Biotech Daily

Tuesday March 15, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CLINUVEL UP 7%; MICRO-X DOWN 7.5%**

*** CLINUVEL: AFAMELANOTIDE 'SAFE FOR STROKE', POSITIVE DATA**

*** VICTORIA, INTERVENN, ST VINCENT'S EARLY CANCER DETECTION**

*** WEAROPTIMO 'MULTI-MILLION DOLLAR HYDRATION DEAL WITH ASPEN'**

*** IMUGENE TO TRIAL HER-VAXX, KEYTRUDA FOR GASTRIC CANCER**

*** RESPIRI: WHEEZO FOR PAID MICHIGAN CHILDREN'S PROGRAM**

*** CANN GROUP: MILDURA FACILITY 'PRACTICAL COMPLETION'**

*** OPTHEA: 100% DIRECTORS PAY HIKE, 2m DIRECTORS OPTIONS EGM**

*** PHARMAUST MANUFACTURES MONEPANTEL FOR TRIALS**

*** RADIOPHARM APPOINTS BILL REGAN REGULATORY STRATEGY HEAD**

MARKET REPORT

The Australian stock market fell 0.73 percent on Tuesday March 15, 2022, with the ASX200 down 52.0 points to 7,097.4 points. Nine of the Biotech Daily Top 40 stocks were up, 23 fell, seven traded unchanged and one was untraded. All three Big Caps were up.

Clinuvel was the best, up $1.30 or 6.8 percent to $20.53, with 172,944 shares traded.

Cochlear, Cyclopharm, Genetic Signatures, Opthea, Orthocell, Polynovo, Resmed and Volpara climbed one percent or more; with CSL, Nanosonics and Pro Medicus up by less than one percent.

Yesterday's 25 percent best, Micro-X led the falls, down 1.5 cents or 7.5 percent to 18.5 cents, with 199,838 shares traded, followed by Antisense down 7.4 percent to 12.5 cents, with 867,115 shares traded.

Avita and Proteomics lost six percent or more; Actinogen and Alcidion were down more than five percent; Medical Developments, Patrys and Universal Biosensors fell more than four percent; Prescient and Resonance were down more than three percent; Imugene, Neuren, Nova Eye, Oncosil and Paradigm shed two percent or more; Compumedics, Cynata, Next Science, Starpharma, Telix and Uscom were down one percent or more; with Emvision down by 0.8 percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says five of six stroke patients in its pilot study evaluating 16mg afamelanotide had improved neurological functions, with no adverse drug reactions in all six patients.
Clinuvel said the trial was conducted by the stroke unit of Melbourne's Alfred Hospital, focused on the safety of multiple implanted afamelanotide doses over eight days and subsequent recovery after 42 days in patients with arterial ischaemic stroke who were ineligible to receive standard treatment of clot removal and/or dissolution.
In 2019, the US Food and Drug Administration approved implanted Scenesse, or 16mg afamelanotide, for the prevention of phototoxic skin reactions in patients with the rare light intolerance disorder erythropoietic protoporphyria (BD: Oct 9, 2019).
In January, Clinuvel said it had dosed all six patients in its phase II afamelanotide for arterial ischaemic stroke study, with no adverse reactions (BD: Jan 17, 2022).
Today, the company said that four patients were administered two doses of afamelanotide, on day-0 and day-1, "since the treating physicians judged that these patients had already recovered well", while the other two patients were administered the remaining doses on day-7 and day-8.
Clinuvel said that the trial used the National Institutes of Health Stroke Scale and brain imagining to assess patient recovery and that by day-8 "five of the six stroke patients showed neurological improvement and strong degree of functional recovery".
Clinuvel said that five of the six patients showed a "clinically meaningful improvement … at day-8" and were assessed as "mild to symptom-free by day-8".
The company said one patient died following a second stroke on day five, but the study safety committee assessed this as "unrelated to the administration of afamelanotide".
Clinuvel head of clinical operations Dr Pilar Bilbao said the trial was "the first time that a melanocortin has been administered to stroke patients".
"No adverse drug reactions were reported and a meaningful improvement was seen in five of the six patients' health by day-8," Dr Bilbao said.
Clinuvel was up $1.30 or 6.8 percent to $20.53 with 172,944 shares traded.

