Biotech Daily

Tuesday June 13, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ATCOR UP 6%, AVITA DOWN 10%**

*** WEHI, PETER MAC COMBO FOR BRCA1 BREAST CANCER IN MICE**

*** PHARMAXIS HITS US BRONCHITOL CF ENDPOINT, MISSES OTHERS**

*** CSL TAKES $466m, 80% STAKE IN CHINA'S WUHAN RUIDE FOR PLASMA**

*** PROTEOMICS VALIDATION STUDY: 'PROMARKERD 86% ACCURATE'**

*** GARVAN'S GENOME ONE JOINS SANFORD FOR PERSONALIZED MEDICINE**

*** GI DYNAMICS ENDOBARRIER: 'WEIGHT, HBA1C DOWN 6 MONTHS LATER'**

*** PATRYS LICENCES YALE NANOPARTICLE, 3E10 LINK**

*** ESENSE, HEALTHY CHOCOLATE FLORIDA TERPENES FOR FOOD**

*** BVF PARTNERS, MARK LAMPERT SELL 12.5m VIRALYTICS SHARES TO 8%**

*** IDT LOSES FOUNDER DR GRAEME BLACKMAN, ADVISOR ROLE**

*** BIOXYNE APPOINTS NAM HOAT CHUA CEO, MAX PARKIN DIRECTOR**

*** MEDADVISOR APPOINTS DR DAVID CHATTERTON CTO**

MARKET REPORT

The Australian stock market climbed 1.67 percent on Tuesday June 13, 2017 with the ASX200 up 95.0 points to 5,772.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 22 fell and six traded unchanged. All three Big Caps were up.

Atcor was the best, up 0.2 cents or 5.7 percent to 3.7 cents with 207,428 shares traded. ITL and Prana climbed more than four percent; Compumedics and Impedimed improved more than three percent; Airxpanders, LBT, Pro Medicus, Starpharma and Universal Biosensors rose more than two percent; Cochlear and CSL were up more than one percent; with Cyclopharm, Nanosonics and Resmed up by less than one percent.

Avita led the falls, down 0.8 cents or 9.8 percent to 7.4 cents with 888,784 shares traded, followed by Viralytics down 9.05 percent to 95.5 cents with 1.65 million shares traded. Genetic Signatures lost 7.7 percent; Dimerix shed 6.25 percent; Opthea and Pharmaxis fell more than five percent; Actinogen, Living Cell, Mesoblast, Oncosil and Orthocell fell four percent or more; Factor Therapeutics, Osprey, Psivida and Reva lost three percent or more; Uscom shed 2.4 percent; Admedus, Bionomics and Medical Developments were down more than one percent; with Clinuvel, Ellex and Sirtex down less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

Walter and Eliza Hall Institute says that combining two immunotherapies could be effective in treating triple negative breast cancers in women with BRCA1 mutations.

WEHI said that working with Melbourne's Peter MacCallum Cancer Centre, researchers found that combining anti-PD1 and anti-CTLA4 immunotherapies with chemotherapy "halted the growth of BRCA1-related tumors and significantly improved survival in laboratory models".

The Institute said that some cancer cells survived by switching off immune cells that would otherwise destroy the tumors and the immune checkpoint inhibitors anti-PD1 and anti-CTLA4 immunotherapies released immune cells, enabling them to attack the tumor.

WEHI said the study's findings suggested that clinical trials of combined immunotherapies should be considered in women with BRCA1 mutation breast cancers.

The study, entitled 'Combined immune checkpoint blockade as a therapeutic strategy for BRCA1-mutated breast cancer' was published in Science Translational Medicine and the full article is available at: http://stm.sciencemag.org/content/9/393/eaal4922.full.

The Institute said the study was led by Dr Emma Nolan, Prof Geoff Lindeman, Dr Daniel Gray and Prof Jane Visvader, with the Peter MacCallum Cancer Centre's Prof Sherene Loi and Prof Phillip Darcy.

WEHI said that immunotherapy worked by boosting the body's immune cells to attack tumors and had been a game-changer for treating melanoma and lung cancers.

The Institute said that breast cancer affected one in eight women in Australia, with 15 percent of those having triple negative breast cancer, or about 2,400 women each year, with triple negative more common in women with BRCA1 mutations.

