Biotech Daily

Tuesday May 15, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GENETIC SIGS UP 14%; AIRXPANDERS DOWN 9%**

*** LIVING CELL: 'NTCELL LONG-TERM PARKINSON'S EFFICACY'**

*** ZOETIS LICENCES ANATARA DETACH FOR ANIMAL DIARRHOEA**

*** TGA APPROVES GENETIC SIGNATURES SUPERBUG TEST**

*** DIMERIX PREPARES FOR 2 PHASE II KIDNEY DISEASE TRIALS**

*** US BEST BUY TO STOCK NUHEARA IQBUDS BOOST**

*** RACE HIRES NOVOTECH FOR US BISANTRENE AML TRIAL**

*** MEDLAB NANABIS READY FOR CANCER PAIN TRIAL**

*** FACTOR RECEIVES $1.2m FEDERAL R&D TAX INCENTIVE**

*** UP TO 22% OF ELIXINOL OPPOSE DIRECTOR PERFORMANCE RIGHTS**

*** MERCHANT FUNDS REDUCES TO 6% OF POLYNOVO**

*** RACE APPOINTS DR SAMAR AL-BEHAISI CHIEF MEDICAL OFFICER**

*** ELLEX LOSES DIRECTOR DR MEERA VERMA, TO CONSULTANT**

*** SUDA APPOINTS DR NAILIN LI, DR RICHARD FRANKLIN SUD-018 ADVISORS**

*** INVICTUS: DR DOUGLAS KALMAN, DR SUSAN HEWLINGS ADVISORS**

*** MGC CEO ROBY ZOMER M-D, M-D NATIV SEGEV EXECUTIVE DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.61 percent on Tuesday May 15, 2018 with the ASX200 down 37.5 points to 6,097.8 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell and 12 traded unchanged.

Genetic Signatures was the best, up four cents or 13.8 percent to 33 cents with 101,812 shares traded. Immutep climbed four percent; both Benitec and Telix were up more than three percent; Actinogen, Impedimed, Opthea and Osprey rose more than two percent; Admedus was up 1.6 percent; with CSL, Sirtex and Starpharma up by less than one percent.

Airxpanders led the falls, down one cent or 8.7 percent to 10.5 cents with one million shares traded. Uscom lost 7.7 percent; Reva was down 6.9 percent; Clinuvel fell 4.8 percent; Cynata, Medical Developments and Volpara were down more than three percent; Factor Therapeutics, ITL, Mesoblast, Prana, Pro Medicus and Universal Biosensors shed two percent or more; Cochlear, Neuren and Pharmaxis were down more than one percent; with Cyclopharm, Resmed and Viralytics down by less than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says 12-month data from its 18-patient, phase IIb trial of NTCell for Parkinson's disease shows a "statistically significant improvement".

Last year, Living Cell said that its NTCell encapsulated pig choroid plexus brain cells, had no statistical significance for efficacy at 26 weeks post-implant, news that caused its share price to fall as much as 88.8 percent (BD: Nov 10, 2017).

In December, the company said that three-year data from its phase I/IIa trial of NTCell showed improvements in some patients, and that determining efficacy in the phase IIb trial would require longer than the 26-week follow-up (BD: Dec 21, 2017).

Today, the company said patients who last year had 40 or 80 NTCell capsules implanted to the putamen on both sides of the brain showed a "statistically significant" improvement according to the Unified Parkinson's Disease Rating Scale, but patients implanted with 120 NTCell capsules did not appear to have a significant improvement change.

Living Cell said the phase IIb study was designed "to confirm the most effective dose of NTCell, define any placebo component of the response and further identify the initial target Parkinson's disease patient sub-group".

Auckland City Hospital principal investigator Dr Barry Snow said the treatment was safe. "There are clinical signals of interest," Dr Snow said. "We need to continue to monitor patients for longer to examine the clinical significance of this efficacy data."

Living Cell chief executive officer Dr Ken Taylor said the company needed "to further analyze this encouraging result at future time points to assess NTCell as a potential treatment for Parkinson's disease".

Living Cell was up 0.4 cents or 16 percent to 2.9 cents with 17.0 million shares traded.

