Biotech Daily

Monday December 6, 2021

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: COMPUMEDICS UP 7.5%; KAZIA DOWN 16%**

*** MESOBLAST: 'REXLEMESTROCEL-L REDUCES ADVERSE EVENTS'**

*** CARDIEX OPTIONS RAISE $7.7m**

*** NUHEARA, SONOVA SIGN SUPPLY AGREEMENT**

*** S&P ASX INDICES: IMUGENE, COGSTATE PROMOTED**

*** CORRECTION: MEDICINES DEVELOPMENT FOR GLOBAL HEALTH**

*** CANN RECEIVES $2.2m FEDERAL R&D TAX INCENTIVE**

*** ANTERIS REQUESTS CAPITAL RAISING HALT**

*** PIE FUNDS REDUCES TO 6.2% OF PROBIOTEC**

*** RADIOPHARM APPOINTS PROF SARA HURVITZ ADVISER**

*** ANATARA APPOINTS SIMON ERSKINE CDO, MICHAEL PRYOR BDM**

MARKET REPORT

The Australian stock market edged up 0.05 percent on Monday December 6, 2021, with the ASX200 up 3.9 points to 7,245.1 points. Just four of the Biotech Daily Top 40 stocks were up, 33 fell, two traded unchanged and one was untraded.

Compumedics was the best, up 2.5 cents or 7.5 percent to 36 cents, with 79,690 shares traded. Mesoblast and Resonance improved more than four percent; with Medical Developments and Resmed up more than one percent.

Kazia led the falls, down 23 cents or 16.1 percent to $1.20, with 321,269 shares traded. Actinogen and Universal Biosensors lost more than 11 percent; LBT and Optiscan fell more than eight percent; Antisense was down 7.7 percent; Imugene and Nova Eye were down more than six percent; Immutep and Starpharma shed five percent or more; Alterity, Cynata, Neuren and Prescient fell four percent or more; Paradigm and Volpara lost more than three percent; Amplia, Avita, Cyclopharm, Dimerix, Oncosil, Patrys, Pharmaxis, Polynovo, Pro Medicus and Telix shed more than two percent; Clinuvel, Genetic Signatures and Orthocell were down one percent or more; with Cochlear, CSL, Next Science, Opthea, Osprey and Proteomics down by less than one percent.

MESOBLAST

Mesoblast says further analyses from its 537-patient, phase III heart failure trial of rexlemestrocel-L shows adverse event benefit for patients with diabetes and/or ischemia.

Mesoblast said the greatest benefit in major cardiovascular adverse events (Mace) of cardiovascular mortality or irreversible morbidity, that is non-fatal heart attack or stroke, was in patients with diabetes and/or myocardial ischemia, with those patients comprising 72 percent of the total treated population and were “at very high risk for mortality and irreversible morbidity due to micro and macro-vascular disease despite receiving optimal standard of care therapies”.

Last year, Mesoblast said the 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).

The company said at that time that its randomized, controlled trial of rexlemestrocel-L showed that patients with advanced chronic heart failure receiving a single endo-myocardial treatment with rexlemestrocel-L on top of maximal therapies 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”.

Mesoblast did not provide specific data on patient numbers for the primary endpoint of “reduction in recurrent non-fatal decompensated heart failure events”.

Rexlemestrocel-L was previously known as Revascor and MPC-150-IM.

Today, Mesoblast said that the benefit for major adverse cardiovascular events in high-risk heart failure patients with diabetes and/or myocardial ischemia endpoint was “in line with [US Food and Drug Administration] guidance on key outcomes in high-risk patients and with pharma industry drugs approved for cardiovascular risk reduction”.

The company said analysis of pre-specified high-risk groups in the Dream-HF trial showed that rexlemestrocel-L with standard-of-care, reduced the three-point Mace composite of cardiovascular death or heart attack or stroke by 37 percent across all chronic heart failure and low ejection fraction patients with diabetes and/or ischemia and by 54 percent in chronic heart failure and low ejection fraction patients with systemic inflammation.

Mesoblast said that the FDA previously accepted three-point Mace reductions of 12 percent to 14 percent for approval of multiple pharmaceutical industry drugs to reduce cardiovascular risk in diabetic patients.

The company said that the FDA had “confirmed that reduction in cardiovascular mortality or irreversible morbidity, non-fatal heart attack or stroke, is an acceptable clinically meaningful endpoint for determining the treatment benefit of rexlemestrocel-L for patients with [chronic heart failure and low ejection fraction]”.

Mesoblast said it would submit its new analyses to the FDA “to agree on a potential pathway to approval”.

The company said its chief executive Prof Silviu Itescu presented the new data at the Cardio Vascular Clinical Trialists Forum in Washington DC on December 3, 2021.

Mesoblast said that a single rexlemestrocel-L dose with standard-of-care therapies reduced the composite three-point Mace in all 537 patients by 33 percent ($p = 0.02$).

The company said that “over a mean follow-up of 30 months, a hierarchical analysis across pre-specified high-risk subgroups showed greatest benefit in patients with diabetes and/or myocardial ischemia ($p = 0.019$).

Mesoblast said that among the 276 control patients receiving standard of care therapies, the risk of three-point Mace was 1.9-fold higher in the 192 controls with diabetes and/or myocardial ischemia, than the 84 control patients with neither diabetes nor myocardial ischemia ($p = 0.02$).

