Biotech Daily

Tuesday September 25, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: AVITA UP 35%; UNIVERSAL BIO DOWN 9%**

*** MESOBLAST MPC-150-IM 'SAFE' FOR HLHS IN CHILDREN**

*** INVION 'PHOTOSOFT ORAL, IVX-P02 KILL CANCER BETTER, IN-VITRO'**

*** PARADIGM CLAIMS PPS 52% REDUCTION FOR OA KNEE PAIN**

*** MGC: VARM COSMO $1m DEFAULT; CANADA DEAL SUSPENSION**

*** PROBIOTEC RELEASES 2m ESCROW SHARES**

*** BIOXYNE PAYS $121k FOR INDONESIA PT GAMAT UTAMA FOR SALES**

*** SIMAVITA REQUESTS 'PLACEMENT' TRADING HALT**

*** ARIX TAKES 11% OF PHARMAXIS**

*** JCP BELOW 5% OF NANOSONICS**

*** JCP BELOW 5% OF OSPREY**

MARKET REPORT

The Australian stock market slipped 0.02 percent on Tuesday September 25, 2018 with the ASX200 down 1.0 points to 6,185.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and four were untraded. All three Big Caps rose.

Avita was the best, possibly on last week's FDA approval, up 3.5 cents or 35 percent to 13.5 cents with 43.1 million shares traded. Cyclopharm climbed 10 percent; Clinuvel was up seven percent; Compumedics improved 5.4 percent; Imugene and Optiscan were up more than four percent; Impedimed and Neuren were up more than three percent; Medical Developments, Mesoblast and Osprey rose more than two percent; Bionomics, Nanosonics, Polynovo, Pro Medicus and Resmed were up more than one percent; with Cochlear and CSL up by less than one percent.

Universal Biosensors led the falls, down two cents or 9.1 percent to 20 cents with 395,016 shares traded. Actinogen lost 5.7 percent; Airxpanders, Dimerix and Ellex fell more than four percent; Factor, ITL and Prescient lost more than three percent; Immutep, Oncosil and Opthea shed more than two percent; Orthocell, Paradigm and Telix were down more than one percent; with Genetic Signatures down 0.8 percent.

MESOBLAST

Mesoblast says a trial of MPC-150-IM in 24 children with hypoplastic left heart syndrome has shown no stem cell-related safety concerns, to date.

Last year, Mesoblast said the US Food and Drug Administration had cleared the use of its stem cells with corrective surgery, in the trial at Boston Children's Hospital, the paediatric teaching hospital of Harvard University, for children under the age of five years with hypo-plastic left heart syndrome (BD: Apr 4, 2017).

Today, the company said that the randomized, placebo-controlled trial combined an injection of the mesenchymal precursor cells MPC-150-IM into the left ventricle with corrective heart surgery and was featured at the First Cardiac Regenerative Symposium for Congenital Heart Disease in Baltimore, Maryland on September 22, 2018.

Mesoblast said that the symposium focused on the potential for using cellular therapies in the treatment of complex congenital heart conditions.

The company said the trial had "the potential to extend the safety profile of MPC-150-IM beyond adults, where it [was] being studied in two complementary late-stage clinical trials in patients with advanced and end-stage chronic heart failure, to children with congenital heart disease".

Mesoblast said that children with hypo-plastic left heart syndrome (HLHS) had a functioning right ventricle, but a small left ventricle that was incapable of supporting the systemic circulation and if left untreated the congenital condition was "uniformly fatal".

The company said that the current treatment, ventricle palliation, used the right ventricle to support the entire circulation through a series of surgeries, but the right ventricle eventually tired, leading to about 50 percent mortality by adolescence.

Boston Children's complex biventricular repair program director and Harvard Medical surgery professor Prof Sitaram Emani, the trial's principal investigator said that injecting Mesoblast's mesenchymal precursor cells into the hypo-plastic left ventricle as an adjunct to surgical rehabilitation of the left heart had "the potential to promote growth and regeneration of that ventricle and recruit it back into the circulation, so that the patient has a chance to regain a normal two-ventricle circulation with improved quality of life and longevity".

Mesoblast said the underlying mechanism of action by which MPC-150-IM had a therapeutic effect in adults and children "based on preclinical evidence, [was] through reduction of damaging inflammation, maturation of the vasculature, reduction in fibrosis and cardiac repair".

The company said that a phase IIb trial comparing an injection of MPC-150-IM or placebo into the left ventricle in 159 adult patients with end-stage heart failure receiving a left ventricular assist device (LVAD) completed enrollment in September 2017, with all patients having a planned follow-up of at least one year.

