Biotech Daily

Monday November 15, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MESOBLAST UP 12%; ACTINOGEN DOWN 6%**

*** MESOBLAST: 'REVISED DATA SHOWS GREATER HEART BENEFIT'**

*** CHIMERIC: CLTX-CAR-T '3 OF 4 GLIOBLASTOMAS STABLE DISEASE'**

*** IMMURON PREPARES FOR USU TRAVELERS' DIARRHOEA STUDY**

*** WOKE ORDERS SYNTHETIC PSILOCYBIN FOR DRUG TRIALS**

*** RESAPP APPROVAL FOR COVID-19 TEST SITE RECRUITMENT**

*** ORTHOCELL LOCKS ORTHO-ATI SHOULDER TENDON STUDY DATABASE**

*** IMMUTEP: EFTILAGIMOD ALPHA CHINA PATENT; POSTERS PUBLISHED**

*** NOXOPHARM $8.8m MRFF GRANT; TRADING HALT**

*** PHARMAUST TAKES DOG LYMPHOMA TRIAL TO NEW ZEALAND**

*** HERAMED PLEADS SCHULTZ TO ASX 64% QUERY**

*** PHARMAXIS REQUESTS CAPITAL RAISING HALT**

*** PYC REQUESTS NON-HUMAN PRIMATE STUDY RESULTS HALT**

*** BAILLIE GIFFORD REDUCES TO 5.2% OF COCHLEAR**

*** ALAN MOSS, BLUEFLAG INCREASE, DILUTED TO 7% OF AMPLIA**

*** KAZIA APPOINTS DR JOHN FRIEND CMO**

MARKET REPORT

The Australian stock market was up 0.36 percent on Monday November 15, 2021, with the ASX200 up 27.1 points to 7,470.1 points. Twenty of the Biotech Daily Top 40 stocks were up, 15 fell, four traded unchanged and one was untraded. All three Big Caps were up.

Mesoblast was the best, up 20 cents or 11.8 percent to $1.90, with 10.8 million shares traded. Antisense, Orthocell and Universal Biosensors climbed more than seven percent; Dimerix was up 6.4 percent; Resmed rose 5.2 percent; Uscom improved four percent; LBT, Nanosonics, Neuren and Pro Medicus were up three percent or more; Clinuvel, Prescient and Proteomics rose two percent or more; Cochlear, Cyclopharm, Kazia, Nova Eye, Opthea and Paradigm were up more than one percent; with Avita, CSL and Polynovo up by less than one percent.

Actinogen led the falls, down one cent or 5.6 percent to 17 cents, with 3.1 million shares traded, followed by Impedimed down 5.4 percent to 17.5 cents with 4.4 million shares traded. Cynata, Patrys and Resonance fell more than four percent; Alterity and Volpara were down more than three percent; Amplia, Next Science, Optiscan and Telix shed two percent or more; Genetic Signatures, Immutep and Medical Developments were down more than one percent; with Imugene down by 0.9 percent.

MESOBLAST

Mesoblast says that a single dose of rexlemestrocel-L with standard-of-care shows greater benefit for class II and III cardiac patients than originally released.

Mesoblast said that its mesenchymal precursor cell product, rexlemestrocel-L, previously known as Revascor and MPC-150-IM, "reduced the incidence of heart attacks or strokes by 65 percent across all 537 [New York Heart Association] class II or class III treated patients compared with standard of care alone ($p = 0.001$).

Last year, the company said its 537-patient phase III trial of its stem cells for chronic heart failure reduced cardiac events, but did not meet its primary endpoint (BD: Dec 15, 2020).

Mesoblast said at that time that with a mean 30 months of follow-up, the trial showed that patients receiving rexlemestrocel-L with standard-of-care had a statistically significant 60 percent reduction of heart attacks or strokes ($p = 0.002$) and a statistically significant 60 percent reduction in death from cardiac causes ($p = 0.037$), "when treated at an earlier stage in the progressive disease process".

Today, Mesoblast chief executive Prof Silviu told Biotech Daily that "a final analysis by a quality-control, third-party statistical analysis found one fewer death in the active group".

"Despite significant reduction in the pre-specified endpoint of cardiac death, there was no reduction in recurrent non-fatal decompensated heart failure events, which was the trial's primary endpoint," Mesoblast said last year. "This suggests that [Revascor] reduces mortality by mechanisms that are distinct from those of existing drugs that reduce hospitalization rates but do not significantly impact cardiac mortality."

Today, the company said that co-principal investigator Dr Emerson Perin presented "new results" at the American Heart Association meeting "showing a significant relationship between presence of systemic inflammation as quantified by high-sensitivity C-reactive protein (hs-CRP) and treatment benefit with rexlemestrocel-L on risk of cardiovascular mortality, heart attacks or strokes".

