Biotech Daily

Tuesday February 21, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: VOLPARA UP 4%; RESONANCE DOWN 12%**

*** CSL HEMGENIX WINS EU OK FOR HAEMOPHILIA B**

*** GLYTHERIX HOPES FOR $14.5m FOR RADIO-PHARMACEUTICALS**

*** EMVISION COMPLETES BRAIN SCANNER TRIAL ENROLMENT**

*** FIREBRICK FILES EU NASODINE NASAL SPRAY PAEDIATRIC PLAN**

*** COGSTATE REQUESTS 'ASX PRICE QUERY' TRADING HALT**

*** UNIVERSAL BIOSENSORS LAUNCHES 5th SENTIA WINE TEST**

MARKET REPORT

The Australian stock market fell 0.21 percent on Tuesday February 21, 2023, with the ASX200 down 15.2 points to 7,336.3 points.

Ten of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and four were untraded.

Volpara was the best, up three cents or four percent to 78.5 cents, with 399,525 shares traded.

Actinogen, Immutep, Mesoblast, Polynovo and Telix improved two percent or more; Clinuvel and Opthea climbed more than one percent; with CSL, Emvision and Pro Medicus up by less than one percent.

Resonance led the falls, down 0.7 cents or 11.7 percent to 5.3 cents, with 424,798 shares traded.

Alcidion and Cynata lost more than six percent; Prescient retreated five percent; Dimerix and Impedimed fell four percent or more; Atomo, Genetic Signatures, Kazia, Proteomics and Universal Biosensors were down more than three percent; Nova Eye shed 2.1 percent; Avita, Neuren and Paradigm were down one percent or more; with Cochlear, Nanosonics, Next Science, Resmed and Starpharma down by less than one percent.

CSL

CSL says it the European Commission has approved Hemgenix single infusion gene therapy for treating haemophilia B in adults without a history of factor IX inhibitors.
CSL said European approval for Hemgenix for severe and moderately severe haemophilia B followed approval by the US Food and Drug Administration on November 22, 2022.
Last year, CSL said it had a “positive opinion” from the European Medicines Agency for Hemgenix, or etranacogene dezaparvovec, for haemophilia B (BD: Dec 19, 2022).
At that time, the company told Biotech Daily the list price of Hemgenix in the US would be $US3.5 million a course, but no decision had been made on European pricing.
Today, CSL said that, separately, the phase III trial of garadacimab (CSL312), a monoclonal antibody for hereditary angioedema attacks showed, that a monthly sub-cutaneous injection “significantly reduced the attack rate compared to placebo”.
CSL said it would proceed with regulatory submissions to health authorities later this year for full approval of garadacimab.
CSL was up four cents or 0.01 percent to $298.44 with 542,445 shares traded.

GLYTHERIX

Glytherix says it hopes to raise $US10 million ($A14.5 million) in Australia ahead of a potential stock-market listing for radio-pharmaceutical diagnostics and therapeutics.
The Sydney based company said the funds would be used to complete a phase Ib study of its Miltuximab antibody.
Glytherix chief executive officer Dr Brad Walsh said the company would most likely list on the ASX, but the Nasdaq was also an option.
The company said that it had begun engaging with advisors for the initial public offer but had not mandated any and welcomed approaches from interested parties.
Glytherix said it had demerged from Minomic International in 2017 and raised $15 million, as well as receiving $3 million from a government grant, and had about 200 shareholders.
Dr Walsh said that Glytherix was “unencumbered by licencing deal obligations given that it owns Miltuximab outright”, but had partnerships with Adelaide’s Carina Biotech, Imagion, China contract research organization Wuxi Biologics, Piscataway, New Jersey’s Genscript Probio and Copenhagen’s Adcendo ApS.
Dr Walsh said Glytherix aimed “to identify multiple potential indications with orphan designations and clinical unmet need”.
Glytherix said it had a lutetium-177 supply agreement with the Australian Nuclear Science and Technology Organisation (ANSTO) for its phase Ib therapeutic trial in patients with prostate, pancreatic and bladder cancers, expected to start in late 2023.
The company said that the lutetium-177 isotope would be used with its Miltuximab antibody targeting tumors expressing Glypican-1 in a phase Ib imaging and therapeutic dose escalation trial.
Glytherix said that Glypican-1 was expressed in a number of aggressive and invasive cancers including prostate, pancreatic, bladder, lung, glioblastoma and ovarian cancer.
The company said that an antibody labelled with 89-zirconium would be used as an imaging agent to select patients showing tumor targeting, followed by a therapeutic dose of 177-Lu-Miltuximab being offered to qualifying patients.
“Lutetium has shown good anti-cancer efficacy with other molecular targeted therapies and we are confident this will be the case with Miltuximab,” Dr Walsh said.
Glytherix said it had completed a first-in-human trial of 12 patients with advanced prostate, bladder and pancreatic cancer using Miltuximab, with no drug-related adverse events.
Glytherix is a public unlisted company.

