Biotech Daily

Monday July 10, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ATCOR UP 23%, PRANA DOWN 13%**

*** CORRECTION: CSL**

*** PARADIGM BEGINS PHASE II PPS FOR ROSS RIVER VIRUS TRIAL**

*** BIOVERATIV: 'CSL IDELVION FOR HAEMOPHILIA INFRINGES PATENTS'**

*** PRIMA PHASE I TRIAL OF IMP321 ROUTES FOR SOLID TUMORS**

*** NOVITA REQUESTS 'BOOK-BUILD, ACQUISITION' TRADING HALT**

*** IMMURON CLAIMS IMM-124E SAFE FOR NASH, EFFICACY UNCERTAIN**

*** RACE JOINT VENTURE WITH TARGIMMUNE FOR CANCER**

*** NEUROTECH SHIPS MENTE AUTISM DEVICES TO TURKEY**

*** US PATENT FOR REGENEUS SYGENUS STEM CELLS FOR ACNE**

*** RHS PG-SEQ FOR EMBRYO SCREENING; ILLIMUNA BENEFIT**

*** MACH7 CEO MICHAEL JACKMAN TO START ON $460k, $39k BONUS**

MARKET REPORT

The Australian stock market was up 0.36 percent on Monday July 10, 2017 with the ASX200 up 20.8 points to 5,724.4 points. Nine of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and four were untraded.

Atcor was the best for the second trading day in a row, up 0.9 cents or 23.1 percent to 4.8 cents with 307,621 shares traded. Airxpanders and Genetic Signatures climbed more than seven percent; Acrux was up 6.25 percent; Living Cell improved 4.8 percent; Benitec and Clinuvel were up more than three percent; Ellex and Resmed rose more than one percent; with Cochlear and Pro Medicus up by less than one percent.

Prana led the falls, down 0.8 cents or 13.3 percent to 5.2 cents with 181,463 shares traded. Compumedics and Dimerix lost more than nine percent; Admedus was down 6.7 percent; Mesoblast and Starpharma fell more than four percent; Factor Therapeutics was down three percent; Nanosonics, Osprey and Polynovo shed two percent or more; Actinogen, LBT, Medical Developments, Opthea, Pharmaxis, Sirtex and Viralytics were down one percent or more; with Cellmid and CSL down by less than one percent.

CSL

Friday's edition reported that CSL briefly fell to 78 cents following its initial public offer at $2.

CSL's then chief financial officer Graeme Kaufman has told Biotech Daily that following the $2.30 a share initial public offer in July 1994, the price dropped to $2.25 during intra-day trading but never closed below $2.30.

The confusion was caused by the three-way split on October 24, 2007, after CSL reached $100 a share the first time, effectively making the actual $2.25 low in 1994, equivalent to 75 cents post-split (BD: Oct 17, 2007).

The mistake was made by the sub-editor who had the chance to buy CSL shares at $15 before the split, equivalent to $5 a share today, and didn't. It's left him CSL-challenged.

CSL fell 85 cents or 0.6 percent to $133.32 with 1,072,750 shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has begun its 24-patient, phase II alphavirus trial of pentosan polysulfate sodium (PPS) for Ross River virus.

Paradigm said that it had been approved for the trials at Brisbane's Mater Research and Geelong's Barwon Health, with the first dosing "expected in the coming weeks", with other Queensland sites under evaluation for the randomized, double-blinded, placebo-controlled trial.

The company said that people with Ross River virus-induced arthralgia, or painful joints, would be evaluated for safety, tolerability and effects on disease symptoms of PPS sub-cutaneous injections, with results expected in mid-2018.

Paradigm chief executive officer Paul Rennie said the company hoped that pentosan polysulfate sodium "can prove effective through this phase II trial, especially as there are no effective pharmaceutical treatments available to [Ross River virus] sufferers, making this a true unmet medical need".

The company said that there were 9,549 cases of Ross River fever notified worldwide in 2015, more than double the previous year, with 21 percent from New South Wales, Victoria, Tasmania, South Australia and the Australian Capital Territory.

Mr Rennie told Biotech Daily that Ross River virus was endemic in Northern Australia and Papua New Guinea.

