Biotech Daily

Wednesday December 13, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: GENETIC SIGNATURES UP 7%; 4D MEDICAL DOWN 12%**

*** SCIENCE TECHNOLOGY AUSTRALIA OPPOSES FEDERAL $46m 'CUT'**

*** PHARMAUST $3.5m 'PREMIUM' PLACEMENT**

*** DOHERTY, MIPS COVID VACCINES 'STRONG IMMUNE BOOST'**

*** RACE: 17-OF-20 BISANTRENE AML PATIENTS DIE; DATA BACKS STUDIES**

*** VIETNAM ADDS TRUSCREEN DEVICE TO 'TECHNICAL LIST'**

*** CYNATA RECRUITS CYP-004 OSTEO-ARTHRITIS PHASE III TRIAL**

*** SYNTARA DOSES 1st PHASE II SNT-5505 MYELOFIBROSIS PATIENT**

*** PATRYS EXPECTS PAT-DX1 FOR 2024 HUMAN TRIALS**

*** HERAMED REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** UNICOR TAKES 12% OF LBT**

MARKET REPORT

The Australian stock market was up 0.31 percent on Wednesday December 13, 2023, with the ASX200 up 22.5 points to 7,257.8 points. Seventeen Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and two were untraded. All three Big Caps rose.

Genetic Signatures was the best, up three cents or 6.7 percent to 48 cents, with 33,042 shares traded; followed by Neuren up $1.05 or 6.5 percent to $17.14 with 756,499 shares traded. Polynovo climbed 5.5 percent; Alcidion, Cynata and Micro-X were up four percent or more; Immutep, Impedimed and Starpharma improved more than three percent; Emvision rose 2.7 percent; Antisense, Cochlear, CSL, Curvebeam, Resmed and Telix were up more than one percent; with Clarity, Nanosonics, Pro Medicus and SDI up by less than one percent.

4D Medical led the falls, down 10 cents or 12.0 percent to 73.5 cents, with 3.8 million shares traded. Clinuvel and Universal Biosensors lost five percent or more; Next Science fell 4.55 percent; Dimerix, Medical Developments and Prescient were down more than three percent; Atomo and Orthocell shed more than two percent; Avita, Compumedics, Imugene and Opthea were down more than one percent; with Volpara down by 0.6 percent.

FEDERAL GOVERNMENT, SCIENCE & TECHNOLOGY AUSTRALIA

Science & Technology Australia says a $46.2 million cut to the 'Economic Accelerator' in today's Mid-Year Economic and Fiscal Outlook (MYEFO) "undermines confidence".

Science & Technology Australia said it was "the nation's peak body representing more than 115,000 scientists and technologists" and the Federal MYEFO cut of $46.2 million over four years to the Economic Accelerator research commercialization fund "amounts to seven percent of the fund capital allocated in the last Budget".

A spokesperson for Federal Education Minister Jason Clare told Biotech Daily: "Over the four years to 2026-'27, the Australian Government will invest around $16.1 billion in research and development, including through the Australia's Economic Accelerator program … [and other programs] via the Australian Research Council."

The Federal Government said that the $46.2 million from the $1.6 billion Economic Accelerator would be redirected to recommendations from the Australian Universities Accord interim plan and was "not expected to adversely affect future research commercialization efforts".

Science & Technology Australia said the fund was announced under the previous Liberal-National Party Government and legislated under the current Labor Party Government and had "strong cross-party support across the Australian Parliament".

The organization said research and development investment had "plunged to a four-decade low … [and] Australia urgently needs to lift its investment … rather than raid it".

A Department of Industry, Science and Resources graph of Australian Government investment in research and development as a percentage of gross domestic product showed that in 2022-'23 the amount was less than 0.5 percent, the lowest point since 1978-'79 and well below the peaks of more than 0.7 percent from 1992-'93 to 1996-'97 and just under 0.7 percent in 2012-'13.

Science & Technology Australia president Prof Sharath Sriram said the budget cut was "a step in the wrong direction".

"Australia urgently needs to invest more, not less, in research and development to generate the next wave of new jobs and income to secure the living standards of our kids and grandkids," Prof Sriram said. "We cannot afford to undermine certainty and confidence, which are crucial to the willingness of Australian industry to engage in research commercialization."

