Biotech Daily

Wednesday July 18, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: REVA UP 23%; ITL DOWN 17%**

*** MESOBLAST CHINA CARDIAC MPC DEAL - $54m CASH, STOCK UPFRONT**

*** DORSAVI: STRYKER LEIBINGER EVALUATES VIMOVE2**

*** FEDERAL $50m FOR CANCER GENOME ANALYSES**

*** DIMERIX: ETHICS APPROVAL FOR 2 DMX-200, PHASE II TRIALS**

*** RACE WINS BISANTRENE FDA RARE PAEDIATRIC DISEASE DESIGNATION**

*** SIENNA REQUESTS CAPITAL RAISING TRADING HALT**

*** ANATARA TO PARTNER BROMELAIN GUT PRODUCT; ZOETIS DETAIL**

MARKET REPORT

The Australian stock market rebounded 0.67 percent on Wednesday July 18, 2018 with the ASX200 up 41.5 points to 6,245.1 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and two were untraded. All three Big Caps were up.

Reva was the best on no news, up five cents or 22.7 percent to 27 cents with 108,522 shares traded.

Mesoblast climbed 10 percent; Prescient was up 9.4 percent; Ellex improved 8.1 percent; Optiscan rose 6.7 percent; Avita was up 4.2 percent; Actinogen, Factor Therapeutics, Immutep, Osprey and Starpharma were up more than three percent; Volpara rose two percent; Cochlear, CSL, Neuren, Opthea, Pro Medicus and Resmed were up one percent or more; with Cynata and Sirtex up by less than one percent.

Yesterday's 34.3 percent best, ITL, led the falls, down four cents or 17.4 percent to 19 cents with 228,319 shares traded.

Telix lost 5.2 percent; Imugene fell four percent; Admedus, Impedimed, Oncosil and Prana shed two percent or more; with Airxpanders, Bionomics, Clinuvel, Dimerix and Medical Developments down one percent or more.

MESOBLAST

Mesoblast says it will receive $54 million on closing a strategic alliance with China's Tasly Group for cardiac indications for its mesenchymal precursor cells.

Mesoblast said that the Tianjin-based Tasly Pharmaceutical Group was "one of China's largest pharmaceutical companies" and the agreement covered the development, manufacture and commercialization in China of Mesoblast's allogeneic, or off-the-shelf, mesenchymal precursor cell (MPC) product candidates MPC-150-IM for the treatment or prevention of chronic heart failure and MPC-25-IC for the treatment or prevention of acute myocardial infarction.

In April, Mesoblast said it was approved to continue its phase III trial of MPC-150-IM for congestive heart failure (BD: Apr 18, 2018).

The company said at that time that its 159-patient phase II trial of MPC-150-IM for end-stage heart failure patients with a left ventricular assist device had completed enrolment with 12-month data expected by October 2018 (BD: Apr 18, 2018).

Today, Mesoblast said it would receive $US40 million ($A54 million) on closing the deal, comprising a $US20 million upfront technology access fee and $US20 million in Mesoblast shares at $1.86 a share, a 20 percent premium to a blended, volume-weighted average price calculated over three months, one month and one day.

The company said it would receive $US25 million on product regulatory approvals in China, double-digit escalating royalties on net product sales and would be eligible to receive six escalating milestone payments when the product candidates reached China sales thresholds.

Mesoblast said Tasly would have exclusive rights for China and fund all development, manufacturing and commercialization activities for MPC-150-IM and MPC-25-IC.

The company said that to expedite development and commercialization of the assets, the two companies would "leverage each other's clinical trial results" in China and the US and other major jurisdictions to support their respective regulatory submissions.

Tasly chairman Yan Kaijing said his company was "very excited to partner with Mesoblast, the premier cellular medicines company, to provide innovative products that have the potential to make a major impact on the high growth cardiovascular market in China".

"This aligns well with our corporate strategy to be the lead provider of therapies for patients with cardiovascular conditions in China," Mr Kaijing said.

Mesoblast chief executive Prof Silviu Itescu said that Tasly's "powerful combination of clinical, regulatory and manufacturing expertise, together with one of the largest commercial footprints in cardiology in China, makes it the ideal partner for Mesoblast and opens up the China market to our cardiovascular franchise".

Mesoblast said that the transaction was subject to governmental approvals from the People's Republic of China.

Mesoblast was up 16 cents or 10 percent to $1.76 with 5.9 million shares traded.

DORSAVI

Dorsavi says the Duisburg, Germany-based Stryker Leibinger Gmbh & Co Kg will evaluate its Vimove2 wearable sensors in a 12-month to 18-month trial.

Earlier this year, Dorsavi said it had signed an agreement with the Kalamazoo, Michigan-based Stryker Corp, the owner of Stryker Leibinger, to use Dorsavi's Visafe wearable sensor workplace assessment product (BD: Feb 22, 2018).

The company said the contract with Stryker was milestone-based and included a mutual right to terminate with 30 days' notice.

Dorsavi was unchanged at 11 cents.

