the world and caused about 60,000 hospitalizations in Australia in 2020 and 2021.

The University of New South Wales said chronic limb-threatening ischaemia patients often had severe pain, gangrene, non-healing ulcers and could require limb amputation, with poor survival rates.

The University said in “many cases, after balloon angioplasty, the treated blood vessel becomes narrower, and the balloon doesn’t stay inflated for long enough … [which] results in the blood vessel becoming blocked again over time”.

The University of New South Wales said Esprit BTK was a mechanical scaffold inserted into blocked lower leg arteries made from poly-l-lactic acid and coated with everolimus to prevent blood vessel narrowing, and safely dissolved into the body in 18 to 24 months.

The University said the stent’s ability to dissolve was a useful quality as the artery only needed to be held open for a limited time to restore blood flow and resolve the blockage.

The University said researchers were working through the Australian Therapeutic Goods Administration Authorised Prescriber Scheme to give patients at Sydney’s Prince of Wales Hospital early access to the stent, with Esprit BTK to be submitted to the US Food and Drug Administration, followed by submissions in Europe, Japan and Australia.

The University said researchers were also working through the TGA Authorised Prescriber Scheme to gain early access for patients at the Prince of Wales Hospital.

The University said its Esprit BTK stent was manufactured by the Chicago, US-based medical device company Abbott Laboratories.

The University of New South Wales said that the trial, titled ‘Drug-Eluting Resorbable Scaffold versus Angioplasty for Infrapopliteal Artery Disease’, was published in the New England Journal of Medicine and an abstract of the article was available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2305637.

The University of New South Wales and Prince of Wales Hospital’s Prof Ramon Varcoe, the first author of the paper and one of three principal investigators, said that the prognosis for peripheral artery disease after amputation was “worse than most cancers”.

“Currently, we use angioplasty, but this has no mechanical scaffolding properties and usually doesn’t stay open very long,” Prof Varcoe said.

“The Esprit scaffold gives mechanical support to the recently opened artery, it delivers a drug to the blood vessel wall that prevents re-narrowing, and then it dissolves, leaving nothing behind to irritate the blood vessel and induce scar tissue formation … [and] avoids burning bridges should the patient require bypass surgery in the future.”

“Once approved, I expect it will become the standard of care,” Prof Varcoe said.

UNIVERSITY OF QUEENSLAND

The University of Queensland says it will open an mRNA laboratory to manufacture mRNA-based vaccines and therapies for use in clinical trials.

The University said the 'Base' facility at its Australian Institute for Bioengineering and Nanotechnology had provided academic and industry partners with more than 150 experimental grade vaccines and therapies for cancers and infectious and genetic diseases and had "become Australia's leading provider of mRNA for research and pilot studies since its launch in 2021".

The University of Queensland said it and the Paris-based Sanofi had committed $1 million each to the laboratory with the Federal Government's Medical Research Future Fund National Critical Research Infrastructure scheme contributing $4.3 million and the Queensland Government committing $250,000.

The University's Base director Prof Tim Mercer said the mRNA industry was worth about $55 billion internationally in 2022 and expected to increase to $107 billion by 2030.

"This will provide the Base facility with end-to-end capabilities for mRNA vaccine development, from their initial design through to clinical trials, allowing the next generation of mRNA vaccines and therapies to be built in Queensland," Prof Mercer said.

Prof Mercer said the group aimed to begin manufacturing mRNA for trials in 2024.

The University of Queensland vice-chancellor Prof Deborah Terry said the capability to produce clinical trial quality mRNA in Australia was a crucial step towards pandemic preparedness and realizing the economic benefits from research.

"Our Base team has already grown from five founding scientists to more than 20 researchers now, and we expect to continue to grow with more highly skilled positions for mRNA manufacture," Prof Terry said.

"This investment builds on the Translation Science Hub partnership announced by the Queensland Government and Sanofi in December, in which [the University of Queensland] is a partner," Prof Terry said.

In October, Sanofi said it was progressing a $280 million translational science hub to bring vaccine research and development to Griffith's Gold Coast campus (BD: Oct 9, 2023).

PRESCIENT THERAPEUTICS

Prescient says results from 14 patients in its PTX-100 for relapsed and refractory T-cell lymphoma trial show that of four responses, two patients had durable responses.