"We urge the Government and Education Minister Jason Clare to rethink this cut especially as the Government considers the final report of the Australian Universities Accord in the months ahead," Prof Sriram said.

Science & Technology Australia said it welcomed investments in access to university for Aboriginal and Torres Strait Islander people, expanding Paid Parental Leave and a new board for the Australian Research Council.

PHARMAUST

Pharmaust says it has binding commitments to raise about $3.46 million through a placement to institutional and sophisticated investors at 10.0 cents a share.

Pharmaust said the placement price was a 4.8 percent premium to the 15-day volume weighted average price and a 10.8 percent premium to the 30-day VWAP.

The company said the funds would be used for a phase II trial of monepantel in motor neuron disease, to manufacture monepantel tablets and for working capital.

Pharmaust said Merchant Funds subscribed for $2.1 million of the offer, director Sam Wright subscribed for $45,000, and Blue Ocean Equities Pty Ltd was the lead manager.

Pharmaust was up half a cent or 4.8 percent to 11 cents.

THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY
MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

The Doherty Institute says a 76-participant, phase I trial shows its protein-based and mRNA-based Covid-19 vaccines had “strong [immunity] boosting capabilities”.

In January, the Doherty Institute said the Federal Government had provided $1.5 million for two safety trials of its Sars-Cov-2 vaccines (BD: Jan 17, 2022).

In March, the Institute said it would begin an up-to 114-person, phase I trial of two Australian-made ‘proof-of-principle’ vaccines for Sars-Cov-2 (BD: Mar 25, 2022).

Today, the Doherty said the research was conducted with the Monash Institute of Pharmaceutical Sciences, with healthy adults previously vaccinated with licenced Covid-19 vaccines, randomized to receive a fourth dose of either a Melbourne-developed protein vaccine, a Melbourne-developed mRNA vaccine or placebo.

The Institute said its protein and mRNA vaccines were distinct from most existing vaccines because they focused “the immune response on the tip of the Sars-Cov-2 spike protein, called the receptor binding domain”.

The Doherty said the receptor binding domain allowed the virus to enter and infect cells in the body and elicited more that 90 percent of neutralizing antibodies, or antibodies that could block the virus, following infection.

The Institute said the protein vaccine was used an engineered part of the virus protein, rather than genetic material or another virus, which created an immune response in the participant.

The Doherty said the mRNA-based vaccine was “the virus genetic sequence of mRNA that codes for the tip of the spike, which leads to production of the receptor binding domain] protein in the recipient”.

The Institute said both the protein and mRNA vaccines boosted participant immunity against Covid-19, even at the lowest tested dose, particularly against omicron sub-variants, with no safety signals observed for either vaccine.

The Institute said it was exploring options to progress to a phase II trial, which would require additional funding and industry support.

The Doherty said that the research study, titled ‘Interim results from a phase I randomized, placebo-controlled trial of novel Sars-Cov-2 beta variant receptor-binding domain recombinant protein and mRNA vaccines as a 4th dose booster’ was published in The Lancet and the full article was available at https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(23)00444-9/fulltext.

The Doherty Institute’s Prof Terry Nolan said “post-market studies of omicron-directed, whole spike bivalent mRNA booster vaccines have shown modest increases in immune responses to omicron variants compared to ancestral vaccine boosts.”

“Because our two vaccines focus the immune response on the receptor binding domain, they avoid unhelpful immune responses against other parts of the spike protein and could therefore provide a more efficient approach for boosting immunity to the virus, presenting a strong case to proceed to phase II clinical trials.”

The Monash Institute of Pharmaceutical Sciences’ Prof Colin Pouton said “both preclinical and clinical studies have shown … the very real potential to develop a multivalent vaccine, on an annual basis and to protect against emerging new variants of Covid-19, which are believed to be the root cause behind the ongoing waves we are still experiencing”.

“New strategies are still needed to improve efficacy of Covid-19 variant vaccines and to reduce death rates, particularly among older and vulnerable patients,” Prof Pouton said.

In the case of our mRNA vaccine, we’ve also seen early potential to address the issue of immune imprinting, which will also need to be a critical feature for a next-generation vaccine,” Prof Pouton said.

