Biotech Daily

Wednesday September 4, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: USCOM UP 14%; AMPLIA DOWN 9%**

*** CYNATA: 'MSCs REDUCE ORGAN TRANSPLANT REJECTION IN MICE'**

*** US FDA LIFTS IDT WARNING LETTER**

*** ORTHOCELL: 8 OF 9 ROTATOR CUFF PATIENTS PAIN-FREE**

*** IMMURON: 'TRAVELAN BINDS TO 71 CHOLERA STRAINS'**

*** CLARITY FDA IND FOR COPPER SARTATE NEUROBLASTOMA TRIAL**

*** ADALTA: I-BODY HALF-LIFE CAN BE CUSTOMIZED**

*** RESPIRI LAUNCHES WHEEZO ASTHMA DIARY**

*** MITSUBISHI TAKES 5% OF TOTAL BRAIN**

*** BTC: SHARON PAPWORTH CFO, CO SEC; STUART JONES CORP DEV**

MARKET REPORT

The Australian stock market fell 0.31 percent on Wednesday September 4, 2019, with the ASX200 down 20.4 points to 6,553.0 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and one was untraded. All three Big Caps fell.

Uscom was the best, up 1.5 cents or 13.6 percent to 12.5 cents, with 150,000 shares traded, followed by Avita up 12.0 percent to 51.5 cents with 13.7 million shares traded. Alterity climbed 7.1 percent; Volpara improved 5.4 percent; Immutep and Medical Developments were up more than four percent; Cynata and Pharmaxis rose more than two percent; Oncosil, Orthocell and Paradigm were up more than one percent; with Ellex up 0.9 percent.

Amplia led the falls, down 0.8 cents or 8.7 percent to 8.4 cents, with 35,984 shares traded. Kazia lost 6.7 percent; Polynovo was down 5.3 percent; Clinuvel, Resonance and Telix fell more than four percent; Compumedics, Genetic Signatures, Nanosonics and Neuren were down more than three percent; Optiscan, Starpharma and Universal Biosensors shed more than two percent; Cochlear, CSL and Opthea were down more than one percent, with Cyclopharm and Resmed down by less than one percent.

CYNATA THERAPEUTICS

Cynata says its mesenchymal stem cells (MSCs) prevent rejection of tracheal transplants in mice, paving the way to a human clinical trial.

Cynata said the research to be published in a paper, titled 'iPSC [Induced pluripotent stem cell]-derived MSC therapy induces immune-tolerance and supports long-term graft survival in mouse orthotopic tracheal transplants' has been accepted for publication in the journal Stem Cell Research & Therapy.

The company said the research was conducted at the Riyadh, Saudi Arabia King Faisal Specialist Hospital and Research Centre led by Dr Mohammad Afzal Khan.

Cynata said that tracheal, or windpipe, transplants were performed on unrelated strains of mice, who were randomly given either a single intravenous injection of its mesenchymal stem cells or a placebo one day before the transplant, and were divided into groups of four to six to evaluate the mice at five timepoints over 90 days, which was repeated in triplicate.

Cynata said the King Faisal Centre performed 1,500 human transplants in 2017, making it one of the largest transplant centres in the world.

The company said the study showed that the stem cells "demonstrated effects expected to prevent organ transplant rejection" including an increase in human tumor necrosis factor-inducible gene 6 (TSG-6) cells and an increase in peripheral mouse regulatory T cells, which limited transplant rejection by establishing immune tolerance.

Cynata said the treatment suppressed inflammation cytokines and increased beneficial immune-modulatory cytokines, reinstated graft functional microvascular blood flow and oxygenation, prevented harmful collagen deposition and limited injury to the transplanted organ.

Dr Khan said his group was "very excited by these results".

"Based on our findings, we believe that a clinical trial of Cymerus MSCs is warranted, as a potential option for immunosuppression in organ transplant recipients," Dr Khan said.

Cynata was up four cents or 2.5 percent to $1.64.