Mesoblast quoted a media release by the American Heart Association, in which Dr Perin said: "Cell therapy has the potential to change how we treat heart failure."

"This study addresses the inflammatory aspects of heart failure, which go mostly untreated, despite significant pharmaceutical and device therapy development," Dr Perin was quoted saying in the AHA media release.

Mesoblast said that in the cohort of 301 class II and class III treated patients with high levels of inflammation (hsCRP ≥ 2mg/L), "rexlemestrocel-L reduced the incidence of heart attacks or strokes by 79 percent compared with standard-of-care alone ($p < 0.001$)".

The company said that among class II patients with high levels of inflammation (hs-CRP ≥ 2mg/L), a single dose of rexlemestrocel-L reduced the incidence of cardiovascular death by 80 percent compared with standard-of-care alone ($p = 0.005$).

Mesoblast said that compared with standard-of-care alone, rexlemestrocel-L with standard-of-care reduced the incidence of cardiovascular death, heart attacks or strokes by 33 percent across all 537 NYHA class II or class III patients ($p = 0.021$) and by 45 percent in the 301 patients with high levels of inflammation (hs-CRP ≥ 2mg/L) ($p = 0.012$).

"Compared with standard-of-care alone, addition of rexlemestrocel-L did not further reduce the frequency of hospitalization for worsening [heart failure] symptoms as previously reported," the company said.

Mesoblast quoted Texas Heart Institute chief executive officer Dr Joseph Rogers saying that "most traditional treatments address the congestion or fluid overload associated with heart failure [but] rexlemestrocel-L addresses the inflammation that is at the centre of advanced chronic heart failure … [which] reflects the unique mechanisms-of-action of this allogeneic cellular therapy on reduction of inflammation and improved microvasculature".

Mesoblast was up 20 cents or 11.8 percent to $1.90 with 10.8 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says its phase I trial of chlorotoxin chimeric antigen receptor T-cells for glioblastoma shows “disease control” in three of four patients at the lowest dose.
Chimeric said that the scorpion venom-derived chlorotoxin chimeric antigen receptor T-cell (CLTX-Car-T) treatment resulted in stable disease in three of the four patients.
The company said that the treatment was “generally well tolerated with no dose limiting toxicities” with persistence of the treatment shown throughout treatment.
Chimeric said that one patient experienced a grade 3 cerebral oedema, which was an adverse event commonly observed in patients with glioblastoma and “that was only possibly attributed to the Car-T cells”.
Last year, Chimeric says it licenced chlorotoxin chimeric antigen receptor T-cells from California’s City of Hope and had begun an about 20-patient trial for glioblastoma, with the first patient recently starting treatment (BD: Sep 22, 2020).
Today, the company said the results gave it “confidence as higher dose levels and dual routes of administration commence”.
Chimeric said the data was reported in two abstracts to be presented at the Society for Neuro-Oncology meeting in Boston from November 18 to 21, 2021.
The company said the first abstract was CTIM-29, titled ‘Clinical evaluation of chlorotoxin-directed Car-T cells for patients with recurrent glioblastoma’ and provided insight into the initial clinical data for chlorotoxin.
Chimeric said that the second abstract, EXTH-10, titled ‘Exploration of a novel toxin-incorporating Car-T cell: how does chlorotoxin recognize glioblastoma cells?” expanded on the translational understanding of Chlorotoxin activity.
The company said that the data focused on the four patients enrolled in the first dose level, treated with 44 x 106 CLTX-Car-T cells through intra-tumoral administration.
Chimeric said the next three dose levels were planned to be both intra-tumoral and intraventricular at 88, 220 and 440 x 106 CLTX-Car-T cells.
The company said the first cohort showed that three of the four patients had “a best response of stable disease”.
Chimeric said that bioactivity of the cells was shown with detection of persistent CLTX-Car-T cells in the tumor cavity throughout treatment, suggesting that CLTX-Car-T cells were not immunogenic, an immune response that could impact the persistence and efficacy of the Car-T.
Chimeric managing-director Jennifer Chow said the data “while early, are highly encouraging as they demonstrate that CLTX-Car-T cells are eliciting disease control in recurrent glioblastoma even at the lowest, sub-therapeutic dose level”.
The company said that translational data in the second abstract focused on the composition and structure of the cell surface complex recognized by CLTX-Car-T, confirming that the correlation between membrane-bound matrix metalloprotease 2 (MMP-2) expression and CLTX binding supported the rationale for exploring MMP-2 as a correlative marker for response to CLTX-Car-T in phase I studies.
Chimeric said that the study was a single arm, open label trial in patients with MMP2+ recurrent or progressive glioblastoma.
The company said that the primary endpoints were to assess the safety of CLTX-Car-T cells, determine the maximum tolerated dose schedule and a recommended phase II dosing plan.
Chimeric said that the secondary endpoints included bioactivity and efficacy measures.
Chimeric was unchanged at 32 cents with 4.5 million shares traded.