ANATARA LIFESCIENCES

Anatara says it has signed a multi-million-dollar exclusive agreement with animal health company Zoetis to licence its Detach for diarrhoea in livestock and horses.

Anatara said the value of the deal was undisclosed but it included an upfront payment, milestone payments and royalties based on product sales, with the intellectual property exclusively licenced to the Florham Park, New Jersey-based Zoetis, but remaining the sole property of Anatara.

Biotech Daily understands that the deal for the pineapple-stem, bromelain-based Detach non-antibiotic diarrhoea treatment could be worth millions of dollars in annual revenue.

In January 2017, Anatara announced its second undisclosed milestone payment from Zoetis, later filing an Appendix 4C quarterly report for the three months to March 31, 2017 citing $328,000 in "other commercial income" (BD: Jan 30, 2017).

In 2016, an Appendix 4C quarterly report for the three months to June 30, 2016 cited $2,283,000 in "receipts from customers" (BD: Jul 22, 2016).

Today, Anatara said Zoetis had the exclusive rights to develop, manufacture, distribute and market Detach worldwide, including in Australia.

Anatara executive chairman Dr Mel Bridges said that the agreement was "a major commercial milestone [and] an exciting moment for our shareholders".

"The global reach and resources that Zoetis is able to apply to making Detach a successful product is of great value to Anatara," Dr Bridges said.

In 2016, Anatara said it would develop Detach for human use and appointed former Alchemia chief scientific officer Dr Tracey Brown as chief development officer to oversee human trials of Detach for gastro-intestinal disease including irritable bowel syndrome, inflammatory bowel disease and travellers' diarrhoea (BD: Nov 22, 2016).

Anatara was up 17.5 cents or 12.1 percent to $1.62.

GENETIC SIGNATURES

Genetic Signatures says it has Australian Therapeutic Goods Administration approval for its Easyscreen kit for hospital acquired and antibiotic resistant pathogens detection.
In April, Genetic Signatures said that it had received Conformité Européenne (CE) mark approval for its Easyscreen extended spectrum beta-lactamase and carbapenemase producing organisms (Easyscreen ESBL & CPO) detection kit for hospital-acquired and antibiotic-resistant pathogens (BD: Apr 20, 2018).
Today, Genetic Signatures chief executive officer Dr John Melki told Biotech Daily that his company previously had approval for its Easyscreen Enteric kit for bacterial, viral and protozoan infections in both Australia and Europe.
In a media release to the ASX, the company said that the Easyscreen ESBL & CPO kit detected hospital superbugs or antibiotic resistant pathogens which were a significant global concern as standard treatments might be rendered ineffective and the kit allowed for “rapid detection in less than three hours with minimal hands-on time for laboratory technicians”.
Genetic Signatures said that the kit was designed “to provide rapid and accurate detection of 16 beta-lactam and carbapenem-resistant pathogen targets”.
Genetic Signatures was up four cents or 13.8 percent to 33 cents.

DIMERIX

Dimerix says it will run two separate phase II trials of DMX-200 for the chronic kidney diseases focal segmental glomerulosclerosis and diabetic kidney disease.
Dimerix said the 10-patient, phase IIa trial for focal segmental glomerulosclerosis (FSGS) would measure proteinuria reduction and run for 41 weeks.
The company said that the 40-patient, double-blind, placebo-controlled, phase IIb trial for diabetic kidney disease (DKD) would run for 31 weeks and measure changes in the 24-hour albumin creatinine ratio, based on responses from the company’s phase IIa trial for DMX-200 in which a subgroup of patients with DKD showed a “clinically and statistically” significant efficacy response, with their results promising enough to result in the follow-up trial (BD: Nov 2, 2017).
Dimerix said it had US orphan drug designation for its trial of FSGS, and that the phase IIa study was a previously planned trial which was part of the its plan to make DMX-200 phase III-ready for the orphan indication, which would then allow it to register the drug with fewer trials and patients.
Dimerix said the Durham, North Carolina-based Iqvia Institute for Human Data Science, formerly Quintiles and IMS Holdings, would provide trial services including clinical project management, data management, biostatistics and medical writing, as well as allow Dimerix access to its renal centre of excellence.
The company said the studies would investigate AT1R and CCR2 targets for inflammatory nephrosis with public hospital leadership from Prof David Power and the principal investigator to be Prof Simon Rogers (BD: May 7, 2018).
Dimerix said it expected to file ethics applications for both trials by July 2018, with recruitment to begin by October 2018 and that it would have preliminary data from the DKD trial by October 2019 and data from the FSGS trial by December 2019.
The company said the two trials would begin at the same time and would be run across the same sites with the same principal investigators and vendors.
Dimerix was unchanged at 11 cents.