Prescient said that an abstract to be presented to the American Society of Hematology meeting on December 9, 2023 "outlines that 14 patients with [T-cell lymphoma] were treated as at the cut-off date, with 10 patients having response assessments after four cycles of therapy, with an overall response rate of 40 percent".

The company said that two patients had durable stable disease greater than six months, "contributing to a 60 percent disease control rate" with the median progression-free survival for all patients was 5.3 months, cutaneous T-cell lymphoma patients 13.6 months and peripheral T-cell lymphoma patients 2.5 months.

The abstract, titled 'Phase I Pharmacodynamic and Pharmacokinetic Study of the Geranylgeranyltransferase I Inhibitor PTX-100 (GGTI-2418) in Patients with Advanced Malignancies' was published online, ahead of presentation on December 9, 2023 and is available at : https://ash.confex.com/ash/2023/webprogram/Paper179411.html.

Prescient said that the data cut off was July 10, 2023 and the trial was "ongoing with patients still on study".

Prescient managing-director Steven Yatomi-Clarke said the data was "very promising".

Prescient fell 0.2 cents or 3.45 percent to 5.6 cents with 2.3 million shares traded.

IMUGENE

Imugene says it has 'early positive signals' from 34 patients in its phase I trial of intravenous or intra-tumoral Vaxinia monotherapy or combination therapy for tumors.
Imugene said the trial had dosed 16 patients with metastatic advanced solid tumors intratumorally and 18 patients intravenously as either monotherapy or in combination with pembrolizumab, with 25 patients evaluable and seven patients awaiting their first scan.
The company said of the evaluable patients the best overall responses were one complete response, one partial response and 16 with stable disease, showing patients "had control and stability of their cancer" with eight patients reporting progressive disease.
Imugene said of the six patients with gastro-intestinal cancers in the monotherapy arm, including two colorectal cancer patients, two bile duct cancer patients and one pancreatic and one liver cancer patient, none reported progressive disease.
The company said that one of the patients with bile duct cancer treated intra-tumorally with a mid-dose level had "pseudo-progression" with a 49 percent increase in tumor burden after two cycles and a complete response by the fourth dose cycle, with no recurrence in more than 200 days.
Imugene said that pseudo-progression was when the cancer initially appeared to be growing, due to the cancer cells being infected by the virus then followed by infiltration of cancer fighting immune cells … [and] was usually followed by a decrease in tumor burden when the therapy takes effect".
The company said the second bile duct cancer patient had stable disease for more than four months after receiving intravenous Vaxinia.
Imugene said the trial expansion was planned for 10 patients with bile duct cancers.
Imugene chief executive officer Leslie Chong said that the "early positive response data we are seeing at the mid-dose level in hard-to-treat bile duct cancer suggests that Vaxinia may be a potent anti-cancer drug as we interrogate higher dose levels".
"With no adverse safety signals, thus allowing us to dose higher, Vaxinia will have a very high therapeutic window which is valuable in oncology drug development," she said.
Imugene was up 0.4 cents or 8.3 percent to 5.2 cents with 147.3 million shares traded.