IDT AUSTRALIA

IDT says its US Food and Drug Administration warning letter has been lifted following its upgrade from 'official action indicated' to 'voluntary action indicated'.

Last week, IDT said the FDA concluded the inspection was closed and had upgraded it to 'voluntary action indicated' following an inspection in May 2019 (BD: Aug 28, 2019).

Last year, the company said it had received an FDA warning letter relating to a range of quality control issues (BD: May 29, 2018).

IDT said that prior to receiving the May 2018 FDA warning letter it maintained a 'voluntary action indicated' inspection classification and the return to voluntary action classification meant that "the FDA's assessment of any pending marketing applications referencing IDT's facility will no longer be directly impacted".

Today, IDT chief executive officer Dr David Sparling said "the removal of the FDA warning letter is a fantastic result for IDT".

"This represents the culmination of over 15 months' of extremely hard work and a company-wide focus on improving our culture and approach to quality and compliance in everything we do," Dr Sparling said.

"The resolution of this warning letter is a significant boost to IDT's reputation in the marketplace and improves our ability to drive the growth of the business, especially in international markets," Dr Sparling said.

IDT was untraded at 14 cents.

ORTHOCELL

Orthocell says eight of nine rotator cuff tendon tear patients returned to pain free function two years after the trial of its Celgro collagen membrane.

Orthocell chief executive officer Paul Anderson told Biotech Daily that the tenth patient's subjective scores were not available but "we know he has not had further surgery".

The company said the trial was conducted with the Perth, Western Australia-based St John of God Hospital surgeon Prof Allan Wang and University of Western Australia's Prof Ming Hao Zheng, the company's chief scientific officer.

Orthocell said the study recruited patients with full thickness tears of the rotator cuff tendon in the shoulder and had chronic pain and difficulty with basic daily living activities.

The company said patients averaged an American Shoulder and Elbow Society (ASES) score of 65 out of 100 before surgery with "significant chronic pain and difficulty performing activities of daily living".

Orthocell said that two years after surgery the average score was 94 with "significant improvements in performing activities, such as brushing their hair with the affected arm, putting on a coat and sleeping at night, and were back at work and playing sport without discomfort or pain".

The company said eight of nine patients (89%) returned to pain-free function and no patients required revision surgery two years after surgery.

Orthocell said Celgro was safe, tolerable and showed no adverse events or side effects.

Orthocell was up half a cent or 1.3 percent to 40 cents with 15.0 million shares traded.

IMMURON

Immuron says its cow-colostrum-derived anti-diarrhoea compound Travelan is reactive and binds to 71 clinical isolates of infectious South East Asian Vibrio cholera strains.

Immuron said the study was sponsored by the US Department of Defence, funded through the US Defence Health Agency and performed at the Bangkok, Thailand laboratory of the Walter Reed Army Institute of Research (WRAIR).

The company said the study aimed to assess Travelan's immune-reactivity and ability to bind to clinical isolates of Vibrio cholera strains, collected from infected Bangladesh, Cambodia and Thailand-based personnel, by comparing it to a placebo.

Immuron said the Travelan polyclonal antibodies were reactive to all 71 clinical isolates and was able to bind these bacteria.

The Walter Reed Institute's head of enteric vaccines and immonology Dr Robert Kaminski said the 71 bound isolates added to 180 Travelan-bound isolates of Campylobacter, entero-toxigenic Escherichia coli and Shigella.

"These results, together with the findings reported from the Travelan shigellosis challenge studies in non-human primates … suggest Travelan may be an effective immune-prophylactic for travellers' diarrhoea caused by Campylobacter [species], Shigella [species] and Vibrio cholera," Dr Kaminski said.

Immuron chief executive officer Dr Gary Jacob said "the work completed by our research collaborators at the WRAIR has provided the company with a comprehensive characterization profile of our flagship product, which clearly demonstrates the potential effectiveness of Travelan and the Immuron technology platform to neutralize pathogenic gastrointestinal bacterial infections, and offers significant potential as a preventive treatment for US military personnel and civilians stationed or traveling in locations where such infections may be debilitating".

