Biotech Daily

Wednesday March 23, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: KAZIA UP 10.5%; DIMERIX DOWN 10%**

*** DOHERTY: SARS-COV-2 VACCINES GIVE 'LASTING' T-CELL IMMUNITY**

*** FLINDERS UNI DISCOVERS GUT-BRAIN COMMUNICATION ROUTE**

*** CHIMERIC RIGHTS RAISE $4.3m; TOTAL $11.7m; $6.4m SHORTFALL HALT**

*** NEUREN: FDA APPROVES NNZ-2591 PHELAN-MCDERMID IND, TRIAL**

*** TELIX APPROVED FOR TLX101 GLIOBLASTOMA TRIAL**

*** IMUGENE: US OKAY FOR PHASE I VAXINIA TUMOR TRIAL**

*** CHIMERIC: CHM2101 'ERADICATES TUMORS', IN MICE**

*** RADIOPHARM: GENESISCARE FOR 1st AUSTRALIAN CANCER TRIAL**

*** PYC: FDA 'CONCURS' WITH PRE-IND PLANS**

*** CLIME DOWN TO 8.6% OF MACH7**

*** LIFE BIOSCIENCES REDUCES TO 10% OF ALTERITY**

*** SG HISCOCK INCREASES, DILUTED TO 5.1% OF ALTHEA**

*** ANTEO TO LOSE CEO DEREK THOMSON, TOO**

MARKET REPORT

The Australian stock market was up 0.5 percent on Wednesday March 23, 2022, with the ASX200 up 36.8 points to 7,377.9 points. Twenty of the Biotech Daily Top 40 stocks were up, 14 fell, four traded unchanged and two were untraded.

Kazia was the best, up nine cents or 10.5 percent to 95 cents, with 43,373 shares traded. Immutep and Imugene improved more than nine percent; Emvision climbed 7.3 percent; Actinogen, Nova Eye and Polynovo were up five percent or more; Atomo, Medical Developments and Patrys were up four percent or more; Antisense and Clinuvel were up three percent or more; Alcidion, Cyclopharm, Genetic Signatures, Neuren, Telix and Volpara rose more than two percent; Opthea, Pro Medicus were up more than one percent; with CSL up 0.8 percent.

Dimerix led the falls, down two cents or 10 percent to 18 cents, with one million shares traded. Mesoblast lost six percent; Paradigm fell 4.35 percent; Amplia, Resmed and Resonance retreated three percent or more; Cynata, Oncosil, Next Science and Universal Biosensors shed more than two percent; Nanosonics, Orthocell and Proteomics were down more than one percent; with Avita, Cochlear and Starpharma down by less than one percent.

THE DOHERTY INSTITUTE

The Doherty Institute says vaccination provides lasting T-cell immunity against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

The Doherty said that it tracked the T-cell responses of people who had recovered from Covid-19 for 15 months and found there was a sustained level of T-cells capable of recognizing the Sars-Cov-2 spike protein.

The research article, titled 'Establishment and recall of SARS-CoV-2 spike epitope-specific CD4+T cell memory', was published in Nature Immunology, with the full article available at https://www.nature.com/articles/s41590-022-01175-5.

The Institute's research fellow and senior author Dr Jennifer Juno said that "despite an initial contraction of the immune response immediately following infection, the T cells stabilized at six months and remained level after 15 months of monitoring".

"Even though some parts of the immune response wane, we can now see that T-cells recognizing the virus are quite stable over time".

"After more than a year, they were still roughly 10-fold higher than someone who had never been exposed to the spike protein through infection or vaccination," Dr Juno said.

The Doherty Institute said that when individuals were re-exposed to the spike protein through vaccination, the part of the virus that enabled Sars-Cov-2 to attach and enter cells in humans, the T-cells quickly reactivated and increased in number.

"Vaccination boosted the levels of these T-cells to be up to 30 times higher than they were before," Dr Juno said. "In general, we saw that the vaccines generate the same amount of T-cells as someone who had been infected."

Dr Juno said that a third dose "does an incredible job" of re-activating T-cells.

The Doherty said the study was a collaboration with Sydney's Kirby Institute.

FLINDERS UNIVERSITY

Flinders University says its researchers have discovered how specialized cells within the gut can communicate with both the brain and spinal cord.

Flinders University said the enteric nervous system in the gastro-intestinal system communicated with the brain using entero-chromaffin cells in the gut that produced and released hormones and neuro-transmitters in response to particular ingested stimuli.

The article 'The gut-brain axis: spatial relationship between spinal afferent nerves and 5-HT-containing enterochromaffin cells in mucosa of mouse colon' was published in the American Journal of Physiology-Gastrointestinal and Liver Physiology, with an abstract at: https://journals.physiology.org/doi/abs/10.1152/ajpgi.00019.2022.

