Biotech Daily

Thursday July 7, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMUGENE UP 9%; EMVISION DOWN 5%**

*** CYCLOPHARM TECHNEGAS 'PREFERRED' FOR COVID IMAGING**

*** ARGENICA ARG-007 SAFETY STUDY: ALLERGIC REACTION 'UNLIKELY'**

*** KAZIA: US FDA GRANTS PAXALISIB RARE PAEDIATRIC DISEASE STATUS**

*** BOTANIX EXPEDITES US SOFPIRONIUM BROMIDE NDA; 2 TRIALS ENROLED**

*** RESAPP, MEDGATE EXTEND RESAPPDX DEAL 12 MONTHS**

*** EURO PATENT FOR IMMURON CLOSTRIDIOIDES DIFICILE DRUG**

*** CRESO APPOINTS GOTRO SINGAPORE DISTRIBUTOR**

*** FIREBRICK REQUESTS 'TGA APPEAL OUTCOME' TRADING HALT**

*** NEUROTECH EXTENDS VOLUNTARY SUSPENSION**

MARKET REPORT

The Australian stock market was up 0.81 percent on Thursday July 7, 2022, with the ASX200 up 53.5 points to 6,648.0 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 13 fell and five traded unchanged.

Imugene was the best, up two cents or 9.1 percent to 24 cents, with 29.25 million shares traded.

Oncosil climbed 8.3 percent; Micro-X was up 6.45 percent; Neuren and Patrys improved more than four percent; Compumedics, Polynovo and Telix were up more than three percent; Avita, Mesoblast, Nova Eye, Pharmaxis and Resonance rose more than two percent; Amplia, Antisense, Atomo, Clinuvel, Immutep, Opthea and Orthocell were up more than one percent; with CSL, Kazia and Volpara up by less than one percent.

Emvision led the falls, down 10 cents or 5.4 percent to $1.75, with 11,823 shares traded; followed by Cynata down 5.3 percent to 36 cents, with 6,530 shares traded.

Alcidion, Dimerix and Impedimed lost more than three percent; Actinogen and Genetic Signatures shed more than two percent; Medical Developments, Nanosonics, Next Science, Resmed, Starpharma and Universal Biosensors were down more than one percent; with Cochlear and Pro Medicus down by less than one percent.

CYCLOPHARM

Cyclopharm says an independent 183-patient study has shown its Technegas technology plays a key role in identifying pulmonary embolism in Covid-19 patients.

Cyclopharm said the study was a collaboration between the French Society of Nuclear Medicine and French clinicians, and showed that Technegas ventilation imaging was used ahead of competitive products for diagnosing pulmonary embolism in Covid-19 patients in 92 percent of the cases evaluated.

The study, titled 'Lung Scintigraphy for Pulmonary Embolism Diagnosis in Covid-19 Patients: A Multicenter Study,' was published in the United States Journal of Nuclear Medicine and was available at: https://jnm.snmjournals.org/content/63/7/1070.

Cyclopharm managing-director James McBrayer said the independent study supported "the importance of Technegas in the diagnosis of [pulmonary embolism] in patients suffering from Covid and highlights the further potential use in this growing patient population".

"Independent, highly credible published studies such as these are playing a key role in the growing demand for Technegas, as clinicians seek to utilize its benefits in managing the impacts of their patients' Covid-19 infections," Mr McBrayer said.

"This study combined with the recent Long Covid study by McMaster University emphasizes the clinical significance of Technegas and its growth potential across the 63 countries in which the product is available," Mr McBrayer said.

"It also underscores the tangible potential of our Beyond PE [pulmonary embolism] initiatives in the diagnosis and patient management into indications such as Long Covid, [chronic obstructive pulmonary disorder], asthma and lung cancer," Mr McBrayer said.

Cyclopharm was unchanged at $1.40.

ARGENICA THERAPEUTICS

Argenica says that an in-vitro safety study of ARG-007 in ex vivo-derived mast cell cultures has shown it is unlikely to cause allergic reaction if administered to patients.

Argenica said the study showed that over a wide range of concentrations from 0.125 µM (micromolar or micromoles/litre) to 16µM, ARG-007 did "not cause any significant degranulation of ex-vivo derived in-vitro cultured naïve or IgE [immunoglobulin E] sensitized human mast cells".

The company said the results also showed the ARG-007 induced only low levels of red blood cell haemolysis, or rupture, and only when exposed to the cells without plasma at 16µM.

Argenica said that the research article, titled 'Assessment of the safety of the cationic arginine-rich peptides (CARPs) poly-arginine-18 (R18 and R18D) in ex-vivo models of mast cell degranulation and red blood cell hemolysis' was published in the Journal of Biochemistry and Biophysics Reports and the full article was available at: https://www.sciencedirect.com/science/article/pii/S2405580822001054?via%3Dihub.

The company said the study was conducted by Argenica chief scientific officer Prof Bruno Meloni and collaborators at Perth's Perron Institute for Neurological and Translational Sciences, the University of Western Australia, and the University of South Australia.

Argenica managing-director, Dr Liz Dallimore said the company was "delighted that this pre-clinical research into important safety aspects of ARG-007 has been recognized by the Journal of Biochemistry and Biophysics Reports."

"It is a testament to the scientific rigor employed by [chief scientific officer] Prof Meloni and his team of collaborators," Dr Dallimore said.

