Biotech Daily

Tuesday September 26, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CYNATA UP 16%; KAZIA DOWN 12.5%**

*** PRO MEDICUS SIGNS $140m BAYLOR SCOTT & WHITE VISAGE DEAL**

*** SOMNOMED RETAIL OFFER RAISES $5.7m; TOTAL $15.45m**

*** CENTENARY: BLOCKMIR CD5-2 REDUCES TUMOR SIZE, IN MICE**

*** WEHI SCREENING MOLECULES TO BOOST SMCHD1 FOR FSHD**

*** NEUROTECH RECRUITS MARIJUANA NTI164 RETT SYNDROME TRIAL**

*** ACTINOGEN REDUCES XANAMEM ALZHEIMER'S TRIAL TIME, COSTS**

*** ANTISENSE ATL1102 'PARTIAL NORMAL FUNCTION' FOR LGMDR2, IN MICE**

*** MAYNE PHARMA COMPLETES $15m RHOFADE PURCHASE**

*** GERMANY APPROVES IMRICOR VISABL-VT TRIALS**

*** FDA REQUESTS BOTANIX SOFPIRONIUM BROMIDE SWEATING LEAFLET**

*** MGC 1000-TO-1 CONSOLIDATION, $12.4m RAISE EGM**

*** CARDIEX REQUESTS 'US UPDATE, CAPITAL RAISE' TRADING HALT**

*** REGAL FUNDS TAKES 23% OF OPTHEA**

MARKET REPORT

The Australian stock market fell 0.54 percent on Tuesday September 26, 2023 with the ASX200 down 38.3 points to 7,038.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and three were untraded. All three Big Caps rose.

Cynata was the best, up two cents or 16.0 percent to 14.5 cents, with 268,662 shares traded; followed by Pro Medicus up 12.4 percent to $80.01, with 360,094 shares traded. Resonance rose 11.3 percent; Actinogen, Compumedics, Pharmaxis and Polynovo were up more than five percent; Opthea was up 4.7 percent; Antisense and Resmed rose more than two percent; CSL, Immutep and Telix were up one percent or more; with Cochlear, Emvision and Volpara up by less than one percent.

Kazia led the falls, down two cents or 12.5 percent to 14 cents, with 64,950 shares traded. Cyclopharm, Dimerix and Imugene lost more than seven percent; Patrys was down 6.7 percent; 4D Medical, Alcidion, Amplia and Next Science fell more than four percent; Prescient lost 3.3 percent; Clinuvel shed 2.2 percent; Medical Developments, Mesoblast, Neuren, Orthocell, Paradigm and SDI were down more than one percent; with Avita and Nanosonics down by less than one percent.

PRO MEDICUS

Pro Medicus says it has a $140 million, 10-year deal with the Dallas, Texas-based Baylor Scott & White Health to licence its Visage 7 Enterprize Imaging platform.

Pro Medicus said its wholly-owned US subsidiary Visage Imaging Inc would licence its Visage 7 imaging platform, including its picture archive and workflow modules, to Baylor Scott & White.

The company said Visage Imaging would help complete the migration from Baylor Scott & White's previous radiology and cardiology picture archive and communication system (PACS) to the Visage 7 Open Archive and provide enterprise distribution of images integrated to its electronic health record.

Pro Medicus said planning for the rollout would begin immediately, with the software expected to be implemented by April 2024.

Pro Medicus chief executive officer Dr Sam Hupert said "the scale and scope of our initiative with Baylor Scott & White Health is noteworthy and will include nearly 500 radiologists who will be exposed to the benefits of Visage 7".

"As has been the case with many of our recent contracts, this deal is for our 'full-stack' comprising all three Visage products namely viewer, workflow and archive, a trend we see continuing," Dr Hupert said.

Pro Medicus climbed $8.82 or 12.4 percent to $80.01 with 360,094 shares traded.

SOMNOMED

Somnomed says its fully-underwritten retail entitlement offer has raised $5.7 million, taking the total raised with the institutional offer and placement to $15.45 million.

Earlier this month, Somnomed said it raised $2.75 million in placements and $7 million in an institutional rights offer at 60 cents a share (BD: Sep 4, 2023).

Today, the company said it received valid applications for about $3.06 million in shares, with the remainder allocated to sub-underwriter TDM Growth Partners Pty Ltd.