CLEO DIAGNOSTICS

Cleo says a retrospective 334-patient "first clinical validation study" of its Cleodx ovarian cancer triage test had 95 percent sensitivity and 95 percent specificity.
Cleo said the study showed its test correctly identified 81 percent of early-stage cancer patients in the cohort, and the study showed its test correctly discriminated malignant from benign samples and it "out-performed and was superior to current clinical methods".
Cleo said the study article, titled 'A novel predictive multi-marker test for the pre-surgical identification of ovarian cancer', was published in the journal Cancers and was available at: https://www.mdpi.com/2072-6694/15/21/5267.
Cleo said the next step would be to confirm the functionality of the commercial kits in an independent trial, with results to be filed to the US Food and Drug Administration.
The company said it expected to begin clinical trials before the end of this year.
Cleo chief scientific officer Dr Andrew Stephens said the results confirmed the technology was robust and accurate and could "identify cancers at an early stage."
"These results strongly support our planned further development of this core technology aimed at ovarian cancer screening in the longer term," Dr Stephens said.
Cleo chief executive officer Dr Richard Allman said "this is an important step forward as we work towards our goal of an FDA approved triage test."
Cleo was up 3.5 cents or 21.2 percent to 20 cents with 1.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has closed recruitment for its phase III trial of CYP-004 for knee osteoarthritis, reducing the number of patients from 440 to 320.
In 2020, Cynata said it had begun the 440-patient, randomized, controlled trial of its Cymerus mesenchymal stem cell product CYP-004 (BD: Nov 11, 2020).
In July, the company said recruitment in its trial of CYP-004 was initially slower than expected but had increased “dramatically”, with 300 patients enrolled and primary evaluation results expected by July 2026 (BD: Jul 24, 2023).
Today, Cynata said the University of Sydney advised that an independent safety and monitoring board had completed a review of the study progress and interim safety data, with no ongoing concerns and recommended the trial continue.
Cynata said a review from a study statistician had recommended the reduced study sample size, and the safety board had considered “the decision to be acceptable”.
The company said the revised target sample size had already been reached, and that it would close patient recruitment by the end of the month.
Cynata chief medical officer Dr Jolanta Airey said the company believed “the revised sample size provides sufficient statistical power to achieve the objectives of this study, and is commensurate with other trials of this nature, so we endorse this decision by the University of Sydney team”.
“Importantly, this means that completion of recruitment, and by extension expected delivery of results, should occur sooner than previously anticipated,” Dr Airey said.
Cynata fell half a cent or 3.7 percent to 13 cents.

IMMUTEP

Immutep says it has dosed six-patients in its up-to 58 patient phase II trial of efti with paclitaxel for the treatment of metastatic breast cancer, with no safety issues.
Immutep said it had dosed the breast cancer patients with a 90 milligram dose of eftilagimod alpha, or efti, in combination with paclitaxel chemotherapy, in the open-label, safety lead-in part of its phase II/III trial and had reported “no safety or tolerability issues” with no dose limiting toxicities.
The company said the trial’s data monitoring committee recommended proceeding to the randomized phase II portion of the trial, which included up-to 58 metastatic breast cancer patients receiving either 30mg or 90mg of efti to determine the optimal dose.
Immutep said determining the optimal dose of efti in this trial was “relevant for the whole efti program across all disease indications”.
Immutep was up half a cent or 1.7 percent to 30.5 cents with 1.2 million shares traded.

PYC THERAPEUTICS

PYC says it has agreed on a clinical trial pathway with the US Food and Drug Administration for PYC-001 for autosomal dominant optic atrophy (ADOA).
In April, PYC said pre-clinical data supported human trials of PYC-001 for the progressive childhood blinding eye disease autosomal dominant optic atrophy in 2024, pending formal toxicological studies (BD: Apr 3, 2023).
Today, PYC said it expected to progress PYC-001 for autosomal dominant optic atrophy to human trials by July 2024, subject to toxicity studies and regulatory endorsement.
PYC said that it had remained on track to realize its objective of progressing a third drug with disease-modifying potential into human studies before the end of 2024.
PYC was up 0.25 cents or 4.5 percent to 5.85 cents with 1.5 million shares traded.

TRUSCREEN

Truscreen says it has a further Zimbabwe purchase order for about $NZ300,000 ($A275,790) of its single use sensors for its cervical cancer screening tests.
Last year, Truscreen said Zimbabwe had ordered 10,800 single use sensors, expected by early 2023, for use with the 16 devices operating in the region (BD: Dec 19, 2023).
Today, the company said under the National Aids Council program, 14,000 women had already been screened in Zimbabwe's Masvingo province and it was expected that the program would be extended nationally.
Truscreen said cervical cancer was the most prevalent and deadly cancer for women in Zimbabwe, with women living with human immunodeficiency virus (HIV) having a six-fold increased risk of developing the disease when compared to women without HIV.
Truscreen chief executive officer Dr Beata Edling said the purchase order was "confirmation that Truscreen is making a difference in ensuring that early treatment for cervical cancer significantly reduces the potential downstream health and human costs".
Truscreen was untraded at 2.1 cents.