RACE ONCOLOGY

Race says 17 of 20-patients, in its phase II trial of bisantrene for relapsed and refractory acute myeloid leukaemia died since treatment, but the data “support further studies”.

Last month, Race said a phase II trial of bisantrene with fludarabine and clofarabine led to a clinical response in six of 15 patients, or 40 percent (BD: Nov 7, 2023).

At that time, the company said results from the 15 evaluable patients showed the combination led to five complete responses and one partial response, with the five complete response patients able to be bridged to a stem cell transplant.

Race said that of the five patients who progressed to stem cell transplants, three had since died, one from graft-versus-host disease, one who relapsed and one from infection, with the other two patients remaining disease free and in complete remission.

The company said the results had been presented in a poster, titled ‘Bisantrene in combination with Fludarabine and Clofarabine as Salvage Therapy for Adult Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML) - An Open-label, Phase II Study’, at the American Society of Hematology meeting in San Diego, California, from December 9 to 12, 2023.

Today, the poster said a total of 17 patients had died in the study, including 14 patients from relapse or disease progression and three patients from non-disease related causes.

The study poster said five patients were not evaluable due to death post-dosing prior to response assessment, with one of five “considered possibly related to study therapy by the investigator”.

The poster concluded that the bisantrene combination therapy was found to be “safe and well tolerated without cardiac toxicity or tumor lysis syndrome” with a maximum tolerated duration of administration of four days due to rapidly reversible liver toxicity and transaminitis.

The poster’s conclusion said that high infection rates were “expected in this highly pre-treated population” and that the results supported further studies of bisantrene-based combinations.

Race fell two cents or 2.3 percent to 83.5 cents.

TRUSCREEN GROUP

Truscreen says its cervical cancer screening device has been approved by the Vietnamese Ministry of Health for use in hospitals and health centres.

Truscreen said the listing on the approved Technical List reduced the need for individual hospitals to seek prior approval before use, which would shorten the procurement process and would allow its distributor to expand sales to Vietnam.

The company said the listing of its device on the list was based on clinical evidence and feedback from local users, including the Hanoi Obstetrics and Gynaecology Hospital.

Truscreen said that the Vietnam Ministry of Health “recognised the value of the Truescreen technology in accelerating the cervical cancer screening at lower public healthcare costs with greater innovative patient-focused approach”.

Truescreen chief executive officer Dr Beata Edling said the company was “delighted that the Ministry of Health in Vietnam has approved Truscreen as the technology that will assist Vietnam in achieving the World Health Organisation targets in cervical cancer screening”.

“The work of our partner in Vietnam, [Gorton Health Services], has prepared Truscreen for an accelerated national uptake,” Dr Edling said.

Truscreen was unchanged at 2.2 cents.

CYNATA THERAPEUTICS

Cynata says it has enrolled all 321-patients in its randomized, placebo-controlled, phase III trial of intra-articular injected CYP-004 for osteo-arthritis.

In 2020, Cynata said it had begun a 440-patient, randomized, controlled trial of its Cymerus induced pluripotent stem cell product CYP-004 (BD: Nov 11, 2020).

In July and November, Cynata said it had closed recruitment for the trial and due to slow recruitment, reduced the number of patients from 440 to 320 (BD: Jul 24, Nov 6, 2023).

Today, the company said patients would be followed up for two years, "to allow sufficient time for a potential disease modifying effect to be assessed" with the last patient visit expected by November 2025, with results expected by July 2026.

Cymerus said the primary endpoints were the proportion of patients achieving patient-acceptable symptom state after two years and central medial femorotibial cartilage thickness change as measured by magnetic resonance imaging.

Cynata managing-director Dr Killian Kelly said "the completion of recruitment is a major milestone in any clinical trial, and especially so in a trial of this magnitude and importance".

Cynata was up half a cent or 4.2 percent to 12.5 cents.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says it has dosed the first of up-to 15 patients in its phase II trial of SNT-5505 with the Janus kinase inhibitor ruxolitinib for bone marrow cancer myelofibrosis.