IMMURON

Immuron says manufacturing has begun for the Uniformed Services University of the Health Sciences trial of Travelan and two other supplements for travelers' diarrhoea.
Immuron said the Bethesda, Maryland-based US Government's Uniformed Services University of the Health Sciences planned to enrol 1,336 participants in the randomized, double-blind, placebo-controlled trial to evaluate the effectiveness of the pre-biotic Bimuno, the probiotic Florastor and IMM124E or Travelan compared to placebo, for prophylaxis during deployment or travel to a high- travelers' diarrhoea risk region, expected to begin in April 2022.
Last week, the company said manufacturing of its cow colostrum-based Camyetec drug product for Campylobacter and entero-toxigenic Escherichia coli (ETEC) was completed in October 2021 and would be transferred to the Baltimore, Maryland based Johns Hopkins Bloomberg School of Public Health for the two trials, with the US Naval Medical Research Center.
Today, Immuron said that manufacture of the first batches of investigational medical products was underway for the planned trial which would be in collaboration with the UK Ministry of Defense and the New York City Travel Clinic.
Immuron was up half a cent or four percent to 13 cents.

WOKE PHARMACEUTICALS PTY LTD

Woke says it has placed an initial order with Purisys LLC for non-good manufacturing practice synthetic psilocybin for the formulation of dose forms for depression.
Woke said that the Athens, Georgia-based Purisys specialized in the synthetic manufacture of active pharmaceutical ingredients, including psychedelic drugs and had a US Drug Enforcement Agency licenced and Food and Drug Administration inspected manufacturing facility with the required quality assurance and quality control to support the company's supply chain needs.
Woke chief executive officer Nick Woolf told Biotech Daily that the initial non-good manufacturing practice batch "will be manufactured in Georgia as a validation batch for the manufacturing facility, which will then produce good manufacturing practice standard drug compound; and it's half the price of a similar GMP batch".
The company said it was developing two dose forms of psilocybin for depression and both candidates were expected to begin phase IIb trials by the end of 2022.
Woke said it had partnered with Monash University's Medicines Manufacturing Innovation Centre to formulate WP001, a 1mg to 5mg low-dose rapid release capsule of psilocybin for moderate depression.
The company said that a second candidate WP002 was a 25mg higher dose for major depressive disorder, with concomitant psychotherapy.
Mr Woolf said the company was "focused on the development of synthetic psychedelics, both novel dosage forms of existing drugs such as psilocybin, but also novel analogues with enhanced properties".
"Our mission is to benefit patients suffering from mental health disorders with unmet medical needs," Mr Woolf said.
Mr Woolf said the company expected a further order of GMP material by April 2022 for the manufacture of clinical material for two phase IIb trials for depression later in the year.
Woke is a private company.

RESAPP HEALTH

Resapp says it has approval to recruit patients from Covid-19 testing clinics for its 1,500-patient US Covid-19 study.
In May, Resapp said it had enrolled the first patient to establish the efficacy of its smartphone application in analyzing cough sounds for Covid-19 (BD: May 17, 2021).
Today, Resapp said it had partnered with the Huntington Beach, California-based Covid Clinic to recruit 100 polymerase chain reaction test-confirmed Covid-19 patients from seven of Covid Clinic's sites.
Resapp managing-director Dr Tony Keating said that "adding the option of recruiting patients at in-person Covid-19 testing clinics will substantially increase our recruitment rate and gives us a high level of confidence that we will complete recruitment by mid-December".
Dr Keating said the company had "a growing dataset of patients from multiple continents to perform the algorithm training and validation processes" for a Covid-19 screening test.
Resapp was up 0.2 cents or 3.9 percent to 5.3 cents with 1.1 million shares traded.

ORTHOCELL

Orthocell says it has locked the database for its trial of Ortho-ATI (autologous tenocyte injection) for shoulder tendon injury and expects topline data by the end of this year.
Last year, Orthocell said it had begun the 30-patient trial to assess Ortho-ATI for shoulder tendinopathy compared to corticosteroid treatment (BD: Jun 30, 2020).
Today, Orthocell managing-director Paul Anderson said "this is an important milestone for Ortho-ATI and the company".
Orthocell was up 3.5 cents or 7.1 percent to 53 cents.