Prof Lindeman, a medical oncologist at the Royal Melbourne Hospital and Peter MacCallum Cancer Centre said that triple negative breast cancers were more aggressive and more likely to recur than other breast cancers.

"Triple negative breast cancers have not seen the same improvement in targeted therapies or survival as some other types of breast cancer," Prof Lindeman said.

"Our study showed that combining anti-PD1 and anti-CTLA4 immunotherapies with chemotherapy halted the growth of BRCA1-related tumors and significantly improved survival in laboratory models," Prof Lindeman said.

Dr Gray said that previous research had shown that immunotherapy was particularly effective at treating tumors that had accumulated many mutations.

"BRCA1-related triple negative breast cancers have some of the most chaotic genomes and we see many immune cells accumulate in and around the tumor," Dr Gray said.

"This suggests that the immune cells can readily detect that something is awry, but they aren't able to respond properly, because they have been disabled by tumor cells," Dr Gray said. "We showed that a combination of anti- PD1 and anti-CTLA4 therapies restored their ability to attack and kill triple negative breast tumor cells and very effectively control tumor growth," Dr Gray said.

Prof Loi said that work was underway to translate the findings from laboratory models of breast cancer into a clinical trial for women with the disease.

"Our lab-based findings provide compelling evidence to progress to a clinical trial of this combination of immunotherapy drugs, and chemotherapy, in women with BRCA1-related breast cancer," Prof Loi said. "There is also a rationale to consider the same for BRCA2-related cancers and triple negative breast cancer more broadly," Prof Loi said.

"Importantly, there are already a number of immunotherapy-based clinical trials underway in breast cancer and these two drugs, anti-PD1 and anti-CTLA4, are in use for other cancers, so we would hope to begin a trial of this specific combination of immunotherapies in suitable breast cancer patients in the near future," Prof Loi said.

PHARMAXIS

Pharmaxis says its 423-patient phase III trial of Bronchitol for cystic fibrosis met its primary endpoint, but other measures were not statistically significant.

Pharmaxis chief executive officer Gary Phillips said he believed the results of the US Food and Drug Administration-directed trial were "sufficient to underpin a resubmission of the Bronchitol new drug application to the FDA … in 2018".

The company said that the study demonstrated the superiority of Bronchitol (mannitol 400mg) compared to the comparator (mannitol 50mg) on the primary endpoint of forced expiration volume for one second (FEV1).

Pharmaxis said the change from baseline after 26 weeks treatment was 54ml ($p = 0.020$), which corresponded to a 2.2 percent relative change ($p = 0.025$).

The company said that the improvement in lung function was less than seen in the adult cystic fibrosis population in previously reported phase III studies.

Pharmaxis said that no statistically significant differences were recorded between treatment groups in secondary endpoints, although a trend was observed in favor of Bronchitol for forced vital capacity, the volume of air forcibly exhaled after full inspiration.

The company said that Bronchitol had a good safety profile with similar rates of adverse events seen compared to control.

Pharmaxis said that the 26-week, randomized, double-blind, parallel group, CF303 trial was designed in consultation with the FDA to gain marketing approval for Bronchitol for adult cystic fibrosis patients in the US and conducted in North and South America, Western and Eastern Europe and Australasia.

Mr Phillips said he was pleased the study met its primary endpoint despite the effect reduced relative to previous studies, Pharmaxis and its US partner Chiesi believed the results sufficient for a resubmission of the Bronchitol new drug application to the FDA.

"Incremental improvements in the standard of care for [cystic fibrosis] have resulted in longer life expectancy and adult patients now exceed 50 percent of the [cystic fibrosis] population in many countries," Mr Phillips said.

"Adult [cystic fibrosis] patients who experience deteriorating health or difficulty in complying with existing medications continue to require access to new treatment options and in this trial Bronchitol brought benefit to patients on top of their existing treatment regimen and had a good safety profile," Mr Phillips said.

In 2014, Pharmaxis said that the Parma, Italy-based Chiesi Farmaceutici SpA would fund up to $US22 million of a pivotal trial of Bronchitol for cystic fibrosis and distribute Bronchitol in the US (BD: Aug 4, 2014, Jan 18, 2015).

Pharmaxis said that Chiesi USA was responsible for completing and filing the updated Bronchitol FDA application.

