Biotech Daily

Wednesday March 10, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: OSPREY UP 25%; PROTEOMICS DOWN 7%**

*** DIMERIX: INDIA APPROVES 600-PATIENT DMX-200 COVID-19 TRIAL**

*** MTP CONNECT IDENTIFIES 20 BIOTECH SKILL GAPS**

*** US PATENT FOR IMMUTEP IMP321 COMBINATION FOR CANCER**

*** ADALTA COMPLETES AD-214 PHASE I PART A STUDY**

*** NEUREN MANUFACTURES NNZ-2591 FOR PHASE II TRIALS**

*** CANN GLOBAL AUSTRALIAN MARIJUANA PILL PATENT, $418k ORDER**

*** CELL CARE REDUCES TO 15% OF CRYOSITE**

MARKET REPORT

The Australian stock market fell 0.84 percent on Wednesday March 10, 2021, with the ASX200 down 57.1 points to 6,714.1 points. Twenty-eight of the Biotech Daily Top 40 stocks were up, six fell and six traded unchanged.

Osprey was the best, up 0.4 cents or 25 percent to two cents, with 15.5 million shares traded.

Optiscan climbed 8.6 percent; Amplia and Oncosil were up more than six percent; Clinuvel, Impedimed, Imugene and LBT improved five percent or more; Compumedics, Dimerix and Paradigm were up four percent or more; Alterity, Antisense, Avita, Cyclopharm, Next Science, Pharmaxis, Polynovo and Prescient were up more than three percent; Kazia, Medical Developments, Mesoblast and Neuren rose two percent or more; Orthocell and Pro Medicus were up one percent or more; with CSL, Genetic Signatures, Nanosonics, Resmed and Telix up by less than one percent.

Proteomics led the falls, down 8.5 cents or 7.1 percent to $1.11, with 182,201 shares traded. Immutep lost three percent; Opthea shed two percent; Starpharma and Volpara were down more than one percent; with Cochlear and Cynata down by less than one percent.

DIMERIX

Dimerix says it has Indian ethics approval for a 600-patient phase III trial of DMX-200 for Covid-19 patients without acute respiratory distress syndrome (Ards).
Dimerix said that India's Central Independent Ethical Review Board approved the phase III 'Clarity 2.0' prospective, multi-centre, randomized, double blind, placebo-controlled feasibility study, which would begin recruitment next month.
The company said the study would be led by the University of Sydney's Prof Meg Jardine, with the George Institute for Global Health India's Prof Vivek Jha.
Dimerix said that Covid-19 patients without Ards would be treated for up-to 28 days and then followed-up for 26 weeks.
The company the primary endpoint was the patient's clinical health at day-14 of treatment, which would score patient outcomes based on a scale of "no hospitalization or ventilation requirement through to death".
Dimerix said that it had established multiple clinical study sites and expected to begin patient recruitment in April, once regulatory approval was obtained.
Dimerix was up one cent or 4.1 percent to 25.5 cents.

MTP CONNECT

MTP Connect says it has identified 20 skill gaps in the medical technology, biotechnology and pharmaceutical sectors and will fund programs to address them.
MTP said the data came from the second of three reports produced by the Researcher Exchange and Development within Industry program, a $32 million initiative operated by MTP Connect and funded by the Medical Research Future Fund, with the first report published last year (BD: Nov 12, 2020).
MTP Connect managing-director Dr Dan Grant said "the MTP sector is already Australia's eighth largest export sector and a major contributor to the Australian economy, but we need to understand where the skills gaps are so we can build the workforce that will power the next wave of innovation and growth".
"In a time of rapid change, advancements in areas such as precision medicine, digital health solutions and regenerative medicine supported by advanced manufacturing technologies present exciting growth opportunities - if we can develop a future ready workforce," Dr Grant said.
"Our report … identifies the priority gaps and helps ensure workforce skills are aligned to the current and future needs of the sector," Dr Grant said.
"The 20 priority skills gaps identified span seven key themes: advanced manufacturing and supply chain; business operations; clinical trials; health data and cybersecurity; health economics and regulatory affairs; product development; and commercialization and specialist and technical skills," Dr Grant said.
Dr Grant said that for the biotechnology sector to continue its trajectory "the workforce will need to retain and evolve skills in current areas of competitive advantage, while also developing new skills that are aligned with these emerging areas".
The report, titled 'Driving skills development and workforce training for the future MTP workforce' is available at https://www.mtpconnect.org.au/reports/redi-skills-gap.
MTP said the Researcher Exchange and Development within Industry program had called for proposals for funding under a second round for national training or education training programs that met specific needs identified in the report, with applications to be submitted at: https://www.mtpconnect.org.au/Category?Action=View&Category_id=270.
MTP Connect said the third of the three reports would be "delivered in late 2021".