Somnomed said Wilsons Corporate Finance Ltd was lead manager, bookrunner and underwriter for the offer.

Somnomed was untraded at 58 cents.

CENTENARY INSTITUTE

Sydney's Centenary Institute says its Blockmir CD5-2 drug in combination with an anti-programmed death 1 (PD1) antibody has reduced liver tumor size, in mice.

The Centenary Institute said the use of an anti-PD1 antibody blocked a protein that hindered immune response.

Lead author of the study Dr Ken Liu said liver tumors often have "abnormal blood vessels and low oxygen levels, creating an environment that suppresses the immune system and the body's ability to fight cancer".

"Blockmir CD5-2 addresses this issue by promoting the health of tumor blood vessels through the activation of a protein called VE-Cadherin … this results in improved blood supply and oxygen levels within the tumors," Dr Liu said. "The enhanced blood vessel conditions within the tumors means that more cancer-targeting immune cells, specifically cytotoxic T-cells, can infiltrate the tumor and effectively combat the disease."

The research, titled 'Novel miRNA-based drug CD5-2 reduces liver tumor growth in diethylnitrosamine-treated mice by normalizing tumor vasculature and altering immune infiltrate' was published in Frontiers in Immunology and the full article is available at: https://www.frontiersin.org/articles/10.3389/fimmu.2023.1245708/.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it is screening drug-like molecules to boost SMCHD1 for facio-scapulo-humeral muscular dystrophy (FSHD).

WEHI said in 2008 researchers found the “silencing” gene SMCHD1 could limit the production of a toxic protein known to trigger the deterioration of healthy muscles in diseases like FSHD.

WEHI said that there were 870,000 FSHD patients globally and it was an inherited disease that was caused by the production of a toxic protein that cannot be effectively “switched off”.

The Institute said that researchers had shown how SMCHD1 switched off this protein, clarifying how the gene’s silencing capabilities could be boosted to find a treatment for the disease.

WEHI said its researchers were screening “thousands of drug-like molecules” in the search for chemicals that boost SMCHD1 activity, with promising molecules to help develop drugs to treat FSHD.

The Institute said the research rewrote “our understanding of how SMCHD1 switches off the toxic protein, clarifying how the gene’s ‘silencing’ capabilities could be boosted to find a future treatment for the condition”.

The Institute said the research with the Netherlands-based Leiden University Medical Centre titled ‘SMCHD1 has separable roles in chromatin architecture and gene silencing that could be targeted in disease’ was published in Nature Communications and was available at: https://www.nature.com/articles/s41467-023-40992-6.

WEHI laboratory head and acting deputy director Prof Marnie Blewitt said it was “invaluable to know the gene can be safely boosted in the [laboratory] after years of research flagging this possibility”.

“The less SMCHD1 people have, the worse the disease symptoms,” Prof Blewitt said.

“The next step is to figure out how to translate these milestone findings to benefit humans, by determining the best way to boost SMCHD1 and its silencing powers to hopefully find a cure for FSHD,” Prof Blewitt said.

WEHI researcher and first author of the study Andres Tapia del Fierro said that “in order to create therapeutics against SMCHD1, we need to have an in-depth understanding into how the protein works”.

“While we don’t yet know how to boost SMCHD1 function in a human context, knowing what won’t work allows us to start a process of elimination that will bring us closer to hitting the molecular jackpot,” Mr Tapia del Fierro said.

NEUROTECH INTERNATIONAL

Neurotech says it has completed recruitment of the 14 patients in its phase I/II trial of daily, oral, marijuana-based NTI164 for Rett syndrome.

Neurotech executive director Dr Thomas Duthy said that there was “a need for safer and more effective therapies that target the persistent neuro-inflammation associated with this rare neurological disorder”.

Dr Duthy said he expected trial results by April 2024.

The trial’s principal investigator Prof Carolyn Ellaway said there was “an overwhelming interest in this clinical trial from my Rett syndrome patients and their families who seek new and effective therapies to improve their clinical symptoms and quality of life”.

Neurotech was unchanged at 6.8 cents with 1.4 million shares traded.

