Biotech Daily

Wednesday November 10, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 3%**
- IMMUTEP DOWN 14%

*** IMMUTEP: IMP321 'NON-SIGNIFICANT' CANCER BENEFIT; SUB-GROUPS**

*** CORRECTION: RAGE BIO**

*** CLARITY RECRUITS PROSTATE CANCER IMAGING DOSIMETRY**

*** IMMURON, US NAVY COW COLOSTRUM DRUG DEVELOPMENT RESUMES**

*** ZUCERO BEGINS PHASE IIa PIXATIMOD TRIAL**

*** IMAGION PLEADS SCHULTZ, 'ENROLMENT' TO ASX 32.5% QUERY**

*** IMPEDIMED AGM 15% OPPOSE PLACEMENT CAPACITY**

*** AVITA 130k DIRECTORS' SHARES, 378k OPTIONS AGM**

*** AROVELLA APPOINTS DR ELIZABETH STONER DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.14 percent on Wednesday November 10, 2021, with the ASX200 down 10.3 points to 7,423.9 points. Six of the Biotech Daily Top 40 stocks were up, 26 fell and eight traded unchanged.

Universal Biosensors was the best, up 2.5 cents or 3.25 percent to 79.5 cents, with 1.4 million shares traded. Antisense climbed 2.4 percent; Cyclopharm and Resmed were up one percent or more; with Nanosonics, Paradigm and Pro Medicus up by less than one percent.

Immutep led the falls, down 9.5 cents or 13.6 percent to 60.5 cents, with 24.2 million shares traded (see trial report, below). Optiscan lost 9.1 percent; LBT was down five percent; Imugene, Nova Eye, Resonance, Telix and Volpara fell four percent or more; Neuren, Polynovo and Uscom were down more than three percent; Amplia, Cochlear, Cynata, Dimerix, Medical Developments, Oncosil, Opthea, Patrys and Starpharma shed two percent or more; Clinuvel, Compumedics, Kazia and Osprey were down one percent or more; with Avita, CSL, Genetic Signatures and Mesoblast down by less than one percent.

IMMUTEP

Immutep says its 227-patient, phase II 'Aipac' trial of IMP321, or eftilagimod alpha, with paclitaxel for metastatic breast cancer showed a "non-significant survival benefit trend".

Immutep said that 114 women with human epidermal receptor 2 (HER2) negative and hormone receptor (HR) positive metastatic breast cancer received IMP321, or eftilagimod alpha (efti) in combination with paclitaxel, while 113 women received placebo and paclitaxel, in the 'active immunotherapy with paclitaxel' or Aipac trial.

The company said that at the May 14, 2021 data cut-off date, patients receiving IMP321 with paclitaxel had a median overall survival of 20.4 months compared to 17.5 months for control group patients, a benefit of 2.9 months ($p = 0.197$) and better quality of life.

Last year, Immutep said that at the September 24, 2020 data cut-off date, patients receiving IMP321 with paclitaxel had a non-significant survival benefit trend and better quality of life (BD: Dec 10, 2020).

Today, the company said that "pre-defined patient sub-groups … [had] a statistically significant and clinically relevant survival benefit".

Immutep said that "both the magnitude and statistical significance of the benefit has improved across the three [sub]-groups, compared with the interim [overall survivial] results reported in December 2020".

The company did not disclose the numbers of patients in the sub-groups.

Immutep said that patients receiving IMP321 under 65 years had a median overall survival of 22.3 months compared to 14.8 months for controls ($p = 0.017$).

The company said that patients with a low monocyte count at the start of the study had a median overall survival of 32.5 months with IMP321, compared to 12.9 months for the comparator group ($p = 0.008$), which supported IMP321's mode of action as an antigen-presenting cell activator, driving an adaptive immune response.

Immutep said that patients with more aggressive cancer, characterized as "luminal B" receiving IMP321 had a median overall survival of 16.8 months compared to 12.6 months for the placebo and paclitaxel group ($p = 0.049$).

The company said that luminal B cancers were "typically more immunogenic [or] receptive to immune system activation to attack cancer".

Immutep said that "an increase in peripheral CD8 T cells was reported in patients in the efti group, consistent with efti's mode of action as an [antigen-presenting cell] activator.

The company said that the increase "significantly correlated with improved [overall survival], demonstrating strong proof-of-concept in a randomized, double blinded setting".

Immutep said that the combination of efti and paclitaxel "was overall safe and well tolerated, further building upon efti's strong safety profile to date" and no new safety signals were observed.

The company said it was preparing a phase III investigation of efti in combination with paclitaxel in metastatic breast cancer, subject to regulatory interactions.