EMVISION MEDICAL DEVICES

Emvision says it has scanned all 30 participants in its stage one, healthy volunteer trial of its first-generation portable brain scanner at Sydney's Liverpool hospital.

Emvision said "early indications from an engineering review of an initial cohort are promising, with high quality signals, that are stable and consistent, having been obtained from the Emvision [first generation] scanner for the healthy baseline scans".

The company said the hardware was "performing as designed" and along with magnetic resonance imaging the participant data would be used to advance its artificial intelligence algorithms and other imaging techniques.

Emvision said the second stage of the trial would enroll up-to 150 acute stroke and stroke mimic patients at comprehensive stroke centres including Liverpool Hospital, Royal Melbourne Hospital and Brisbane's Princess Alexandra Hospital.

Last year, the company said it had begun trial enrolment, with endpoints of verification, safety and data to "enhance artificial intelligence algorithms" (BD: Nov 30, 2022).

Emvision chief executive officer Dr Ron Weinberger told Biotech Daily that stroke mimics were non-vascular conditions which presented with similar neurological deficits.

"Interestingly mimics account for almost half of hospital admissions for suspected stroke," Dr Weinberger said.

In the media release to the ASX, Dr Weinberger said the stage one scanning was "an encouraging start".

"Having highly reproducible inputs to our algorithms is a critical first step and a key aim of this phase," Dr Weinberger said.

"We are excited to shortly move our potentially game-changing technology into the emergency department environment to begin generating valuable acute stroke and stroke mimic data," Dr Weinberger said.

Emvision was up one cent or 0.7 percent to $1.485.

FIREBRICK PHARMA

Firebrick says it has filed a paediatric investigation plan to the European Medicines Agency for its Betadine-based anti-viral Nasodine nasal spray for the common cold.

Firebrick said the paediatric investigation plan was to ensure the data supported the use of Nasodine in children aged six-to-11 years and was a step towards filing a European marketing authorization application (MAA).

Firebrick executive chair Dr Peter Molloy said the paediatric investigation plan could take up to nine months to be accepted by the EMA paediatric committee "so filing it at this time was critical to achieving our planned filing of the Nasodine MAA later this year, after we have the results of our second pivotal common cold trial in adults".

"As every parent knows, children suffer a much higher frequency of colds than adults and often pass on the infection to other family members," Dr Molloy said.

Dr Molloy said approval "would be a boon for parents", expanding the addressable market.

Firebrick said that the paediatric investigation plan proposed the trials focused on safety and compliance only "because efficacy as a treatment for the common cold can be extrapolated from the results of the adult phase III trials, the second of which is expected to be completed this year".

Last year, Firebrick said it had recruited 224 of up-to 450 adults in its confirmatory phase III trial for Nasodine nasal spray for the common cold, but would pause until March 2023 for the Southern Hemisphere Summer (BD: May 3, Nov 1, 2022),

Firebrick fell 2.5 cents or 11.6 percent to 19 cents.

COGSTATE

Cogstate has requested a trading halt to respond to an ASX letter sent February 21, 2023 “in regard to a price query”.
Trading will resume on February 23, 2023 or on an earlier announcement.
Cogstate last traded down 27.5 cents or 14.5 percent to $1.625 with 2.3 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has launched its acetic acid biosensor test, the fifth test on the Sentia wine testing platform.
The company said that acidity in wine was an important component of quality and taste but “high levels of acetic acid in wine [was] considered a highly undesirable fault”.
Universal Biosensors said that levels of acetic acid were tested throughout the year, with the timing of the launch of the test “ideal for the upcoming fermentation and maturation period for wineries in the northern hemisphere”.
Universal Biosensors chief executive officer John Sharman said the launch was “another milestone for the Sentia platform”.
“We have two more Sentia products in development being a titratable acidity test and our next generation free sulphur dioxide test, which will be a significant enhancement for the very good free sulphur dioxide product already in market,” Mr Sharman said.
“Both products are scheduled for launch within the next two months,” Mr Sharman said.
Universal Biosensors fell one cent or 3.2 percent to 30.5 cents.