Argenica fell four cents or 8.3 percent to 44 cents.

KAZIA THERAPEUTICS

Kazia says the US Food and Drug Administration has awarded rare paediatric disease designation to paxalisib for atypical rhabdoid-teratoid tumors.

In June, Kazia said the FDA has granted orphan drug designation to paxalisib for the paediatric brain cancer atypical rhabdoid-teratoid tumors (BD: Jun 16, 2022).

Today, Kazia said the rare paediatric disease designation might entitle it to receive a paediatric priority review voucher if the drug was approved for atypical rhabdoid-teratoid tumors, which would grant it an expedited six-month review of a new drug application.

The company said paediatric priority review vouchers were also tradeable, and had "historically commanded prices in excess of $US100 million" ($A147 million).

Kazia chief executive officer Dr James Garner said "this is the second time that paxalisib has been granted [rare paediatric disease designation], and it demonstrates the importance of childhood brain cancer in the overall paxalisib development program".

"Brain cancer is the most common cause of cancer death in children and outcomes in many forms of childhood brain cancer have not improved in decades," Dr Garner said.

"We very much hope that paxalisib can make a difference to families affected by both [diffuse intrinsic pontine glioma and atypical rhabdoid-teratoid tumors], and we will be working closely with clinicians, researchers and [the] FDA to determine the optimal way to move the drug forward," Dr Garner said.

Kazia was up half a cent or 0.8 percent to 62.5 cents.

BOTANIX PHARMACEUTICALS

Botanix says it expects to file its US regulatory application for sofpironium bromide for excessive underarm sweating and complete two trials by October 2022.

Botanix said it had accelerated its new drug application to the US Food and Drug Administration for sofpironium bromide gel 15 percent for primary axillary hyperhidrosis, or excessive underarm sweating, and would be ready to file the application by October.

The company said that as a result of the acceleration of the regulatory timeline, it would commence FDA pre-approval activities and had begun preparing for commercial launch post-FDA approval.

Botanix said both its phase I/II study of its synthetic cannabidiol BTX1702 for rosacea and its pilot study of its synthetic cannabidiol BTX1204A for canine dermatitis were fully enrolled and on track for completion in by October 2022, with subjects due to begin treatment in the coming weeks (BD: Mar 30; Sep 29, 2021).

Botanix was up half a cent or 8.5 percent to 6.4 cents with 1.9 million shares traded.

RESAPP HEALTH

Resapp says the Basel, Switzerland-based Medgate AG will use its Resappdx smartphone respiratory diagnostic on its telehealth platform for a further 12 months.

In August, Resapp said it had licenced its Resappdx smart-phone respiratory diagnostic to Medgate for tele-health in Europe and the Philippines, and to Alodokter for Indonesia (BD: Aug 4, 2021).

Today, the company said that it had extended its agreement with Medgate to take the Resappdx to Germany in 2023.

Resapp managing-director Dr Tony Keating said Medgate was "a long-standing, global leader in telehealth [and the agreement was] further strong endorsement of the value of Resappdx to patients, clinicians and telehealth providers".

Resapp was unchanged at 13 cents with 15.9 million shares traded.

IMMURON

Immuron says the Europe Patent Office intends to grant a patent relating to the treatment and prophylaxis of Clostridioides difficile associated disease.
Immuron said the patent was titled 'Methods and Compositions for the treatment and/or prophylaxis of Clostridium difficile associated disease" and would provide intellectual property protection until 2034.
Immuron was up 0.7 cents or 8.75 percent to 8.7 cents.

CRESO PHARMA

Creso says Singapore's Gotro Global will market its Sierra Sage Herbs animal healthcare products in Singapore.
Creso said that under a non-binding, non-exclusive heads of agreement Gotro agreed to enter and progress a collaborative agreement by August 31, 2022, with both parties able to extend this timeframe by mutual agreement.
The company said the agreement would set out terms relating to Gotro's distribution of Sierra Sage Herbs products in Singapore, as well as further commercialization options for current and future products.
Creso was up 0.2 cents or 5.1 percent to 4.1 cents with 2.5 million shares traded.

FIREBRICK PHARMA

Firebrick has requested a trading halt "pending an announcement about the outcome of the appeal filed against the TGA's initial decision not to approve Nasodine nasal spray".
In March, Firebrick said it would appeal the Australian Therapeutic Goods Administration initial decision not to approve Nasodine nasal spray, based on the existing clinical data (BD: Mar 1, 2022).
At that time, Firebrick executive chair Dr Peter Molloy said that "Nasodine is clearly safe and has met all of the TGA's stringent quality and manufacturing requirements, with the TGA delegate's residual concern being whether there is sufficient proof of clinical efficacy as a treatment for the common cold".
Trading will resume on July 11, 2022.
Firebrick last traded at 26 cents.

NEUROTECH INTERNATIONAL

Neurotech has requested an extension to its voluntary suspension pending results from a phase I/II trial of its marijuana for paediatric autism spectrum disorder.
Yesterday, Neurotech requested a suspension to follow the trading halt requested on July 4, 2022 "pending an announcement regarding the results of its Phase I/II clinical study of the NTI164 strain in paediatric autism spectrum disorder" (BD: Jul 4, 6, 2022). Today, the company said that the suspension would continue until the start of trading on July 8, 2022, or on the release of an announcement.
Neurotech last traded at 7.5 cents.