Flinders University co-author Prof Nick Spencer said entero-chromaffin cells released the majority of serotonin, so the study found "a major clue into how the food we eat stimulates the release of serotonin' which acted on the nerves to communicate with the brain.

"There is a direct connection between serotonin levels in our body and depression and how we feel," Prof Spencer said. "So, understanding how the gut [entero-chromaffin] cells communicate with the brain is of major importance."

The University said the research team used a neuronal tracing technique they developed, allowing them to see the gut wall sensory nerve endings with clarity, for the first time.

"This has not been possible, until now, because there were so many other types of nerves also present in the gut - it's like finding a needle in a haystack," Prof Spencer said.

The University said the technique allowed the researchers to see that entero-chromaffin cells likely release substances by a process of diffusion, which then acted on the sensory nerves to the brain; but no direct physical connection between entero-chromaffin cells and sensory nerve endings were found, contrary to some suggestions.

CHIMERIC THERAPEUTICS

Chimeric says its retail one-for-3.15 rights offer at 17 cents a share has raised $4.3 million of a hoped-for $10.7 million, taking the total raised to $11.7 million.
Last month, Chimeric said it raised $7.4 million in the institutional rights offer with a total target of $18.1 million (BD: Feb 22, 23, 2022).
The company said at that time that each new share came with an attaching option, exercisable at 25.5 cents by March 31, 2024.
Chimeric executive chair Paul Hopper said that “in light of the current geo-political situation and challenging equity market conditions impacting the biotechnology sector, this capital raising result represents a strong outcome for the company”.
The company requested a trading halt to place the $6.4 million shortfall through its lead manager for the offer, Bell Potter Securities.
Trading will resume on March 25, 2022, or on an earlier announcement.
Chimeric last traded at 14.5 cents.

NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has approved its NNZ-2591 for Phelan-McDermid syndrome investigational new drug application and phase II trial.
The company said the up-to 20 children, phase II trial would be conducted at four US hospitals, to examine safety, tolerability, pharmaco-kinetics and efficacy over 13 weeks of treatment with NNZ-2591.
Neuren chief executive officer Jon Pilcher said the company was “excited to be able to proceed with this eagerly anticipated trial following FDA approval of our second IND for NNZ-2591 and we look forward to advancing in partnership with the Phelan-McDermid community in the US.
Neuren said Phelan-McDermid syndrome trial top-line results were expected by July 2023.
Neuren was up nine cents or 2.15 percent to $4.27 with 235,726 shares traded.

TELIX PHARMACEUTICALS

Telix says it has approval for a 12-patient, phase I, dose-escalation study of TLX101 with external beam radiation therapy and temozolomide for glioblastoma multiforme.
Telix said the Ipax-2 study would be carried out at Melbourne’s Olivia Newton-John Cancer Research institute to gather safety and drug interaction profile data to evaluate whether TLX101 was suitable to progress to a phase II study.
The company said TLX101 targeted the L-type amino acid transporter 1 (LAT-1), which was “typically over-expressed in [glioblastoma multiforme]”.
Telix said it had ethics approval for the Ipax-L phase II study of TLX101 with external beam radiation therapy in patients with relapsed glioblastoma, at the Linz, Austria-based Kepler University Hospital.
Telix chief medical officer Dr Colin Hayward said that “running these concurrent studies will build on the promising data generated in the Ipax-1 study, supporting our goal to expedite the development of a potential new therapy in an aggressive cancer with limited therapeutic options”.
“With Ipax-2, Telix is taking the development of TLX101 into the front-line setting for the first time,” Dr Haywood said. “Following the promising insights from the previous Ipax-1 study we are excited to see the potential impact of targeted radiation in patients after their initial surgery.”
Telix was up 11 cents or 2.2 percent to $5.12 with 796,988 shares traded.