LBT INNOVATIONS

LBT says it has deferred repayments of its $1.74 million loan with the South Australian Government Financing Authority, except for interest, until 2026, effective immediately.
In 2018, LBT said the South Australian Government had approved a $4 million low-cost loan as part of a jobs and innovation initiative (BD: Aug 28, 2018)
In 2021, the company said the South Australian Government had deferred its loan repayment of $512,000 by six months to November 22, 2022 (BD: Oct 8, 2021).
Today, LBT said it had received approval from the South Australian Government to pay the interest on its quarterly repayments until 2026, currently 2.8 percent per annum, with the principal repayment in payments of $870,000 on April 30 and October 31, 2026.
The company said the agreement included an early repayment clause contingent on future proceeds it might receive through the exercise of options in its rights offer.
Last month, LBT said it hoped to raise $4.5 million in a four-to-one entitlement offer at 0.5 cents a share, and that Candour Advisory Pty ltd had been appointed underwriter and committed about $3.6 million to the raise (BD: Oct 13, 27, 2023).
Today, the company said it would retain the first $1 million from the exercise of options expiring September 2024, with the remaining funds to be used to repay the loan and any funds from the exercise of options expiring November 2025 to be used to repay the loan.
LBT said the loan restructure was subject to raising the minimum $3.5 million under the rights offer, which was underwritten to Candour for up-to $3.6 million.
The company said the restructure improved its cashflow by about $1.7 million for the 18-month period.
LBT was up 0.1 cents or 25 percent to 0.5 cents.

DIMERIX

Dimerix says Advanz Pharma has paid EUR6.5 million ($A10.7 million) as the upfront payment for the rights to DMX-200 for focal segmental glomerulosclerosis (FSGS).
Last month, Dimerix said Advanz Pharma would pay up-to $229.8 million for the rights to DMX-200 for FSGS in Europe, the UK, Canada, Australia and New Zealand through $10.8 million upfront and up-to $219 million in potential milestones (BD: Oct 5, 2023).
Dimerix fell half a cent or 2.9 percent to 17 cents with 10.5 million shares traded.

BCAL DIAGNOSTICS

Bcal says it has filed a further Australian provisional patent application for its blood test for breast cancer, covering additional lipid biomarkers in the diagnostic.

Bcal chief executive officer Dr John Hurrell told Biotech Daily that the patent was titled 'Diagnostic Signature', was "a utility patent application" and when granted would provide intellectual property protection until October 31, 2043.

In a media release, Bcal said the patent application expanded its pending patent estate to cover additional lipid biomarkers that would supplement those covered in its foundational patent filings and the final version of its Breastest was "expected to contain a subset of all lipids identified to have diagnostic utility [and] widening our patent cover provides both flexibility in test design and stronger protection from potential competition".

Bcal was unchanged at 10.5 cents.

MAYNE PHARMA GROUP

Mayne Pharma says the US Patent and Trademark Office has granted a patent for its orally dosed Nextsellis contraceptive.

Mayne Pharma said the patent, a continuation of a previous patent, was titled 'Orodispersible dosage unit containing an estetrol component' and would protect its intellectual property relating to the formulation of Nextsellis until 2036.

Mayne Pharma was up 17 cents or 4.6 percent to $3.89.

BIOXYNE

Global CR Holdings Ltd says it has reduced its substantial shareholding in Bioxyne from 182,661,044 shares (9.61%) to 149,987,988 shares (7.89%).

The Grafton, New Zealand-based Global CR said that on October 12, 2023 it sold 20,000,000 shares for $250,000 off-market, or 1.25 cents a share, and sold a further 12,673,056 shares on-market but failed to disclose the date and price of the sale.

Bioxyne was untraded at 1.3 cents.

ANTERIS TECHNOLOGIES

Melbourne's L1 Capital Pty Ltd says it has increased its substantial shareholding in Anteris from 1,526,756 shares (10.98%) to 2,513,398 shares (14.62%).

L1 Capital said that between February 16 and May 31, 2023 it sold shares and on October 30 it bought 750,000 shares in a placement for $15,000,000, or $20 a share.

Last month, Anteris said it raised $40 million at $20.00 a share (BD: Oct 26, 2023).

Anteris was unchanged at $19.30.

RESPIRI

In an announcement after the market closed on Friday, Respiri says non-executive director Brian Leedman had resigned "effective immediately".

Respiri said Mr Leedman was appointed in May 2023 "but due to personal circumstances has decided to resign".

Respiri fell 0.2 cents or 7.1 percent to 2.6 cents.