Paradigm said that chikungunya virus was closely related to Ross River virus and pentosan polysulfate sodium had been tested in a pre-clinical model of chikungunya virus "and proven to be successful".

The company said that chikungunya virus was more widespread compared than Ross River fever with more than one million cases reported in the first six months of 2017 in the Americas.

Paradigm said that following a successful phase II trial for Ross River virus it planned to apply for accelerated approval.

The company said that it expected results from its phase IIa open-label bone marrow oedema lesion trial by October 2017.

Paradigm said it was awaiting data analysis of its phase I and II allergic rhinitis, or hay fever, trials of data before announcing the next steps.

In June, Paradigm said its phase IIa allergic rhinitis trial did not meet its primary endpoints of total nasal symptom score and peak nasal respiratory flow, blaming the formulation (BD: Jun 16, 2017).

Paradigm was unchanged at 29.5 cents.

CSL

CSL says that the Waltham, Massachusetts-based Bioverativ claims that CSL's Idelvion factor IX albumin fusion protein infringes three Bioverativ patents.
Bioverativ's website said it was a Biogen haemophilia spin-out.
CSL said that Bioverativ's complaints were lodged with the US District Court for the District of Delaware and with the International Trade Commission.
The company said that Bioverativ alleged that the use of Idelvion by patients and physicians constitutes patent infringement and that the US Food and Drug Administration-approved label for Idelvion infringed three Bioverativ patents.
CSL said it was "highly confident of its intellectual property position for Idelvion, a product of over a decade of innovative research by CSL Behring and representative of a major advance for patients suffering haemophilia B and will vigorously defend against the claim".
The company said that Idelvion was approved by the FDA in March 2016 for use in children and adults with haemophilia B, or congenital factor IX deficiency, for on-demand control and prevention of bleeding episodes, perioperative management of bleeding and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
CSL said it was committed to making Idelvion available to patients and believed that patients and physicians had the right and should have the ability to choose among a variety of treatment options for haemophilia B, including Idelvion.

PRIMA BIOMED

Prima says it has approval for an investigator-sponsored German trial of up to 40-patients exploring different routes of administration of IMP321 for solid tumors.
Prima said that Frankfurt-based collaboration partner, Institut für Klinisch-Onkologische Forschung (the Institute of Clinical Cancer Research) at Krankenhaus Nordwest GmbH had regulatory and ethical approvals for the 'Insight' trial.
The company said that the Insight trial was an explorative, single centre, open-label, phase I trial to evaluate the feasibility and safety of intra-tumoral, intra-peritoneal and sub-cutaneous injections with IMP321 for advanced stage solid tumors.
Prima said the trial was under the direction of lead investigator Dr Salah-Eddin Al-Batran.
Dr Al-Batran said that his group was "thrilled by the prospect of injecting an active immunotherapy directly at the tumor site to see whether the locally-induced, antigen-presenting cell activation leads to a regression of distant tumor masses, a characteristic of anti-tumor CD8 T-cell responses".
"In addition, analysis of local tumor biopsies before and after IMP321 injection will inform us about the immune infiltrates induced by this [antigen-presenting cell] activator," Dr Al-Batran said.
Prima chief executive officer Marc Voigt said that it was "the first ever investigation of whether direct injection of IMP321 into a solid tumor can activate the antigen presenting cells located inside the tumor to boost the body's immune response".
Prima was unchanged at 2.9 cents with 1.1 million shares traded.

NOVITA HEALTHCARE (FORMERLY AVEXA)

Novita has requested a trading halt pending an announcement regarding "a book-build as part of a major issue of new shares in conjunction with a corporate acquisition".
Trading will resume on July 12, 2017 or on an earlier announcement.
Novita last traded at 3.2 cents.

IMMURON

Immuron says an interim analysis of its 133-patient phase II trial of IMM-124E for non-alcoholic steato-hepatitis, shows safety, with efficacy yet to be demonstrated.

Immuron said that the objectives of the analysis were to establish safety and provide a preliminary read on efficacy signals.

The company said the pre-planned analysis was triggered when 80 subjects completed treatment.