Chiesi USA chief executive officer Ken McBean said "the conclusion of this key pivotal trial, conducted as a partnership between Pharmaxis and Chiesi [research and development] teams, provides a foundation for moving towards FDA approval, recognizing the challenge of the agency scrutiny of such assets".

Mr Phillips said that the aim "in assigning Bronchitol to distributers in existing markets, launching in new markets like Russia and partnering this study to gain access to the US market has been to manage our spend whilst increasing overall volumes".

"We believe the Bronchitol business segment based out of our manufacturing facility in Sydney will transition to profitability over the next 12 to 24 months irrespective of any approval in the US," Mr Phillips said.

"The cash that this will return will help fund Pharmaxis' drug discovery activities and the exciting pipeline of assets we have developed," Mr Phillips said.

Pharmaxis fell 1.5 cents or 5.7 percent to 25 cents.

CSL

CSL says it will acquire 80 percent of plasma therapies manufacturer Wuhan Zhong Yuan Rui De Biological Products Co from Humanwell Healthcare for $US352 million.

CSL said that the $A465.8 million transaction would provide “a strategic presence in the Chinese domestic plasma fractionation market” and complemented CSL Behring’s leadership as a 20-year provider of imported albumin in China.

The company said that the Wuhan, Central China-based based Wuhan Zhong Yuan Rui De Biological Products Co, known as Ruide, developed, manufactured and commercialized plasma-derived products for the Chinese domestic market, including albumin, immunoglobulin for intra-venous injection, as well as several hyperimmune immunoglobulin products.

CSL said that Ruide had a manufacturing facility and four plasma collection centres and an advanced pipeline of multiple coagulation factor products that it planned to launch, including plasma-derived factor VIII.

CSL chief executive officer Paul Perreault said that Humanwell was “a leading Chinese healthcare company with strong capabilities in pharmaceutical manufacturing, sales and distribution, as well as healthcare services”.

Mr Perreault said the expansion in China through Ruide supported the delivery of CSL’s promise “to save lives and protect the health of people around the world”.

Mr Perreault said that with Humanwell, CSL would work with local regulators and the sector to improve plasma safety and quality, as well as improve the donor experience.

CSL said that China’s plasma products market was more than $US3.3 billion in 2016, with a 15 percent growth rate for the past five years, with China the fastest growing immunoglobulin market in the world, and in volume, second only to the US.

The company said the agreement included a milestone-based performance and payment mechanism to increase its ownership in Ruide over time with the initial 80 percent stake expected to be finalized by the end of 2017 funded through existing debt facilities.

CSL was up $2.60 or 1.9 percent to $137.65 with 1.4 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its 792-patient validation study shows that the Promarkerd blood test “can predict the onset of diabetic kidney disease better than any current measure”.

Proteomics said the study findings were presented by the University of Western Australia Medical School’s Prof Tim Davis at the American Diabetes Association meeting in San Diego, California June 9 to 13, 2017.

The company said that the study was undertaken as a joint collaboration with the University of Western Australia and was “the largest prospective clinical study on diabetic kidney disease in the community”.

Proteomics said the results confirmed that Promarkerd predicted rapid decline in kidney function in type 2 diabetes, across clinically significant definitions of disease, independently of recognized clinical risk factors.

The company said that in the four-year prospective study, Promarkerd predicted 86 percent of previously disease-free patients who went on to develop chronic kidney disease with sensitivity of 86 percent and specificity of 78 percent.

Prof Davis said the data supported “the use of the protein biomarker panel in conjunction with estimated glomerular filtration rate in patients with type 2 diabetes to monitor and predict their decline in kidney function”.

Proteomics was up two cents or 10 percent to 22 cents.