IMMUTEP

Immutep says China has granted a patent for its eftilagimod alpha (IMP321) a soluble lag-3 fusion protein, in combination with a programmed death (PD-1) pathway inhibitor.
Immutep said that the patent, titled 'Combined Preparations for the Treatment of Cancer or Infection' would protect its intellectual property until January 8, 2036.
Immutep fell one cent or 1.6 percent to 60 cents with 5.7 million shares traded.

IMMUTEP

Immutep says posters presented at the Society for Immunotherapy of Cancer meeting relating to three of its eftilagimod alpha (IMP321) trials are available on its website.
Last week, Immutep said its Aipac trial had a "non-significant survival benefit trend" but pre-defined patient sub-groups had a statistically significant benefit (BD: Nov 10, 2021).
Today, the company said the posters were presented at the Society's meeting from November 10 to 14, 2021 and its poster on Aipac showed "very encouraging overall survival data" and "statistically significant quality of life" data.
Immutep said its Tacti-002 poster showed "an encouraging overall response rate" with 11 of 37 (29.7%) second-line head and neck squamous cell carcinoma patients responding to a combination of IMP321 and pembrolizumab.
The company said its poster on Tacti-003 outlined the design of its 154-patient, phase IIb study into the efficacy of IMP321 in patients with first-line head and neck squamous cell carcinoma.
The posters are at: https://www.immutep.com/investors-media/presentations.html.

NOXOPHARM

Noxopharm says the Federal Government's Medical Research Future Fund has granted it $8.8 million and it has called a trading halt for an update on the grant.
Noxopharm said the grant was "one of the largest grants of its kind by [the] MRFF for any biotechnology company for a single drug program" and the funding related to its development of Veyonda as a chemotherapy enhancer in cancer patients.
Separately, the company requested a trading halt "in respect of an update on the recently announced Australian government grant".
Trading will resume on November 17, 2021, or on an earlier announcement.
Noxopharm last traded at 48.5 cents.

PHARMAUST

Pharmaust says it is expanding its trial of monepantel for dog lymphoma trial to New Zealand in preparation of a pivotal trial expected in May next year.
Pharmaust said it that Veterinary Specialists Auckland's Dr Mike Coleman and Dr Tommy Fluen were able to accept dog lymphoma referrals from in New Zealand's North Island.
Pharmaust fell one cent or 8.3 percent to 11 cents with 2.6 million shares traded.

HERAMED

Heramed has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 12.5 cents or 64.1 percent from a low of 19.5 cents on Thursday November 11 to an intra-day high of 32.0 cents today, November 15, 2021, and noted a "significant increase" in trading volume.
Heramed was up 1.5 cents or 5.7 percent to 28 cents with 1.8 million shares traded.

PHARMAXIS

Pharmaxis has requested a trading halt pending an announcement "in relation to the outcome of a capital raising".
Trading will resume on November 17, 2021 or on an earlier announcement.
Pharmaxis last traded at 11.5 cents.

PYC THERAPEUTICS

PYC says it has requested a trading halt pending an announcement "regarding the company's non-human primate tolerability and safety results".
Trading will resume on November 17, 2021 or on an earlier announcement.
PYC last traded at 15 cents.

COCHLEAR

Baillie Gifford and subsidiaries say they have reduced their holding in Cochlear from 4,098,207 shares (6.24%) to 3,435,399 shares (5.22%).
Baillie Gifford said that between May 4, 2020 and November 12, 2021, it bought and sold shares in more than 450 separate transactions, with the largest sale 34,561 shares for GBP4,143,444 ($A7,584,113) or GBP119.89 ($A219.45) a share.
Cochlear was up $3.98 or 1.8 percent to $223.55 with 98,035 shares traded.

AMPLIA THERAPEUTICS

Allan Moss and Blueflag Holdings say they have increased and been diluted in Amplia from 8,750,000 shares (7.02%) to 10,780,000 shares to (6.96%).
The substantial shareholder noticed was signed by Blueflag director Allan Moss, the former managing-director of Macquarie Group.
Mr Moss said that Blueflag bought 2,028,000 shares, and was diluted, in last week's $5.4 million placement at 18.0 cents a share (BD: Nov 8, 2021).
Amplia fell 0.5 cents or 2.6 percent to 18.5 cents.

KAZIA THERAPEUTICS

Kazia says it has appointed Dr John Friend as its chief medical officer to oversee the development and commercialization of the company's drug pipeline.
Kazia said that Dr Friend was based in New Jersey and previously was an executive at Helsinn Therapeutics and the Florham Park, New Jersey-based Cellectar Biosciences chief medical officer.
The company said that Dr Friend held a Bachelor of Arts from the Dallas, Texas-based Southern Methodist University and a Doctor of Medicine from New Jersey's Rutgers University.
Kazia was up two cents or 1.3 percent to $1.57.