Immuron was up 1.5 cents or 14.3 percent to 12 cents.

CLARITY PHARMACEUTICALS

Clarity says it has filed a US investigational new drug application for a 34-paediatric patient, phase I/IIa trial of copper-64 and copper-67 Sartate for neuroblastoma.

Clarity said the proposed multi-centre, dose escalation, open-label, non-randomized trial would be both diagnostic and therapeutic for children with somatostatin receptor-2 positive, relapsed or refractory, high-risk neuroblastomas.

The company said the study was supported by an imaging study of 10 patients with neuro-endocrine tumors and preliminary results from a first-in-human study of adult patients with meningioma, who were administered a diagnostic dose of 64-sopper-Sartate followed by up to four doses of 67-copper Sartate

Clarity executive chairman Dr Alan Taylor said the application was “a major milestone for our team and our collaborators”.

“We hope to receive a confirmation from the FDA shortly in order to progress this trial at major cancer centres in the United States and advance closer to our ultimate goal of better treating children and adults with cancer,” Dr Taylor said.

Clarity is a public unlisted company.

ADALTA

Adalta says the half-life of its i-bodies can be customized using multiple technologies and without affecting binding properties.

Adalta previously said that i-bodies were named from the “intermediate” of four groups of immunoglobulin or immunoglobulin-like domains” (BD: Feb 28, 2019).

Adalta said a paper, titled ‘Half-life extension and non-human primate pharmacokinetic safety studies of i-body AD-114 targeting human CXCR4’ was published in the journal mAbs (monoclonal anti-bodies).

The article is at: https://www.tandfonline.com/doi/full/10.1080/19420862.2019.1626652.

The company said the ability to modify the half-life of the i-body and not affect binding properties of the long loop that enabled access to difficult drug targets showed “the flexibility of its i-body platform and increases the utility of the platform for treating a wide variety of diseases”.

Adalta executive chairman Dr Paul MacLeman said the i-body platform provided “the ability to develop multiple therapeutics, targeting a range of disease areas, which have previously been considered untreatable”.

“We can apply this technology to our own drug development, and also apply it to commercial partnerships with pharmaceutical or biotech companies,” Dr MacLeman said.

Adalta fell one cent or 7.7 percent to 12 cents.

RESPIRI

Respiri says it has launched its Wheezo self-assessment diary application software for people with asthma in Australia.

Respiri said the Wheezo diary would be free with options to subscribe for information on atmospheric conditions and pollen and weather alerts and the diary software would include the identification of asthma symptoms and triggers, a medication diary, medication reminders and a feature to share asthma history with doctors.

Respiri said the Wheezo, asthma wheeze diagnostic was pending Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approval, but the diary would be available in software retailers, the App Store and Google Play, this week.

Respiri was up 0.7 cents or 8.2 percent to 9.2 cents.

TOTAL BRAIN

Mitsubishi UFJ Financial Group says it has become a substantial shareholder in Total Brain with 40,238,333 shares or 5.17 percent.

The Tokyo, Japan-based Mitsubishi said that between May 16 and August 29, 2019 it acquired 29,625,014 shares for $819,068.88 or an average of 2.76 cents a share, with the single largest purchase of 25,900,000 shares on May 16 for $700,699 or 2.7 cents a share.

The numbers were the same as a Morgan Stanley substantial shareholder notice announced yesterday and Mitsubishi said that Morgan Stanley was the holder of the securities.

Total Brain was up half a cent or 10.2 percent to 5.4 cents with 19.0 million shares traded.

BTC HEALTH

BTC says it has appointed Sharon Papworth as chief financial officer and company secretary, replacing Stuart Jones effective from October 1, 2019.

BTC said Mr Jones would move to the role of corporate development director.

The company said Ms Papworth was a chartered accountant and was previously the chief financial officer of Symbion and the chief financial officer and company secretary of Acrux.

BTC was untraded at 13.5 cents.