Immuron said that IMM-124E was safe and there were no safety signals when compared to placebo, with the treatment well-tolerated and no subjects discontinued therapy due to side effects.

The company said that no difference between treatment groups was noted in the hepatic fat fraction, the study's primary endpoint.

Immuron said the lack of statistically significant difference was "most likely attributable to the small sample size in this analysis".

The company said all three groups, IMM-124E 1200mg and 600mg and placebo, demonstrated a significant change of the liver enzyme alanine aminotransferase (ALT) at 24 weeks compared to baseline ($p = 0.0038$, $p = 0.016$ and $p = 0.0337$), but "no statistical difference was noted between the groups".

Immuron said that accounting for all ALT values though the study period, the area under the curve was calculated, and when correcting for ALT baseline values, a trend ($p = 0.067$) in ALT improvement was noted in the 1200mg group compared to placebo.

The company said that using the predicted ALT area under the curve values, the overall ALT value was statistically significantly lower for the 1200mg and 600mg groups ($p = 0.0036$ and $p = 0.0075$, respectively) compared to placebo.

Immuron said that for the second liver enzyme aspartate aminotransferase (AST) the area under the curve, when corrected for baseline values, was also significantly lower in the 1200mg and 600mg dose groups ($p = 0.0036$ and $p = 0.0098$, respectively) compared to placebo.

The company said that there was no evidence of systemic absorption of IMM-124E as assessed by circulating bovine immunoglobulin.

Immuron said that the data safety monitoring board (DSMB) recommendation was to continue the trial to completion, as there was no concern for safety or futility.

Immuron medical head Dan Peres said the company was "encouraged as both ALT and AST demonstrated strong correlation, suggesting an improvement of liver injury in the IMM-124E treated patients".

"We believe the additional [mechanism of action] data we are generating in partnership with Duke University and Sanyalbio will further strengthen our prior data to support IMM-124E's unique mechanism of action which will assist us to design of the next phase in our clinical program," Mr Peres said.

Immuron chief executive officer Thomas Liquard said the company was "encouraged by the results of this interim-analysis and are pleased by the DSMB's recommendation to continue the study to completion".

"NASH is increasingly viewed as a multifactorial disease whereby the approval of several chronic therapies, with different [mechanisms of action] and used in combination will be needed to control its long-term effects," Mr Liquard said.

"These results support our belief that IMM-124E is a compound with a complex [mechanism of action] that has the potential to have a beneficial impact in hard-to-treat fatty-liver diseases," Mr Liquard said.

Immuron said that 133-patient top-line results were expected by the end of 2017.

Immuron fell three cents or 10.3 percent to 26 cents with 1.1 million shares traded.

RACE ONCOLOGY

Race says it intends to develop a joint venture with the Basel, Switzerland-based Targimmune Therapeutics AG to combine their cancer therapies.

Race said that the 50-50 joint venture would be called Race Immunotherapeutics and would focus on “developing new and improved cancer therapies based on combining Bisantrene with Targimmune’s targeted cancer therapy technology”.

The company said that all new intellectual property would be equally co-owned and Race Immunotherapeutics would be independently funded, with operations beginning once funding was in place and formal agreements executed, pending approvals.

Race said that all core development work would be conducted by Targimmune in Basel, under a steering committee including Race staff and Race would provide scientific support and Bisantrene drug product, but no direct funding to the venture.

The company said that the Targimmune technology platform was licenced from the Hebrew University of Jerusalem and encompassed a proprietary non-viral vector to target receptors that were overexpressed on cancer cells, such as those found in breast cancer and several other important cancers.

Race said that once at the target cell, the vector delivered an immune-modulating agent known as polycytidylic acid, (poly-IC or pIC) into the cell, which then triggered apoptosis, or programmed cell death, and an immune response against the cancer.

The company said that the overall targeting technology was known as cancer-targeted delivery of pIC (CTPIC).

Race said that Targimmune believed that therapeutic synergies could be achieved by combining CTPIC with a broad spectrum chemotherapy and because of its reduced cardio-toxicity and mode of action, Bisantrene was “the ideal chemotherapy to combine with the Targimmune CTPIC platform”.