IMUGENE

Imugene says it has US approval for an up-to 10-patient phase I, dose-escalation trial of Vaxinia CF33-hNIS oncolytic virotherapy for metastatic or advanced solid tumors.
Imugene said the first US hospital with ethics approval was the Duarte, California-based City of Hope and the open-label study would assess the safety and tolerability of Vaxinia, or CF33-human sodium iodide symporter (hNIS) as a monotherapy or in combination with pembrolizumab in metastatic or advanced solid tumors.
The company said it expected the study would expand to more sites during 2022.
Imugene managing-director Leslie Chong said the start of the US Vaxinia study was "a significant milestone for Imugene and clinicians treating Americans faced with the challenge of metastatic advanced solid tumors".
"Following the outstanding work of Prof Yuman Fong and the City of Hope team, in addition to the positive pre-clinical results, we're incredibly eager to unlock the potential of Vaxinia and the oncolytic virotherapy platform more broadly," Ms Chong said.
Imugene was up 2.5 cents or 9.6 percent to 28.5 cents with 41.6 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says its CHM2102, which targets the cell surface marker CDH17 "completely eradicated tumors" with no relapse or toxicity, in mice with eight types of cancer.
Chimeric said the study focused on the potential of chimeric antigen receptor t-cells for the treatment of gastro-intestinal and neuro-endocrine cancers, and showed that CDH17 targeting chimeric antigen receptor T-cells (Car-T) "completely eradicated tumors with no relapse or toxicity in eight different in-vivo models including colorectal cancer, gastric cancer, pancreatic cancer, and neuroendocrine tumors".
The company said the total elimination finding, and that Car-T-cells destroyed CDH17-expressing tumors but not normal CDH17-expressing tissues such as the small and large intestines, suggested optimal design of the T-cell and a therapeutic treatment window.
Chimeric said that the study, titled 'Potent suppression of neuroendocrine tumors and gastrointestinal cancers by CDH17CAR T cells without toxicity to normal tissues' was "published as the cover story" in Nature Cancer, with an abstract available at: https://www.nature.com/articles/s43018-022-00344-7.
Chimeric chief business officer Dr Eliot Bourk said the data was "rigorous, scientifically elegant and suggest great promise for CHM 2101 as a potential Car-T-cell therapy".
"The optimized construct targeting CDH17 presents a novel and highly differentiated approach to overcoming the challenges observed to date with T-cell therapies in solid tumors," Dr Bourk said.
Chimeric managing-director Jennifer Chow said the company was "rapidly advancing CHM2101 toward first-in-human clinical studies, with the hope of bringing the promise of cell therapy to life for patients with currently incurable [gastro-intestinal] cancers".

RADIOPHARM THERANOSTICS

Radiopharm says it has a letter-of-intent with Sydney's Genesiscare for its first Australian phase I trial of its nano-monoclonal antibodies in non-small cell lung cancer.
Radiopharm said the agreement was being negotiated, but it expected the initial project to be 18 months, and would involve its RAD204 radio-pharmaceutical targeting programed death ligand-1 (PD-L-1) at Australian research centres.
The company said non-small cell lung cancer was the most common type of lung cancer.
Radiopharm fell two cents or 7.4 percent to 25 cents.

PYC THERAPEUTICS

PYC says the US Food and Drug Administration “concurred with [its] plans” in a pre-investigational new drug meeting for VP-001 for retinitis pigmentosa type 11.
PYC said it planned to submit the investigational new drug application this year.
PYC was untraded at 9.2 cents.

MACH7 TECHNOLOGIES

Clime Investment Management says it has reduced its substantial holding in Mach7 from 24,712,209 shares (10.45%) to 20,544,804 (8.62%).
The Sydney-based Clime said that between September 8, 2021 and March 21, 2022, it bought and sold shares at prices ranging from 71 cents to $1.04.
Mach7 was unchanged at 81 cents.

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Boston’s Life Biosciences LLC says it has reduced its substantial holding in Alterity from 269,905,533 shares (11.2%) to 243,396,873 shares (10.1%).
Life Biosciences said that between March 2 and 21, 2022 it sold American depositary shares (ADSs) at prices from 70.26 US cents (94.18 Australian cents) to 82.02 US cents ($AI.0993) per ADS share.
Each ADS is equivalent to 60 Australian shares, implying the sale was at 1.57 Australian cents to 1.83 Australian cents per Australian share.
In 2019, Prana said shareholders approved Life investing the $41.8 million for 63 percent of the company, appointing Life’s co-founders Dr David Sinclair and Tristan Edwards as directors and the name-change to Alterity Therapeutics (BD: Mar 6, Apr 5, 2019).
Alterity was unchanged at 1.9 cents with 1.9 million shares traded.

ALTHEA GROUP

The Sydney-based SG Hiscock says it has increased and been diluted in the Althea from 18,969,215 shares (6.07%) to 19,550,636 shares (5.06%).
SG Hiscock said that between March 18 and 21, 2022, it bought shares, with the single largest purchase 240,717 shares for $41,274, or 17.1 cents a share.
Althea was up half a cent or 2.5 percent to 20.5 cents.

ANTEOTECH

Anteo says chief executive officer Derek Thomson has given notice of his resignation but will serve out a six-month notice period.
Last week, Anteo said chair Dr Jack Hamilton announced his intention to retire, with non-executive director Christopher Parker promoted to executive director (BD: Mar 14, 2022).
Today, the company said Mr Thomson was appointed as its chief executive officer on July 30, 2019, and would begin a search for a new chief executive officer.
Anteo was up 0.8 cents or 8.25 percent to 10.5 cents with 12.3 million shares traded.