VICTORIA GOVERNMENT

The Victoria Government says Intervenn is developing an artificial intelligence platform to detect cancer and will establish a laboratory at Melbourne's St Vincent's Hospital.
A media release from the Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said that the South San Francisco-based Intervenn Biosciences would establish a commercial and research laboratory at the Hospital.
Ms Pulford said in partnership with mRNA Victoria, Intervenn would work with local RNA researchers on developing new therapeutics for cancer detection using RNA markers.
The State Government said that Intervenn's platform identified "patient-specific cancer biomarkers and then uses those to develop liquid biopsy tests to both detect cancer and determine how well each patient will respond to available treatments".
The media release said that it was hoped the non-invasive precision medicine would find new ways to treat ovarian, pancreatic, liver, prostate and kidney cancer.
The Government said Intervenn had two offices in Asia and had raised $US201 million for a blood test to match cancer patients to immune-oncology therapies.
The Government said that Intervenn's presence in Melbourne would provide an opportunity for the company to partner with universities and local research institutes to develop RNA products and support clinical trials.
Intervenn chief operating officer Erwin Estigarribia said the partnership with the Victorian Government would "bring glycol-proteomics to researchers and physicians".

WEAROPTIMO

Brisbane's Wearoptimo says it has a "multi-million-dollar strategic deal" with Canberra's Aspen Medical to develop a wearable dehydration sensor.

Wearoptimo founder and chief executive officer Prof Mark Kendall told Biotech Daily that the agreement was "multi-layered" and included development of the sensor and then distribution and commercialization of the product.

In a media release, the company said that its "first product [was] a micro-wearable sensor that detects and alerts an individual to dehydration risk", which needed to be refined and tested across industries including the military, mining and resource sectors.

Wearoptimo said the Aspen deal consisted of an initial funding round, and an agreement for development, trials, refinement, commercialization and distribution of the sensors.

Prof Kendall said the investment was "a significant commercial partnership and major step in Wearoptimo's journey to accelerate the development of its product launch and gain access to key markets".

Wearoptimo said that "investment opportunities remain open to investors with aligned interests in healthcare technology that revolutionizes the future of health science and market delivery".

Aspen executive chair Glenn Keys said that Wearoptimo's hydration micro-wearable sensor was "exciting … as this is an important issue for several of our clients who are focused on ensuring safety and optimal performance of their employees".

Wearoptimo said it was incorporated in 2018, as part of the Australian National University's innovation program and ANU vice-chancellor Prof Brian Schmidt said the partnership with Wearoptimo was "an example of how universities and private companies can deliver the innovation our nation needs; taking ideas from the lab to the wider world".

Wearoptimo is a private company.

IMUGENE

Imugene says it will conduct a phase II trial to evaluate its HER-Vaxx with Merck &Co Inc's pembrolizumab, or Keytruda, in patients with HER-2 positive gastric cancer.

Imugene said the open-label, signal-generating trial was designed to assess the safety and efficacy of HER-Vaxx with chemotherapy or the anti-programmed death-1 (PD-1) pembrolizumab in patients with metastatic human epidermal receptor-2 (HER-2)-Neu over-expressing gastric or gastro-oesophageal junction adeno-carcinomas who had progressed on trastuzumab.

The company said the primary endpoints were safety and response rate, with secondary endpoints including duration of response, progression free survival, overall survival, and biomarker evaluation.

Imugene said it would sponsor the study and fund it from its existing budget, while the Kenilworth, New Jersey-based Merck & Co would provide Keytruda for the study.

Last year, Imugene said the US Food and Drug Administration had approved a 30-patient phase II, HER-Vaxx trial for HER-2 positive gastric cancer (BD: Dec 13, 2021).

Today, Imugene managing-director Leslie Chong said HER-Vaxx had "shown a tolerable safety profile and encouraging efficacy in patients with metastatic HER-2 positive gastric cancer and [the] collaboration with [Merck] is significant for our company as it provides the opportunity to optimize and enhance our formulations and utility in an additional setting in an effort to improve outcomes for more patients".

The company said that the study was expected to run for at least 24 months.

Imugene fell half a cent or two percent to 24.5 cents with 27.2 million shares traded.

RESPIRI (FORMERLY KARMELSONIX, ISONEA)

Respiri says Detroit's Children's Hospital of Michigan will include its Wheezo asthma management device in a pilot remote patient monitoring program for children.

Respiri said that the program was secured with its partner, the Coral Springs, Florida-based Access Telehealth, and would provide the remote patient monitoring program for a group of children living with asthma to reduce exacerbations and hospitalizations, improve patient outcomes and reduce healthcare costs.