NUHEARA

Nuheara says that the US-based consumer electronics retailer Best Buy will stock its Iqbuds Boost hearing devices in its new “senior technology assured living” category.
Nuheara said that the Richfield, Minnesota-based Best Buy selected Iqbuds Boost from a group of products for its hearing health benefits that addressed the more than 30 million people in the US who had mild to moderate hearing loss.
The company said that Best Buy had more than 1,500 shops and would launch the in-store senior technology category with 600 units of Boost in 15 targeted stores from June 11, 2018, with a view to expansion through 2018.
Nuheara chief executive officer Justin Miller said that the company was “delighted that our relationship with Best Buy has now extended to support their rapidly expanding senior technology category and that they have recognised the value of our game-changing hearing bud [products]”.
Nuheara was up 0.3 cents or 3.1 percent to 9.9 cents with 12.9 million shares traded.

RACE ONCOLOGY

Race says it has hired Sydney-based Novotech as the clinical research organization for the international trial of Bisantrene for acute myeloid leukaemia.
Race said the trial was expected to include US and potentially European sites, with the size and cost of the trial to be determined after discussions with the US Food and Drug Administration.
Race chief executive officer Peter Molloy said the agreement “signals that Race is now committed to proceeding with the clinical trial, which is intended to be the pivotal trial in support of US [Food and Drug Administration] approval of Bisantrene”.
Mr Molloy said that Bisantrene had been in more than 40 phase II clinical studies before it was “lost in a series of pharmaceutical mergers in the 1990s” and it had been approved in France for acute myeloid leukaemia in 1990 but not marketed, and that the company would use the French Autorisations Temporaires d’Utilisation (temporary authorisations for use) to allow named patient access (BD: Mar 16, 2017).
Race was unchanged at 28 cents.

MEDLAB CLINICAL

Medlab says it has completed the first shipment of its marijuana-based Nanabis to Royal North Shore Hospital for cancer pain trials (BD: Nov 7, 2016).
Medlab chief executive officer Dr Sean Hall said the shipment and site initiation was “what we have been working towards”.
“It’s a key milestone for the company, we have a validated [good manufacturing practice] Australian manufactured product that is being used in a robust and much-needed trial,” Dr Hall said.
“This trial will test the safety, efficacy and dose tolerance of cancer patients with both managed and unmanaged pain,” Dr Hall said.
Medlab said the trial was expected to run over the next few months, with data available later in the year.
Dr Hall said that the trial would “form the basis of a Nanabis drug application being put before the [Australian Therapeutic Goods Administration] and subsequent global regulatory agencies”.
Medlab was up 4.5 cents or 8.2 percent to 59.5 cents.

FACTOR THERAPEUTICS

Factor Therapeutics says it has received $1,226,202 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Factor said that the Federal R&D Tax Incentive refund related to expenditure in the six months to December 31, 2017 following the change in its financial year to December 31.
The company said the expenditure related to its phase IIb study of VF001 for venous leg ulcers which was “approaching completion of recruitment” (BD: May 14, 2018).
Factor Therapeutics fell 0.1 cents or 2.5 percent to 3.9 cents.