Mesoblast climbed 6.5 cents or 4.2 percent to $1.62 with 2.4 million shares traded.

CARDIEX

Cardiex says it raised $7,666,510 through the exercise of listed and unlisted options exercisable at five cents and expiring on November 30, 2021.
Cardiex said that 92.82 percent of the options on offer were exercised, with directors exercising more than 40 million options of a total 165,175,656 options on offer; a maximum within regulations.
The company said that 153,330,197 of the November options were exercised.
Cardiex was up 0.4 cents or eight percent to 5.4 cents with 2.6 million shares traded.

NUHEARA

Nuheara says it has appointed the Stäfa, Switzerland-based Sonova as a supplier of its hearing and sound filtering products.
Nuheara said Sonova had a three-year, non-exclusive supply agreement with no minimum volume commitments, but would begin selling its products online and in the US and Australia, with Europe, the UK and Canada prioritized thereafter.
The company said Sonova was the largest manufacturer of hearing aids in the world, and that the deal would add 3,200 points of sale to Nuheara's network.
Nuheara was up 0.1 cents or 5.3 percent to two cents with 30.9 million shares traded.

STANDARD AND POOR'S DOW JONES INDICES

Two biotechnology companies, Imugene and Cogstate, have been promoted in changes to Standard & Poor's ASX indices.
Standard & Poor's said that Imugene had been promoted into the ASX200 and that Cogstate had been promoted into the ASX All Technology Index.
Previously, Standard & Poor's has told Biotech Daily that inclusion in the indices is based solely on market capitalization.
The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.
Standard & Poor's said the changes would be effective prior to the open of trading on December 20, 2021.
Cogstate fell seven cents or three percent to $2.26.
Imugene fell 3.5 cents or 6.9 percent to 47.5 cents with 43.2 million shares traded.

MEDICINES DEVELOPMENT FOR GLOBAL HEALTH

The Mesoblast article on Friday said that Clinuvel was the first Australian company to take a drug all the way to US Food and Drug Administration registration.
Clinuvel was the first ASX-listed company to do so, on October 9, 2019, for Scenesse for erythropoietic protoporphyria, but followed the public, not-for-profit Medicines Development for Global Health, which won FDA registration on June 13, 2018 for its Moxidectin for Ross River blindness (BD: Jun 14, 2018; Oct 9, 2019).
Biotech Daily understands that although CSL has many drugs registered with the FDA it has used intermediaries to take the drugs through the regulatory pathway.
Chemgenex Omapro, later known as Synribo, for chronic myeloid leukaemia, was taken most of the way to regulatory approval, by gthe Australian company, but was completed by Teva which acquired the Chemgenex acquirer Cephalon (BD: Feb 14, 2014).
No sub-editors were hurt in correcting this history.

CANN GROUP

Cann says it has received $2,186,538 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Cann said the tax incentive related to expenditure for the year to June 30, 2021.
Cann fell 1.5 cents or five percent to 28.5 cents.

ANTERIS TECHNOLOGIES

Actinogen has requested a trading halt “pending an announcement in relation to a proposed underwriting transaction of the company’s listed options”.
Trading will resume on December 8, 2021 or on an earlier announcement.
In January, Anteris said it had a $20 million funding package with Mercer Street Global Opportunity Fund (BD: Jan 17, 2021).
Anteris said it had completed a $2.7 million capital raising in April, a $2.3 million capital raising in May, a $9 million capital raising in August, and a $5 million capital raising in October (BD: Apr 12, May 25, Aug 2, Oct 27, 2021)
Anteris last traded at $8.40.

PROBIOTEC

Auckland’s Pie Funds Management says it has reduced its substantial holding and been diluted in Probiotec from 5,677,383 shares (7.592%) to 5,000,874 shares (6.150%).
Pie said that between November 12, 2020 and October 19, 2021 it sold 679,509 shares at prices ranging from $2.138 to $2.435 a share, and was diluted in a share issue.
Probiotec fell two cents or 0.9 percent to $2.20.

RADIOPHARM THERANOSTICS

Radiopharm says is has appointed Prof Sara Hurvitz to its scientific advisory board.
Radiopharm said that Prof Hurvitz was a professor of medicine at the University of California Los Angeles’ School of Medicine, medical director of UCLA’s Comprehensive Cancer Center’s research unit, co-director of the Santa Monica-UCLA outpatient oncology practice, and director of the UCLA breast oncology program.
According to Prof Hurvitz’s UCLA profile, she holds Doctor of Medicine from the University of Southern California.
Radiopharm fell 3.5 cents or 10.1 percent to 31 cents with 4.7 million shares traded.

ANATARA LIFESCIENCES

Anatara says it has appointed Simon Erskine chief development officer, and Michael Pryor head of business development and marketing communications.
Anatara said that Mr Erskine had more than 10 years’ experience in biotechnology and in-vitro diagnostic technology, having worked for Genetic Signatures and Speedx.
The company said Mr Pryor had more than 20 years marketing, sales and account management experience in the pharmaceutical sector, and was previously Menarini Group commercial manager.
Anatara fell half a cent or 3.45 percent to 14 cents.