GARVAN INSTITUTE OF MEDICAL RESEARCH

Sydney's Garvan Institute subsidiary Genome One says it has partnered with Sanford Health to develop a data capture platform to aid personalized health-care.
Genome One said the Sioux Falls, South Dakota-based Sandford Health would take the self-assessment platform to its network of US hospitals and clinics.
The company said the platform would translate information from patient questionnaires, clinical notes and other sources into a common language for analysis.
Genome One said its "self-phenotyping platform [would] link patient-provided data with the most up-to-date research and genetic knowledge".
Genome One chief executive officer Dr Marcel Dinger said the partnership would "enable integration of comprehensive patient information to unlock the benefits of advances in genetic knowledge for patients, such as diagnosis of rare diseases and uncovering treatments for previously untreatable conditions".
Dr Dinger said his company wanted to lead the integration of genomic information into health care.
Sanford executive director Dr Cornelius Boerkoel said the partnership formed "a crucial piece of its Imagenetics program".
"The self-phenotyping program will allow us to further integrate patient-generated and clinical data with genetic information," Dr Boerkoel said.
"The integration of data from many sources will help Sanford's primary care physicians provide the best care to our patients and will be critical in realising the benefits of genome-based personalized health care," Dr Boerkoel said.
Genome One said that the program collected patient data and translated it into machine-readable terms and providing access to more detailed, patient-specific information would improve clinicians' ability to tailor treatments and interventions, leading to better healthcare outcomes for the patient.

GI DYNAMICS

GI Dynamics says that 12-patient data shows its Endobarrier duodenal implant for obesity and type 2 diabetes has an impact at six months after removal.
GI Dynamics said that data from a UK National Health Service Endobarrier Registry presented at the American Diabetes Association meeting showed that average blood sugar HbA1c levels were reduced from 9.7 percent at baseline to 7.2 percent at 12 months when the Endobarrier was removed, rising to 7.7 percent six months later.
The company said that average total body weight fell from 117kg percent at baseline to 99kg at 12 months when the Endobarrier was removed, rising to 102kg six months later; body mass index was reduced from 42 at baseline to 35 at 12 months, and 36 six months later; and average insulin use of the nine subjects using insulin was reduced from 104 international units (iU) a day to 48iU at 12 months and 10iU at six months post-explant.
GI Dynamics said that three of nine patients discontinued insulin at month 12 and a fourth patient eliminated insulin use during the 6 months following explant.
The company said that the data was presented as a poster entitled 'Maintenance of Efficacy After Endobarrier in UK 1st National Health Service (NHS) Endobarrier Service' and detailed data from 12 patients at the first NHS Endobarrier service at City Hospital in Birmingham, UK.
City Hospital consultant Dr Robert Ryder said that "in addition to sustained weight loss, BMI reduction and glucose improvement, these patients self-reported considerable improvements in well-being, energy, fitness and exercise ability".
GI Dynamics fell 0.3 cents or 5.9 percent to 4.8 cents.

PATRYS

Patrys says it has licenced the rights to develop and commercialize technology linking the anti-DNA antibody 3E10 to nanoparticles from Yale University.

Last year, Patrys said it had acquired a licence to a Yale University-discovered portfolio of preclinical anti-DNA antibodies, fragments and variants that penetrated cell nuclei, with lead candidates the auto-antibodies known as 3E10, or Deoxymab, and 5C6, which had "the capacity to penetrate cancer cell nuclei, damage DNA, inhibit DNA repair and kill DNA repair-deficient cancer cells" (BD: Mar 29, 2016).

Today, the company said that nanoparticles could be loaded with standard chemotherapeutic or other drugs and had been shown to increase the efficacy of drug therapy in pre-clinical models.

Patrys said the new technology built on one of the attributes of 3E10, that it was attracted to the extracellular DNA associated with dying cancer cells.

The company said that using the targeting mechanism, the 3E10-nanoparticle conjugate was preferentially attracted to tumor tissues and delivered its payload, such as the chemotherapy, to where it was most needed.

Patrys said the action drove "a virtuous cycle" as increased cancer cell death attracted more of the conjugated 3E10-nanpoparticle to the tumor and enhanced treatment efficacy in animal models.

The company said that the 3E10-nanoparticle conjugation intellectual property was the subject of a patent application filed by Yale University and patent protection if granted would extend to 2036.

Patrys chief executive officer Dr James Campbell said the licence was "a logical progression for Patrys, building on the significant progress we have made with Deoxymab 3E10 over the past year".

Dr Campbell said the company was attracted "to the potential of the 3E10-nanoparticle conjugates to drive our core mission of developing enhanced cancer therapeutics and see broader partnership potential in a range of other indications".

Patrys said that lead candidate PAB-DX1 was in pre-clinical trials with data expected by October 2017.

The company said that development of the 3E10-nanoparticle conjugates would be incorporated into the existing research and development agreement between Patrys and Yale University and the researchers would begin efforts to conjugate PAB-DX1 to nanoparticles to determine effectiveness.