Immutep said the final data would be presented at the Society for Immunotherapy of Cancer meeting November 10 to 14 2021.

Immutep chief executive officer Marc Voigt said the "very pleasing final results give us additional confidence that efti can ultimately deliver a meaningful clinical improvement for diverse sets of cancer patients".

"The results from our Aipac trial are especially pleasing because metastatic breast cancer patients in the chemotherapy setting are a difficult to treat and large patient population where immunotherapies often fail to provide an additional benefit," Mr Voigt said.

Immutep chief medical officer Dr Frederic Triebel said it was "remarkable to see efti has significantly improved the survival in three pre-defined sub-groups of patients".

Immutep fell 9.5 cents or 13.6 percent to 60.5 cents with 24.2 million shares traded.

CORRECTION: RAGE BIOTECH

Last night's edition included two errors in the article on Rage raising $3.7 million from London's IP Group, with support from Monash Investment Holdings.
The headline incorrectly gave the name of the recently-appointed chief executive officer as Dr Christ Wraight, whereas his name is Dr Christopher, or Chris, Wraight.
Dr Wraight's qualifications were earnt at Melbourne's La Trobe University, without the stray extra "t".
The mistake was made by the distracted Tuesday sub-editor, fielding a call from a reader. She has been admonished for the mistakes and has repented, with a litany of Hail Marys and Our Fathers.
Rage is a private company.

CLARITY PHARMACEUTICALS

Clarity says it has completed recruitment of six patients in the initial phase of its trial of 64-copper isotopes for prostate cancer imaging.
In August, Clarity said it had dosed the first US patient in its 'Secure' trial of 64-Cu SAR-bis-PSMA for metastatic castrate resistant prostate cancer at the Omaha, Nebraska-based Urology Cancer Center and GU Research Network (BD: Aug 25, 2021).
In May, Clarity said the US Food and Drug Administration had cleared an investigational new drug application for the 44-patient, phase I/IIa, single arm, dose-escalation prostate cancer trial (BD: May 4, 2021).
The company said at that time that 64-Cu-SAR-bis-PSMA was used to image and select patients for 67-Cu-SAR-bis-PSMA therapy.
Today, the company said the 'Secure' multi-centre, single arm, dose escalation study had a cohort expansion planned for up to 44 patients to determine the safety and efficacy of 67 copper SAR-bis-PSMA as a therapy.
Clarity chair Dr Alan Taylor said the team was "very pleased to have quickly and successfully completed the recruitment for the initial dosimetry phase of the Secure trial".
"The [positron emission tomography] imaging data acquired in the Secure trial to date looks very promising and the images confirm our excellent preclinical results of high tumor targeting and retention whilst seeing washout in other tissues," Dr Taylor said.
Clarity was unchanged at $1.03.

IMMURON

Immuron says its clinical development programs with the US Naval Medical Research Center are "back on-track … [after] a 12-month hiatus due to the Covid-19 pandemic".
Last year, the company said that with the NMRC it intended to conduct two phase II trials in 2021, one focused on the ability of its hyperimmune cow colostrum-based product to protect volunteers against moderate to severe campylobacteriosis and the second trial to focus on Escherichia coli infections (BD: June 9, 2020).
Today, the company said manufacturing of drug product for Campylobacter and entero-toxigenic Escherichia coli (ETEC) was completed in October 2021 and would be transferred to the Baltimore, Maryland based Johns Hopkins Bloomberg School of Public Health for the two trials.
Immuron said the US NMRC planned to file two investigational new drug applications to the US Food and Drug Administration by April 2022 with trials to begin by July 2022.
Immuron was unchanged at 12.5 cents.

ZUCERO THERAPEUTICS

Zucero says based on data from its phase Ib trial, it has begun an up to 61 patient, phase IIa study of pixatimod with nivolumab for colorectal cancer.
In June, Zucero said the US approval of a 61-patient, phase II cancer trial contributed to delaying a proposed $30 million initial public offer (BD: June 22, 2021).
In 2019, the company said its phase Ib study showed meaningful anti-cancer activity in patients with micro-satellite stable metastatic colorectal cancer (BD: Jul 29, 2019).
Today, Zucero said its phase I data would be presented at the Society for Immunotherapy of Cancer meeting in Washington, DC, on November 10, 2021.
The company said the abstract, titled 'A phase Ib expansion cohort of pixatimod plus nivolumab in previously treated, microsatellite stable metastatic colorectal cancer (MSS mCRC)', would be presented by Scientia chief medical officer Dr Charlotte Lemech.
Zucero said the presentation would describe safety and anti-tumor activity of pixatimod, in combination with the programmed cell death protein 1 (PD-1) inhibitor nivolumab and describe the changes in primary pharmaco-dynamic markers.
Zucero said on the basis of the data, it had begun a phase IIa trial at the University of Pittsburgh Medical Center with Dr Diwakar Davar as principal investigator.
Zucero said the study would investigate pixatimod plus nivolumab in metastatic melanoma and non-small cell lung cancer and with nivolumab and low-dose cyclo-phosphamide in microsatellite stable metastatic colorectal carcinoma.
Zucero is a public unlisted company.