Mesoblast said that the FDA had granted it a regenerative medicine advanced therapy designation for MPC-150-IM in these patients based on prior phase II trial results showing improved heart function, prolonged time to re-hospitalization and improved early survival after a single intra-myocardial injection of its stem cells at the time of the LVAD implant, with results to be presented by the trial's investigators at an upcoming conference.

The company said that a 600-patient, US phase III congestive heart failure trial had enrolled more than 85 percent of the expected patients.

Mesoblast said the trial objectives were to evaluate the ability of a single catheter-based injection of MPC-150-IM to reduce heart failure-related major adverse cardiac events (HF-MACE) in patients with left ventricular dysfunction, as well as delay or prevent disease progression to end-stage heart failure and terminal cardiac events.

Mesoblast climbed four cents or 2.2 percent to $1.87 with 1.1 million shares traded.

INVION

Invion says that a new formulation of the Photosoft technology is “significantly more efficient at killing ovarian cancer cells” in-vitro, with human trials planned for 2019.

Invion said that researchers at Melbourne’s Hudson Institute of Medical Research compared the efficacy of four photo-sensitizers used in photodynamic therapy, including Photosoft Oral and an improved formulation of Photosoft called IVX-P02, in in-vitro tests against ovarian cancer cells and found that IVX-P02 had a 15-fold greater cytotoxicity against ovarian cancer cells, compared to Photosoft Oral.

The company said Photosoft and IVX-P02 showed “enhanced cytotoxicity in-vitro compared to the two commercially available photo-sensitizers Talaporfin and Temoporfin.

Invion said that neither Photosoft Oral nor IVX-P02 showed toxicity towards cells until they were activated.

The company said the data was presented at Combio 2018, in Sydney from September 23 to 26, 2018.

Last year, Invion said it had a “strategic alliance” with Hong Kong’s Cho Group, which invested $656,682 at 0.3 cents a share for 15.03 percent of the company and later said it would licence “new generation photo dynamic therapy” for cancers from the Group for $5.5 million in shares at 0.2 cents a share (BD: Apr 18, Aug 31, 2017).

The company said at that time that it would be the exclusive distributor and licencee in Australia and New Zealand for the technology and would conduct research and development, initially targeting prostate cancer, with the Cho Group providing non-dilutive funding for the trials.

Today, Invion said the Photosoft in-vitro findings included how Photosoft killed cancer cells, where the photo-sensitizer acted within the cell and the molecular mechanisms induced to kill the cancer cells.

Invion chief executive Dr Greg Collier said that IVX-P02 had “a greatly improved ability to kill cancer cells, even moreso than its predecessors [and] that's an important finding”.

“This data lays the groundwork for ongoing preclinical trials of Photosoft and IVX-P02 as an indication for chemo-resistant, solid ovarian tumors,” Dr Collier said.

“We are making good progress and could move to clinical trials early next year,” Dr Collier said.

Invion said that with the Hudson Institute it was ready to start pre-clinical studies to determine the in-vivo effects of Photosoft Oral and IVX-P02 as a direct treatment for ovarian cancers and to induce an anti-tumor immune response which could potentially provide effective protection after treatment, with results expected “in the next few months”.

The company said that the ability of a photo-sensitizing compound such as Photosoft to kill cells depended on both the concentration of the compound and how much light energy was delivered to activate it, which in turn was dictated by both the light intensity and duration of exposure.

Invion said the Hudson Institute study used the same concentration of Photosoft Oral and IVX-P02, the same activation time and the same intensity of light.

Hudson ovarian cancer biomarkers research group head Dr Andrew Stephens said that all the parameters were identical and “using IVX-P02, you get a 15-fold increase in cell death”.

“That means you can either increase how rapidly you kill the cells, or you can increase the proportion of cells that you kill for the same concentration, in the same amount of time,” Dr Stephens said.

Invion said that IVX-P02 was made and synthesized in a different manner to Photosoft Oral.