The company said that the anti-cancer effects of Bisantrene could be greatly enhanced by combination with CTPIC.

Race said that the initial focus would be to develop combinations of Bisantrene with CTPIC aimed at epidermal growth factor receptor, an important target in breast and other cancers, opening therapeutic opportunities in breast cancer, as well as non-small-cell lung cancer and head and neck cancers.

The company said the joint venture would explore combinations of Bisantrene with CTPIC targeted at other cancer targets, including a prostate cancer marker.

Race chief executive officer Peter Molloy said the company expected the joint venture to be “significantly value accretive”.

“Bisantrene has demonstrated therapeutic benefit in acute myeloid leukaemia, which is a relatively rare disease,” Mr Molloy said. “The joint venture opens up potential therapeutic opportunities for Bisantrene in all the major cancers, greatly expanding the pool of patients who could benefit from this valuable chemotherapeutic agent.”

Race was up one cent or 4.35 percent to 24 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has shipped 25 Mente Autism devices for monitoring and training children on the autism spectrum to Turkey.

Neurotech said that delivery of the shipment to Turkish distributor ESE Pazarlama followed the renewal of the distribution contract for a further three years.

The company said that there were 20,000 children registered with autism spectrum disorder in Turkey “and many more expected to be unregistered”.

Neurotech fell one cent or 4.3 percent to 22.5 cents.

REGENEUS

Regeneus says that a US patent has been allowed covering the composition, manufacture and use of its Sygenus stem cell technology platform for acne.
Regeneus said that the patent, entitled 'Pharmaceutical compositions and topical use thereof' would provide commercial rights to 2032, with corresponding patents granted in Australia, China, Europe and Japan and being pursued in other territories.
The company said that Sygenus included elements such as exosomes, cytokines and growth factors that were secreted by mesenchymal stem cells and worked in concert to reduce pain and inflammation and encourage accelerated healing and repair.
Regeneus said it had developed technology and protocols for the production of secretions of mesenchymal stem cells which had the potential to be used for multiple indications and in a range of delivery methods, with skin conditions and wound healing one of the most promising and near-term areas for cell-based regenerative medicine products.
Regeneus was unchanged at 12.5 cents.

RHS (FORMERLY REPRODUCTIVE HEALTH SCIENCE)

RHS says it has developed PG-Seq for embryo pre-implantation genetic sequencing and could benefit from San Diego, California-based Illimuna's termination of its products.
RHS said that the PG-Seq was a pre-implantation genetic screening product using sequencing that included its Doplify whole genome amplification, library preparation reagents and software for data analysis.
The company said the Illumina had announced it would no longer supply its pre-implant embryo genetic screening microarray products 24Sure and 24Sure Plus from 2018.
RHS said the termination of the products had "increased interest in RHS Embryocellect".
RHS fell half a cent or 3.2 percent to 15 cents.

MACH7 TECHNOLOGIES

Mach7 says it has appointed Michael Jackman as its chief executive officer, starting on $US350,000 ($A459,735) with a $US30,000 bonus, effective from August 1, 2017.
Mach7 said Mr Jackman had nearly 30 years' experience in developing health care and technology businesses and had built sales and service teams, and managed research and development teams in the US, Europe, Middle East, Japan and China, most recently as GE Healthcare's Americas chief executive officer.
Mach7 said that prior to GE, Mr Jackman worked for Carestream Health, Isoft Health Group, Eastman Kodak and IBM.
The company said Mr Jackman held a Bachelor of Engineering from the University of Rhode Island and a Master of Business Administration from the Fort Lauderdale, Florida-based Nova Southeastern University.
Mach7 said that Mr Jackman would have a base salary of $US350,000 ($A459,735) a year, increasing on January 1, 2018 to $US375,000 ($A492,587) and would receive "a one-off sign-on bonus" of $US30,000 ($A39,406) by August 15, 2017, had undertaken to buy $US30,000 of shares within one month of his start and would be entitled to a short-term incentive of up to 70 percent of his base salary and long term equity incentives of 7,094,832 "performance" rights, pending milestones.
Mach7 was unchanged at 19 cents.