IMAGION BIOSYSTEMS

Imagion has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said Imagion's share price climbed 32.5 percent from 7.7 cents on November 8 to 10.2 cents on November 9, 2021 and noted a "significant increase" in the trading volume.
Imagion said that in its May 26, 2021 Appendix 4C quarterly report it said screening in its Magsense breast cancer trial was "below pre-pandemic levels" and in its October 29, 2021 quarterly report said four sites were "actively screening patients" which "could have had an impact on the recent trading".
Imagion fell 1.6 cents or 16.0 percent to 8.4 cents with 47.2 million shares traded.

IMPEDIMED

Impedimed says all resolutions to its annual general meeting were passed but it faced 15.37 percent opposition to the 10 percent placement capacity.
Impedimed said the 10 percent placement resolution was opposed by 91,441,706 votes (15.37%) with 503,474,479 votes (84.63%) in favor.
The company said the resolution to amend the company constitution was opposed by 53,890,120 votes (8.85%), with all other resolutions including the remuneration report, the election of Amit Patel and Donald Williams, the grant of performance rights to chief executive officer Richard Carreon and options to Grant Williams, the employee incentive plan and the renewal of proportional takeover provisions passed overwhelmingly.
According to the company's most recent filing, Impedimed had 1,726,609,925 shares on offer meaning the opposition to the 10 percent placement capacity amounted to 5.3 percent of the company, sufficient to requisition extraordinary general meetings.
Impedimed was unchanged at 17.5 cents with 5.5 million shares traded.

AVITA MEDICAL

Avita says its annual general meeting will vote to issue 130,055 restricted US stock units, equivalent to 650,275 Chess depositary interests (CDIs), and 75,525 US options equivalent to 377,625 Australian options to seven directors.
Avita said the “restricted stock units” would vest on anniversaries of the grant date.
The company said it would issue 4,350 restricted US stock units and 2,550 US options each to chair Louis Panaccio, and directors Prof Suzanne Crowe, Jeremy Curnock Cook, Louis Drapeau, James Corbett and Prof Jan Stern Reed, with the options exercisable at the closing price of Avita shares of common stock on Nasdaq on the date the options were granted, and within 10 years.
Avita said shareholders would vote to issue 8,675 restricted US stock units and 4,925 US options to Prof Stern Reed for her appointment as a director.
The company said it proposed to issue 95,280 US shares and 55,200 US options to chief executive officer Dr Michael Perry.
Avita said it would issue Dr Perry 23,800 restricted stock units and 13,800 options, representing 25 percent of the total grant value and based on his tenure, with the remaining portion to be awarded based on performance objectives and 23,820 restricted stock units and 13,800 options would be granted based on “stretch” performance milestones.
The company said the options were exercisable at the price of US shares on the Nasdaq on the date of grant and within 10 years.
Avita said shareholders would vote to increase the fee pool for non-executive directors from $US600,000 ($A815,000) to $US750,000 ($A1,018,000).
Avita said the meeting would vote on amendments to its amended and restated bylaws and the ratification of the issue of 3,214,250 US placement shares at US$21.50 each and to elect directors Mr Panaccio, Dr Perry, Mr Curnock Cook, Mr Drapeau, Prof Crowe, Mr Corbet and Ms Stern Reed.
The virtual meeting will be on December 15, 2021 at 8am (AEDT).
Avita fell two cents or 0.4 percent to $4.58.

AROVELLA THERAPEUTICS (FORMERLY SUDA PHARMACEUTICALS)

Arovella says it has appointed Dr Elizabeth Stoner as an independent non-executive director.
Arovella said the Boston-based Dr Stoner had more than 30 years’ experience in the life-sciences sector and was currently a partner at US-based healthcare investment firm, MPM Capital.
The company said Dr Stoner was previously Semma Therapeutics interim chief executive officer and Merck Research Laboratories’ head of clinical development operations.
Arovella said that Dr Stoner was currently a board member of Triplett Therapeutics.
Arovella said Dr Stoner held a Doctor of Medicine from New York’s Albert Einstein College of Medicine.
Arovella 0.3 cents or 6.8 percent to 4.1 cents with 4.8 million shares traded.