Patrys was unchanged at 0.6 cents with four million shares traded.

ESENSE-LAB

Esense says it has a memorandum of understanding with food manufacturer Healthy Chocolate Florida for terpene and chocolate dietary supplements.

Esense said that the Sarasota, Florida-based Healthy Chocolate Florida was "a specialty nutrition, chocolate and chocolate based nutritional supplements manufacturing and marketing company with in-house [research and development] capabilities to develop wellness, 4-No-Guilt branded products as well as white labelled products".

The company said it would collaborate with Healthy Chocolate Florida in the development and marketing of terpene and chocolate based controlled dietary supplements.

Esense said its terpenes were organic compounds found in plants responsible for flavor and fragrance, along with health and medical benefits.

Esense was unchanged at 28.5 cents.

VIRALYTICS

BVF Partners and Mark Lampert say they have reduced their substantial holding in Viralytics from 32,568,321 shares (13.55%) to 20,007,902 shares (8.32%).
Last year, BVF and Mark Lampert said they had reduced their holding in Viralytics from 34,604,778 shares (14.58%) to 32,568,321 shares (13.55%) (BD: Nov 18, 2016).
Today, The San Francisco, California-based BVF Partners and Mr Lampert said they bought sold the shares between November 17, 2016 and June 12, 2017 in 43 separate trades, with the single largest disposal 4,454,740 shares for $4,677,477 or $1.05 a share.
In 2015, BVF acquired 11,032, 845 shares when Viralytics was trading around 60 to 65 cents and in 2014, BVF acquired 2,000,000 shares on-market for $600,000 or 30 cents a share (BD: Nov 28, 2014; Jan 25, 2016)
Viralytics fell 9.5 cents or 9.05 percent to 95.5 cents with 1.65 million shares traded.

IDT AUSTRALIA

IDT says that founder Dr Graeme Blackman retired on June 9, 2017 but remains an advisor to the company.
IDT said it was founded as the Institute of Drug Technology in 1975 by the Pharmaceutical Society of Victoria and the Victorian College of Pharmacy.
The company said that in 1986, the College's professor of pharmaceutical chemistry Dr Blackman acquired the business as a spin-out of the drug development services unit of the College.
IDT said it moved to its current home in Boronia, in Melbourne's Eastern suburbs and listed on the ASX in 1988.
The company said that it developed and marketed active pharmaceutical ingredients specializing in difficult and complex to manufacture drugs and remained the only commercial scale supplier of these in Australia.
IDT said that Dr Blackman had resigned "due to the growing demands of his positions as the chair of industry organization Leading Aged Services Australia, as well as other philanthropic board and trustee roles.
IDT fell 0.2 cents or 2.1 percent to 9.3 cents.

BIOXYNE

Bioxyne says it has appointed Nam Hoat Chua as its chief executive officer and director, with Maxwell Parkin appointed as an executive director.
In April, Bioxyne said it would raise $3,064,350 to acquire companies to sell products in Asia, with Mr Chua to be appointed chief executive officer (BD: Apr 19, May 29, 2017).
Today, Bioxyne said that Mr Chua was previously New Image Asia-Pacific vice-president for more than 10 years and began his direct sales career in 1985 when he launched First Image Sdn Bhd in Malaysia.
The company said that Mr Chua was fluent in Malay, Indonesian, Mandarin and several other Chinese dialects and held a Bachelor of Arts from the University of Toronto.
Bioxyne said Mr Parkin had more than 35 years' experience of dairy management and consulting experience in New Zealand, Australia, China and South East Asia Pacific, the Americas, Africa and the Middle East and was formerly Fonterra's manufacturing group general manager and served on the board of the New Zealand Dairy Research Institute.
The company said that Mr Parkin was a former director of New Image and was currently a director of Miraka and chairman of Combined Technologies.
Bioxyne was up 0.3 cents or 17.65 percent to two cents with 1.5 million shares traded.

MEDADVISOR

Medadvisor says it has appointed Dr David Chatterton as its chief technology officer.
Medadvisor said that Dr Chatterton had experience leading global software development operations and had spent nearly twenty years working across software and hardware development projects, responsible for the implementation and growth of multiple technology platforms.
The company said that most recently Dr Chatterton was Aconex' chief information officer and previously was the company's chief technology officer.
Medadvisor was unchanged at three cents.