ELIXINOL GLOBAL

Up to 22 percent of Elixinol’s annual general meeting opposed the issue of performance share rights to chairman Andrew Duff and director Stratos Karousos.
The meeting results said 20.8 million votes (77.8%) supported the issue of up to 675,000 performance rights to Mr Duff and up to 300,000 performance share rights to Mr Karousos, with 5.9 million votes (22.0%) opposed and 0.2 percent at the proxy’s discretion.
Elixinol said the issue of up to 900,000 performance rights each to managing-director Linda McLeod and chief executive officer Paul Benhaim were passed overwhelmingly, as were the re-election of Mr Benhaim and approval of the remuneration report.
The company said the strongest opposition vote was against the additional share issue capacity with 16,984,460 votes (20.98%) opposed and 63,919,743 votes (78.94%) in favour, with 66,076 votes (0.08%) at the proxy’s discretion.
Elixinol’s most recent Appendix 3B new issue announcement said it had 102,928,540 shares on issue, meaning that the largest opposition vote amounted to 16.5 percent of the company, sufficient to requisition extraordinary general meetings.
Elixinol fell four cents or 2.4 percent to $1.65.

POLYNOVO

Merchant Funds Management says it has reduced its substantial shareholding in Polynovo from 50,000,000 shares (7.56%) to 38,999,960 shares (5.93%).
The Perth-based Merchant Capital said that between April 10 and May 14, 2018, it sold 11,000,040 shares for $5,504,222, or 50.0 cents a share.
Polynovo was unchanged at 54 cents with 1.1 million shares traded.

RACE ONCOLOGY

Race says it has appointed Swiss-based oncologist Dr Samar Al-Behaisi as chief medical officer and vice president of medical affairs, effective from May 16, 2018.
Race said Dr Al-Behaisi would ensure “effective execution of the Bisantrene clinical registration trial and bolster the named-patient program”.
The company said Dr Al-Behaisi would be scientific leader of the Bisantrene for acute myeloid leukaemia patient programs.
Race said that Dr Al-Behaisi held a Doctor of Medicine from Hungary’s University of Debrecen and a Doctorate of Philosophy from Budapest’s Semmelweis University.
The company said that Dr Al-Behaisi had worked for two Hungarian pharmaceutical companies as a clinical trial manager and medical advisor, before working with Novartis as oncology medical marketing manager.

ELLEX MEDICAL LASERS

Ellex says that director Dr Meera Verma has resigned for personal reasons, effective immediately.
Ellex said that Dr Verma also resigned from her positions as the executive director of the Core Laser and Ultrasound business
The company said that Dr Verma had been a non-executive director since 2013 and in 2017 agreed to assist the business in an executive capacity to assist in the transition of the chief executive officer Tom Spurling to the US.
Ellex said that Dr Verma had agreed to act as an advisor on an ongoing basis.
Ellex chairman Victor Previn said “the company thanks Meera for her service which she delivered with great energy and enthusiasm and wishes her all the best for the future”.
The company said it was “actively recruiting a new board member with global commercial experience and expects to make an appointment in the near future”.
Ellex was unchanged at 72 cents.

SUDA PHARMACEUTICALS

Suda says it has appointed Dr Nailin Li and Dr Richard Franklin to its scientific advisory board for SUD-018.
Suda said SUD-018 was a first-in-class, oral spray of the platelet-lowering drug anagrelide for the treatment of solid cancers.
The company said Dr Li held a Doctorate of Philosophy from Sweden’s Karolinska.
Suda said that Dr Franklin held a Doctorate of Philosophy from the UK’s Surrey University and had worked in research and development for Glaxo, Wyeth, Sterling Winthrop and Astrazeneca, as well as heading Shire Pharmaceuticals’ new product innovation department where he filed more than 40 drug patents.
Suda was unchanged at 1.2 cents.

INVICTUS BIOTECHNOLOGY

Invictus says it has appointed Dr Douglas Kalman and Dr Susan Hewlings as members of its scientific advisory board.
Invictus said that Dr Kalman was “an expert on claims substantiation for dietary supplements” and had been involved in more than 200 clinical trials and projects within the pharmaceutical, medical and nutrition fields.
The company said that Dr Hewlings held a Doctor of Philosophy in nutrition from Florida State University and specialized in “substantiation from study design to publication” with more than 15 years’ experience designing, supervising and conducting research in sports nutrition, dietary supplements and exercise physiology.
Invictus is a private company.

MGC (MEDICAL GRADE CANNABIS) PHARMA

MGC says that chief executive officer Roby Zomer has been appointed managing-director replacing Nativ Segev who has been appointed executive director and head of strategy.
MGC fell 0.1 cents or 1.4 percent to 7.2 cents with 4.9 million shares traded.