ADALTA

Adalta says its 34-participant phase I trial of AD-214 shows that the compound is “very well-tolerated in single doses up to 20mg/kg”.
Adalta said that the “positive” results from part A of the phase I program trial of AD-214 for idiopathic pulmonary fibrosis would influence the protocol of part B of the trial.
Last year, Adalta said it had treated 34 healthy volunteers with AD-214 or placebo at doses ranging from 0.01mg/kg to 10mg/kg in part A of its phase I study and had approval to extend to the maximum planned dose of 20mg/kg (BD: Dec 14, 2020).
Today, the company said that said part A showed that along with being tolerated to 20mg/kg, AD-214 engaged the target receptor, C-X-C chemokine receptor type 4 (CXCR4), at “higher levels of receptor occupancy for longer than predicted”.
Adalta said that part B of the trial had been modified and would be a multiple ascending dose study in healthy volunteers with longer dosing intervals.
The company said the part B protocol would test the safety, pharmacokinetics and receptor occupancy of a radio-labelled version of AD-214 for positron emission tomography imaging, which would be used to measure the effect of elevated CXCR4 in interstitial lung disease and idiopathic pulmonary fibrosis patients taking AD-214.
Adalta said part B might explore the use of AD-214 in other fibrotic indications, the effect of AD-214 when administered for 18 weeks, and the safety of AD-214 when used in combination with standard-of-care therapies.
The company said the change to part B would allow the phase II data would enable a safety package for a US Food and Drug Administration investigational new drug application “by the end of 2021”.
Adalta said that the clinical validation of the I-body platform was expected “to increase partner interest in both AD-214 and co-development opportunities, contributing significantly to the acceleration of [its] asset creation strategy”.
The company previously told Biotech Daily that I-bodies were named from the intermediate group of immunoglobulin or immunoglobulin-like domains (BD: Jul 7, 2016).
Today, Adalta said that it aimed to have nine products in discovery research through to phase II by the end of 2023.
Adalta fell 1.5 cents or 8.3 percent to 16.5 cents with 1.4 million shares traded.

IMMUTEP

Immutep says the US Patent and Trademark Office has granted a patent for its IMP321 in combination with a PD-1 pathway inhibitor for cancer and infection.
Immutep said the patent, titled ‘Combined Preparations for the Treatment of Cancer or Infection’ would protect IMP321, or eftilagimod alpha, combined with the programmed death-1 (PD-1) pathway inhibitors pembrolizumab or nivolumab, until January 20, 2036.
The company said the patent was filed as a divisional application and followed the grant of the “parent patent” on December 30, 2020 (BD: Jan 17, 2021).
Immutep said the patent would build on the protection provided by the parent patent and was directed to methods of treating cancer by administering IMP321 and either pembrolizumab or nivolumab.
The company said it had filed a further divisional application to pursue other aspects of IMP321 including combinations with a programmed death ligand-1 (PD-L1) inhibitor.
Immutep chief executive officer Marc Voigt said the patent grants were “important as they underpin ongoing investment in clinical development of efti and allow us to confidently engage in business development discussions”.
Immutep fell one cent or three percent to 32 cents with 2.3 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has completed the manufacturing of its NNZ-2591 for phase II trials for Phelan-McDermid, Angelman and Pitt Hopkins syndromes.

Last month, Neuren said NNZ-2591 was "safe and well tolerated in healthy volunteers," allowing the company to progress to the placebo-controlled trials (BD: Feb 15, 2021).

Today, the company said the manufacturing had been completed on schedule.

Neuren chief executive officer Jon Pilcher said the company had "successfully developed a proprietary process for large scale manufacturing with exceptional purity and high yield".

"This is a key part of the strong foundations we have built for NNZ-2591, which can now be leveraged across multiple valuable indications," Mr Pilcher said.

"As well as supplying the upcoming trials in Phelan-McDermid, Angelman and Pitt Hopkins, the campaign has produced enough drug substance at no extra cost to supply a phase II trial in Prader-Willi syndrome," Mr Pilcher said.

Last month, Neuren said it would add Prader-Willi syndrome to the developmental pipeline for NNZ-2591 based on "compelling results" from a mouse study (BD: Feb 16, 2021).

Neuren was up 2.5 cents or two percent to $1.28.

CANN GLOBAL

Cann Global says the Australian Patent Office has granted its joint venture partner, Canntab Therapeutics, a patent for immediate release cannabidiol tablets.

Cann Global said the patent, titled 'Immediate release cannabidiol formulations' would protect the formulations in hard pill form as a medical marijuana delivery method for therapeutic applications until January 22, 2038.

Last year, the company said the 50-50 joint venture with the Toronto-based Canntab had launched the medical marijuana tablets in Australia (BD: Oct 26, 2020).

Today, Cann Global said it was confident in the demand for these products and placed an initial order worth $C406,200 ($A418,000) order for six products from the Canntab range including two tetrahydrocannabinol (THC) only products, two cannabidiol (CBD) only products and two THC and CBD blends.

The company said it had an import permit and Canntab would fill the order when it received a Health Canada export permit, with the tablets available through the Australian Therapeutic Goods Administration special access and authorized prescriber schemes.

Cann Global was unchanged at 0.8 cents with 122.9 million shares traded.

CRYOSITE

Cell Care Australia says it has reduced its substantial shareholding in Cryosite from 7,460,000 shares (15.92%) to 6,913,807 shares (14.75%).

The Melbourne-based Cell Care said that between March 5 and 9, 2021 it sold shares at prices ranging from 17.01 cents to 18.79 cents.

In February, Cell Care announced that it had sold Cryosite shares for the first time since 2015, and has continued to sell shares, reducing from 9,229,995 shares or 19.69 percent on three previous dates (BD: Nov 26, 2015; Feb 17, 24, Mar 8, 2021).

Cryosite fell one cent or 5.9 percent to 16 cents.