ACTINOGEN MEDICAL

Actinogen says it will reduce dose arms and patient numbers in its phase IIb trial of Xanamem for Alzheimer's disease to reduce the cost and time to initial results.
In May, Actinogen said it had amended its 330-patient phase IIb trial of Xanamem for Alzheimer's disease and expected a delay of up to 12 months (BD: May 24, 2023).
Today, the company said the previous three-arm trial would remove its 5mg dose group, leaving a two-arm trial of 10mg Xanamem measured against the placebo, and reduce the patient cohort from 330 to 220 patients.
Actinogen said the first 100 patients would be enrolled at clinical sites in Australia instead of simultaneous international site activation as was previously intended.
Actinogen said the changes reduced trial costs significantly and increase forecast receipts from its Federal Research and Development Tax Incentive by focusing on Australian activities in the near term.
The company said it expected net savings between now and June 2025 to be around $30 million, compared to the original plan.
Actinogen said the trial would finalize Australian clinical site start up activities "as soon as possible" with patient recruitment expected before the end of the year.
Actinogen was up 0.1 cents or 5.3 percent to two cents.

ANTISENSE THERAPEUTICS

Antisense says ATL1102 partially returned calf muscle function and physiology to normal in 30 mice with limb girdle muscular dystrophy R2 (LGMDR2) or dysferlinopathy.
Last year, Antisense said a mouse study had led it to nominating limb girdle muscular dystrophy R2 (LGMDR2), or dysferlinopathy, as a target for ATL1102 (BD: Jun 20, 2022).
At that time, the company said that LGMDR2 was a rare genetic muscle disease caused by a mutation in the dysferlin gene, leading to significant reduction or absence of dysferlin protein levels in muscle fibres
Today, Antisense said the present study investigated a longer duration of treatment, 16 weeks compared to six in the previous study, in mice calf muscles with a more advanced disease.
Antisense said the study investigated the soleus and gastrocnemius calf muscles of 30 mice compared to 12 "wildtype" mice, and treatment "appeared to cause a trend towards partial normalization in the size of the gastrocnemius muscle".
The company said the function of the soleus muscle, as measured through fatigability and recovery, also showed a return towards the normal values seen in healthy animals.
Antisense said ATL1102 was currently the subject of an ongoing phase IIb clinical trial in Duchenne muscular dystrophy, and that unlike Duchenne muscular dystrophy, LGMDR2 typically presented later in life with no US Food and Drug Administration-approved therapies.
Antisense was up 0.2 cents or 2.9 percent to 7.2 cents.

MAYNE PHARMA

Mayne Pharma says it has completed its purchase of Rhofade for facial erythema and rosacea from the Durham, North Carolina-based Novan Inc and Novan's EPI Health LLC.
Earlier this month, Mayne said it bought the rights to Rhofade, or oxymetazoline hydrochloride cream for $US9.5 million ($14.76 million) (BD: Sep 4, 2023).
Today, the company said it expected to launch Rhofade in October 2023.
Mayne Pharma fell four cents or 1.2 percent to $3.38.

IMRICOR MEDICAL SYSTEMS

Imricor says Germany has approved its Visabl-VT interventional cardiac magnetic resonance (ICMR) for ventricular tachycardia ablation trial.

In August, Imricor said it had Netherlands approval for a 64-patient, safety and efficacy trial of its Vision-magnetic resonance imaging ablation catheter for ventricular tachycardia, to support its Conformité Européenne (CE) mark (BD: Aug 1, 2023).

Last week, Imricor said its Netherlands trial had been delayed due to its first patient developing a serious infection prior to the procedure (BD: Sep 20, 2023).

At that time, the company said it expected to expand the trial to begin at other sites in the Netherlands before the end of the year, with German sites expected to be added upon approval, which was then under review.

Today, the company said it had approval from Germany's Federal Institute for Drugs and Medical Devices and preparation, set-up and training would be completed at each German site before enrolling patients, with enrolment expected to begin by April 2024.

Imricor said prior to enrolling patients in Germany it planned to submit an amendment to the German regulator and ethics committees to align the German trial protocol with the protocol approved in the Netherlands.

Imricor said when the German protocol was originally submitted, its Northstar 3D mapping system was not complete and therefore was not included.

Imricor said "the amendment approval was not expected to take long".

Imricor chief executive officer Steve Wedan said "with this major approval by the German competent authority, we can expand … [the trial] to sites across Germany".