FEDERAL GOVERNMENT

The Federal Government says it will provide $50 million for genomic analysis of rare and advanced stage cancers for patients with little or no treatment options available.
A media release from Federal Health Minister Greg Hunt said that the Australian Genomic Cancer Medicine Program would treat more than 5,000 patients with rare cancers and advanced stage cancers, including patients with ovarian cancer, pancreatic cancer, thyroid cancer, renal cell cancer and sarcomas.
The media release said that each patient would have their cancer tested through genomic sequencing “to work out how to target and destroy the cancer”.
The Government said the first clinical trials were expected to be held early next year, to provide evidence to support Pharmaceutical Benefits Scheme listing of the drugs being tested, with “thousands of other patients … able to benefit from this trial”, with patients able to access the trial in their own state or territory.
The media release said the result would be a tailored treatment based on the individual circumstances of the patient.
“This means we can find out what medicine might work for a particular cancer and then get it to the patient,” Mr Hunt said.
“Genomic testing will transform prevention, prediction, diagnosis and treatment of disease … [providing] precision medical care, targeting the unique genetic make-up of individuals,” Mr Hunt said.
“This is world-leading treatment and means each patient gets treated for their own individual cancer in their own home state or territory,” Mr Hunt said.
“This will save lives and protect some of our sickest Australians and … extend the lives of so many more, offering hope and delivering more time for so many families,” Mr Hunt said.
“I want to thank and acknowledge the support and strong advocacy of the program by [South Australia] Senator Stirling Griff,” Mr Hunt said.
The Federal Government media release said the Australian Genomic Cancer Medicine Program was a collaboration of eight cancer centres and three research institutes.
The Government said the $50 million contribution brought the total commitment to $160 million over five years.

DIMERIX

Dimerix says it has ethics approvals for two trials of DMX-200 for chronic kidney disease.
Dimerix said that it would conduct a 10-patient phase IIa trial of DMX-200 in patients with focal segmental glomerulosclerosis, with efficacy measured by the reduction of protein concentration in urine.
The company said that a 40-patient phase IIb trial would study the effects of DMX-200 on diabetic kidney disease, with the primary endpoint a change in the 24-hour albumin creatinine ratio compared to results from last year’s phase IIa trial (BD: Nov 2, 2017).
Dimerix said that both studies would be randomized, double blind and placebo-controlled, crossover studies.
The company said that patient recruitment was on track to begin by October 2018, with the director of the Gosford, New South Wales Renal Research private practice Prof Simon Roger as principal investigator (BD: May 7, 2018).
Dimerix said that preliminary data was expected for both studies by end of 2019.
Dimerix said the receipt of ethics approval triggered milestone C of the class C performance shares that were issued to Dimerix Bioscience vendors in 2015 and as a result 3,750,002 performance shares had converted to ordinary shares (BD: Jul 3, 2015).
Dimerix fell 0.1 cents or 1.05 percent to 9.4 cents.

RACE ONCOLOGY

Race says the US Food and Drug Administration has granted Bisantrene rare paediatric disease designation for paediatric acute myeloid leukaemia.
Race said the designation meant the FDA could further award Bisantrene a priority review voucher that would allow an accelerated six-month review of its drug approval application.
The company said it would need to conduct an FDA-approved trial in childhood leukaemia to be considered for the priority review voucher, but there was no guarantee of award.
Race said the voucher, once awarded, could be sold, with prices ranging between $150 million and $175 million and it would sell the voucher if it were awarded to Bisantrene.
Race chief executive officer Peter Molloy said the rare paediatric disease designation was "a game-changing outcome for Race that adds substantial value to the company."
"In parallel to the adult [acute myeloid leukaemia] program, we plan to expedite a paediatric program directed towards securing the [voucher]," Mr Molloy said.
Race closed up 4.5 cents or 29.0 percent to 20 cents with 1.4 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna has requested a trading halt "in connection with a proposed capital raise".
Trading will resume on July 20, 2018 or on an earlier announcement.
Sienna last traded at 5.1 cents.

ANATARA LIFESCIENCES

Anatara says it intends to develop a pineapple stem bromelain-derived dietary supplement for human gastro-intestinal disorders and licence the product.
Earlier this year, Anatara said it had signed a multi-million-dollar deal with animal health company Zoetis to licence its bromelain-derived Detach treatment for diarrhoea in livestock and horses (BD: May 15, 2018).
Today, Anatara said the deal with Zoetis comprised of an upfront payment of $US2.5 million ($A3.4 million) with aggregate milestone payments of up to $US6.3 million and royalties of three to four percent.
Anatara said its "gastro-intestinal reprogramming product", or Garp, was a dietary supplement for gut health that would treat disorders such as irritable bowel syndrome and inflammatory bowel disease.
Anatara chief development officer Dr Tracey Brown told Biotech Daily that the company would take the clinical formulation for humans through to pig efficacy trials and hoped to licence it as an over-the-counter dietary supplement to a partner.
Dr Brown said that the components of the potential product had US Food and Drug Administration generally regarded as safe (GRAS) status, with proof-of-concept studies planned ahead of pig efficacy studies expected in 2019.
An Anatara presentation said the product intended to re-establish homeostasis of the gut microbiome, treat inflammation associated with irritable bowel syndrome and inflammatory bowel disease and repair the mucosal damage, thereby reducing associated diarrhoea.
The company said it had $8.8 million in cash and funding was in place to progress the first human product through to an expected partner in 2020.
Anatara was up six cents or 9.2 percent to 71 cents.