In July, the then Pharmaxis said five of nine patients in its open-label, phase II trial of the then PXS-5505 for bone marrow cancer myelofibrosis had shown improved bone marrow fibrosis (BD: Jul 12, 2023).

At that time, the company said it had applied to the US Food and Drug Administration for the next study cohort in combination with a Janus kinase (JAK) inhibitor.

Today, Syntara said the trial had begun following an FDA review of the protocol and data from the earlier cohort, which showed an "excellent safety profile and encouraging signs of efficacy when used in patients who had failed on current standard-of-care".

The company said the additional cohort of the phase II trial aimed to show that a twice-daily, oral 200mg dose of SNT-5505 was safe and effective in myelofibrosis patients who were already treated with ruxolitinib.

Syntara said the study's secondary endpoints included pharmaco-kinetics, reduction in bone marrow fibrosis, response rates, efficacy measured by spleen size reduction, efficacy based on myelofibrosis symptom assessment scores, platelet response, the impact on ruxolitinib dosing and the connection of disease burden-related biomarkers and risk genes.

The company said it hoped to complete recruitment at the 19 clinical trial sites in Australia, South Korea, Taiwan and the US by July 2024, and expected to report six-month interim data by 2025 with final data from 12 months of treatment by July 2026.

Syntara chief executive officer Gary Phillips said the study began recruitment today and was "crucial in establishing the place for SNT-5505 in the treatment regimen of myelofibrosis patient".

"The open-label design enables us to assess the performance of SNT-5505 in real time and we are targeting a major interim data update at [the American Society of Haematology] 2024 that will also trigger follow up discussions with the FDA on the pivotal registration study design and support ongoing discussions with strategic partners," Mr Phillips said.

Syntara was unchanged at 2.4 cents.

PATRYS

Patrys says it will have good manufacturing practice PAT-DX1 produced in time to begin its first-in-human clinical trial of the cancer drug before 2025.
Earlier this year, Patrys said its phase I trial of its humanized deoxymab antibody PAT-DX1 for cancerous tumors had been delayed to 2024 due to sporadic issues relating to the cell line used to produce the drug (BD: Mar 31, 2023).
In May, the company said rat and non-human primate toxicology studies of PAT-DX1 for cancer found no safety or tolerability issues (BD: May 24, 2023).
At that time, Patrys managing-director Dr James Campbell said the company believed it would be able "to restart manufacturing for the PAT-DX1 material for the clinical trial … [by October] 2023".
Today, Dr Campbell said: "I am delighted to confirm that, based on the extensive and rigorous investigations by both our [contract manufacturing and development organization] and external manufacturing consultants, we are now able to recommence our manufacturing program of PAT-DX1 in the upcoming quarter."
"This manufacturing run is expected to produce the drug material that Patrys will use in the phase I clinical trial of PAT-DX1 that is scheduled for the second half of 2024," Dr Campbell said.
"With positive results from our final pre-clinical toxicology studies in hand, we look forward to reporting on the progress of manufacturing and other activities as we work towards initiating the clinical development of our deoxymab technology," Dr Campbell said.
Patrys was up 0.05 cents or 6.7 percent to 0.8 cents with 7.3 million shares traded.

HERAMED

Heramed has requested a trading halt "for the purposes of considering, planning and executing a capital raising".
Trading will resume on December 15, 2023, or on an earlier announcement.
Heramed last traded at three cents.

LBT INNOVATIONS

Unicore Investments Pty Ltd says it has increased its substantial shareholding in LBT from 101,980,000 shares (9.51%) to 149,460,000 shares (11.90%).
The Adelaide-based Unicore said that on November 20 and December 8, 2023 it bought 47,480,000 shares in placements for $237,400, or 0.5 cents a share.
In October, LBT said it hoped to raise $4.5 million in a one-for-four rights offer at 0.5 cents a share; and later said it raised $1,030,228 from shareholders and $2,549,772 from the underwriter, leaving a $920,000 shortfall (BD: Oct 13, Nov 15, 2023).
Later, LBT said it placed $420,000 of the shortfall; and then placed the remaining $500,000, taking the total raised to $4.5 million (BD: Nov 20, Dec 8, 2023).
LBT was unchanged at 1.1 cents with 1.3 million shares traded.