Invion was up 0.1 cents or 2.9 percent to 3.6 cents with 4.3 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says 25 more osteo-arthritis patients treated with pentosane polysulfate sodium have taken the average pain reduction to 51.5 percent for 125 patients.
Last month, Paradigm said the total self-reported average knee pain reduction for 100 patients in the Australian Therapeutic Goods Administration special access scheme for injected pentosane polysulfate sodium (PPS) was 52.9 percent (BD: Aug 15, 2018).
Today, the company said the results were due to "a vast proportion of the patients undergoing a six-week treatment period replicating the same dosing regimen of the phase IIb osteo-arthritis clinical trial, suggesting a greater response compared to a three or four week treatment period".
Paradigm said that of the 125 patients treated, 85.6 percent responded with a reduction in joint pain and 91.2 percent an improvement in knee function.
The company said that the patients' self-reported pain scores were reduced by more than 51.5 percent and function was improved 69.1 percent on average, from baseline pain scores in patients with knee osteo-arthritis and concurrent bone marrow lesions.
Paradigm fell one cent or 1.1 percent to 88 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has issued "a formal contract default notice" to South Korea cosmetics manufacturer Varm Cosmo for its failure to meet obligations agreed last year.
Last year, the MGC share price climbed 100 percent to 7.6 cents after news that Varm Cosmo had signed a $40 million a year binding agreement to buy marijuana-based cosmetics from Ljubljana, Slovenia-based subsidiary MGC Derma (BD: Oct 20, 2017).
Later in October last year, MGC said it expected the first $1 million payment of an $8 million binding agreement from Varm Cosmo in November 2017 (BD: Oct 30, 2017).
In January 2018, MGC told the ASX it had not received the $1 million payment expected in November and that the delay in the receipt of the $1 million payment had been caused by "operational and logistics factors, including damage in transit to some of the bulk sample containers" (BD: Jan 21, 2018).
Today MGC said it would "seek a minimum of $500,000 from Varm Cosmo in restitution, plus damages to the company for Varm Cosmo repeatedly failing to deliver on its commercial obligations to MGC Derma for the production and supply of $8 million bulk cosmetics product purchase order, signed … in November 2017".
Separately, MGC requested a voluntary suspension, following its trading halt announced on September 21, 2018, pending "the release of an announcement regarding a material commercial transaction with a Canadian cannabis company" (BD: Sept 21, 2018).
MGC last traded at 4.8 cents.

PROBIOTEC

Probiotec says that 1,975,000 shares, held by an entity associated with the vendor of South Pack Laboratories, will be released from voluntary escrow on October 4, 2018.
Probiotec chief financial officer Jared Stringer told Biotech Daily that following the release of the shares, the company would have 61,854,356 shares available for trading, with a further 1,9750,000 shares held in voluntary escrow until October 4, 2019.
The company said the shares related to the 2017 acquisition of Sydney's South Pack for $8 million in cash and 7.9 million shares (BD: Sep 21, Oct 3, 2017)
Probiotec was up half a cent or 0.4 percent to $1.37.

BIOXYNE

Bioxyne says it has paid $121,000 for a 95 percent interest in the Jakarta, Indonesia-based PT Gamat Utama to market its food supplements and cosmetics.
Bioxyne said a further $44,000 would be payable to the direct sales company if “revenues from existing sales exceed $450,000 in the year following the date of acquisition”.
The company said it was required to capitalize the Indonesian company up to $900,000 to comply with Indonesian foreign investment regulations.
Bioxyne chief executive officer Nam Hoat Chua said PT Gamat Utama had “significant growth potential” and the acquisition was “a key milestone” in Bioxyne’s Asian strategy.
Bioxyne was up 0.2 cents or 5.4 percent to 3.9 cents.

SIMAVITA

Simavita has requested a trading halt “pending an announcement regarding a proposed placement to sophisticated and professional investors”.
Trading will resume on September 27, 2018 or on an earlier announcement.
Simavita last traded at three cents.

PHARMAXIS

Arix Bioscience says it has increased its substantial shareholding in Pharmaxis from 20,148,000 shares (5.6%) to 43,693,000 shares (11.1%).
The London-based Arix said it acquired the 23,545,000 shares for $7,652,125, or 32.5 cents a share, in last month’s placement which raised $24 million (BD: Aug 6, 2018).
Pharmaxis was unchanged at 31 cents.

NANOSONICS

JCP Investment Partners says it has reduced its substantial shareholding in Nanosonics from 18,446,857 shares (6.16%) to less than five percent.
The Melbourne-based JCP said that between August 16 and September 20, 2018 it bought and sold shares, but transferred out 4,530,818 shares for no payment.
JCP previously said its shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees, JP Morgan Nominees and UBS Nominees.
Nanosonics was up five cents or 1.6 percent to $3.16 with 4.5 million shares traded.

OSPREY MEDICAL

JCP Investment Partners says it has ceased its substantial shareholding in Osprey.
The Melbourne-based JCP said that between October 25, 2017 and September 20, 2018, it bought and sold shares, and transferred out 5,553,597 shares for no price.
Last year, the company said it became a substantial shareholder in Osprey with 17,401,322 shares or 5.13 percent (BD: Oct 27, 2017).
Osprey was up half a cent or 2.2 percent to 23 cents.