"It will take a little time to get the Northstar amendment approved, but we have been told that it is a much faster process, and we will begin site preparation in parallel," Mr Wedan said. "In the end, we believe that including Siemens sites with Northstar in Germany will allow the trial to be completed faster."

"Meanwhile, two potential [ventricular tachycardia] patients are being screened at Haga Hospital this week, and we look forward to performing the world's first [ventricular tachycardia] ablation guided by real-time ICMR soon".

Imricor fell seven cents or 11.1 percent to 56 cents.

BOTANIX PHARMACEUTICALS

Botanix says the US Food and Drug Administration has denied its new drug application of sofpironium bromide for excessive sweating, requesting printed instruction changes.

Botanix said the only areas to be addressed in the FDA's complete response letter were edits to the printed "instructions for use" document and "minor wording on the product carton, followed by another short human factors validation study before the [new drug application] can be resubmitted."

The company said the FDA raised "no clinical efficacy, safety, pharmacology, non-clinical or manufacturing issues" and that no additional studies were required for approval.

Botanix said it would meet with the FDA, implement the "relatively minor" changes and hoped to resubmit the application by April 2024, with approval by "mid-2024".

Botanix said that since the commercial launch of sofpironium bromide was previously planned for March 2024, the resubmission and approval timing would delay its plans by "only three to six months".

Botanix chair Vince Ippolito said "we are now clear on what is required by the FDA, and it is our goal to work with FDA to address their comments on the patient instructions, so that we can resubmit for approval as rapidly as possible".

Botanix fell four cents or 22.2 percent to 14 cents with 37.6 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMA

MGC says an extraordinary general meeting will vote for a 1,000-to-one consolidation of its shares and options and to issue 31,000,000 post-consolidation shares.
According to its most recent filing, MGC had 4,314,968,187 shares on issue, which would become 4,314,968 post-consolidation shares.
The company said it would not raise more than $12,400,000.
A letter to shareholders from MGC managing-director Roby Zomer said that the company "finds itself at a critical financial juncture".
"The company's share price has failed to appreciate and underwhelming fundraising efforts during the year have not provided the company with the medium to long term financial stability required," Mr Zomer said.
"Regrettably, due to market conditions, we have faced extreme difficulties in raising funds in the UK primarily, and in Australia," Mr Zomer said.
Mr Zomer said the financial and capital restructuring would "bring greater stability and re-position the company to be more attractive for institutional support".
"We understand this restructure will be difficult for many shareholders … [but it is] a necessary action," Mr Zomer said, but the letter did not specify details of "the restructure".
The meeting will be held at Suite 1, 295 Rokeby Road, Subiaco, Perth, Western Australia on October 25, 2023 at 4pm (AWST).
In 2021, MGC said it opened on the London Stock Exchange following a GBP6.5 million ($A11.6 million) 'oversubscribed' placement at 1.475 British pence (BD: Feb 4, 10, 2021).
In London last night, the company closed at 0.11 pence or GBP1.10 post-consolidation.
On the ASX, MGC rose 0.05 cents or 25 percent to 0.25 cents ($2.50 post-consolidation).

CARDIEX

Cardiex has requested a trading halt pending an announcement related to a corporate update a US regulatory filing and capital raising activities.
Last month, Cardiex said it would offer 1,333,333 American depositary shares, equivalent to 100,000,000 Australian shares to list on the Nasdaq and it had updated its registration statement with the US Securities and Exchange Commission (BD: Aug 31, 2023).
Trading will resume on September 28, 2023 or on an earlier announcement.
Cardiex last traded at 13.5 cents.

OPTHEA

Regal Funds Management Pty Ltd says it has increased its holding in Opthea from the equivalent of 96,368,923 shares (20.63%) to 152,169,776 shares (22.96%).
Sydney's Regal Funds said it traded Australian shares and American depository shares (ADSs), between June 30 and September 21, 2023, with the single largest purchase 36,248,358 Australian shares on September 4 for $16,674,245, or 46 cents a share.
In August, Opthea said it raised $20.0 million in a placement and expected to raise $70.0 million in a rights offer at 46 cents a share (BD: Aug 24, 28, 2023).
Regal Funds said it currently held 129,001,880 Australian shares (19.46%) and 2,895,987 ADSs (3.50%), with each ADS equivalent to eight Australian shares.
Opthea was up 1.5 cents or 4.7 percent to 33.5 cents.