The company said the Wheezo devices would be supplied and paid for by Access Telehealth with the US Federal and state Medicaid program reimbursing the monthly data fees associated with software as a service.

In February, Respiri said it had a second, five-year, non-exclusive distribution and marketing agreement with Access Telehealth for the US but was "unable to reliably quantify the future revenue potential through this agreement by way of device sales and subscription revenues" (BD: Feb 7, 2022).

Today, the company said that the Children's Hospital of Michigan had "extensive asthma outpatient services" and that the program would include Wheezo devices as a standard in remote patient monitoring for children with asthma.

Respiri managing director Marjan Mikel said the company was "very excited about this important [remote patient monitoring] collaboration with the Children's Hospital and Access Telehealth, as it demonstrates that there is a strong acceptance of Wheezo as part of asthma management".

"This partnership continues to demonstrate that we are executing on our US strategy as planned and our progress is well ahead of where we had planned to be at this stage of our commercialization journey," Mr Mikel said.

Respiri, and previously Isonea and Karmelsonix, has been attempting to commercialize its wheeze test for asthma since 2006, saying it would be available in Europe and the US in February 2007 (BD: Nov 24, 2006).

Respiri fell 0.3 cents or 5.45 percent to 5.2 cents.

CANN GROUP

Cann Group says its Mildura marijuana production facility has reached "practical completion" with the Federal Office of Drug Control allowing commercial growing to begin.

Cann Group said that final fit-out and commissioning would continue in some areas of the facility but that the site had been "handed over by the principal builder … and an occupancy certificate has been issued".

The company said that the Office of Drug Control granted them a permit which allowed the cultivation and production of medicinal marijuana, as well as research activities in relation to medicinal marijuana.

Cann Group said that a separate permit covering the manufacture of medicinal marijuana products at the Mildura, Victoria facility expected to be issued "in the near future".

Cann Group said that the facility included automated climate control to balance temperature, airflow and humidity, a mobile table system to ensure plants were in the best position for growth, lighting technology, an automated screening system to maximize crop cycles, energy savings and plant protection, and a multiple-stage water filtration, irrigation and nutrient delivery system.

Cann Group was up two cents or 8.7 percent to 25 cents with 2.8 million shares traded.

OPTHEA

Opthea says investors will vote to double the directors' remuneration pool to $1,000,000 and grant Dr Susan Orr and Quinton Oswald 1,000,000 options each.
Opthea said that it proposed to appoint Dr Orr and Mr Oswald as directors and their options would be exercisable at the five-day volume weighted average price to the grant date, and within four years, vesting in four equal tranches from the grant date and over the subsequent three years.
The company said that the extraordinary general meeting would vote to increase the aggregate maximum of remuneration of non-executive directors from $500,000 to $1,000,000 to "accommodate the appointment of additional directors brining expertise to the board necessary for the current stage of its development".
Opthea said it would vote to elect Dr Orr and Mr Oswald as directors and amend its constitution to hold virtual meetings "as a health measure and for administrative convenience".
Opthea said the extraordinary general meeting would be held virtually on April 21, 2022 at 9am (AEST) and would be: https://meetnow.global/MMLM9N9.
Opthea was up 1.5 cents or 1.8 percent to 84.5 cents with 1.4 million shares traded.

PHARMAUST

Pharmaust says it has completed manufacture of current good manufacturing practice-grade monepantel for its motor neuron disease and Covid-19 clinical trials.
Pharmaust said that it had shipped monepantel to the US and tableting was underway in San Diego.
The company said that completion of manufacturing would allow it to begin the motor neuron disease trial in May, as well as the Covid-19 trials.
Pharmaust chief scientific officer Dr Richard Mollard said that "now we have a defined process for producing scalable [good manufacturing practice] material, Pharmaust will commence planning a further manufacturing round to supply monepantel for cancer and other trials in humans".
Pharmaust was up 0.4 cents or 4.3 percent to 9.8 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it appointed Bill Regan as the head of regulatory strategy, effective from March 1, 2022.
Radiopharm said that Mr Regan had 40 years of experience in compliance, quality manufacturing, change control and regulatory affairs in the pharmaceutical and biotechnology industry and was most recently the chief compliance officer at Dublin, Ohio's Navidea Biopharmaceuticals.
The company said that previously Mr Regan was the principal of Regan Advisory Services, Global Regulatory Advisory Services and was Bristol Myers Squibb Medical Imaging head of regulatory affairs.
Radiopharm was unchanged at 28.5 cents.