Biotech Daily

Tuesday January 27, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: RESMED UP 7%, GENETIC TECHNO DOWN 14%**

*** PRIMA'S IMMUTEP EARNS '$1m-PLUS' GSK MILESTONE**

*** FINLAND, LUXEMBOURG APPROVE PSIVIDA'S ILUVIEN**

*** BIOTECH WINS 4 OF 10 FEDERAL 'RESEARCH CONNECTIONS' GRANTS**

*** VIRALYTICS BEGINS CAVATAK BLADDER CANCER TRIAL**

*** BRAIN RESOURCE PREPARING FDA DEPRESSION TEST APPLICATION**

*** CHINA RE-REGISTERS USCOM 1A MONITOR**

*** AUSBIOTECH: QUEENSLAND LNP PROMISES $90m FUND IF RE-ELECTED**

MARKET REPORT

The Australian stock market climbed 0.83 percent on Tuesday January 27, 2015 with the S&P ASX 200 up 45.4 points to 5,547.2 points.

Ten of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and two were untraded. All three Big Caps were up.

Resmed was the best, up 58 cents or 7.4 percent to $8.38 with 45.6 million shares traded.

Impedimed and Prima climbed more than six percent; Acrux and Ellex rose more than five percent; Biotron was up 4.2 percent; Optiscan and Tissue Therapies were up more than three percent; Cochlear and Psivida were up more than two percent; Antisense and CSL were up more than one percent; with Mesoblast up 0.25 percent.

Genetic Technologies led the falls, down 0.2 cents or 14.3 percent to 1.2 cents with 1.2 million shares traded.

Pharmaxis and Starpharma fell more than seven percent; Benitec was down 5.45 percent; Admedus and Anteo fell four percent or more; Bionomics, IDT, Phosphagenics and Viralytics were down more than three percent; GI Dynamics, Nanosonics, Osprey and Prana shed two percent or more; Avita, Clinuvel and Universal Biosensors were down more than one percent; with Sirtex down one cent or 0.04 percent.

PRIMA BIOMED

Prima says that through its Immutep acquisition, it will earn a “single digit million dollar” payment from Glaxosmithkline for the first patient dosed with an anti-LAG-3 antibody.
Last year, Prima acquired Immutep for its cancer immuno-therapies based on its lymphocyte activation gene 3 (LAG-3) technology (BD: Oct 2, Dec 17, 2014).
Today, Prima said that Glaxosmithkline had licenced the development rights to the IMP731 antibody technology from Immutep in December 2010.
The company said that GSK2831781 was an anti-LAG3 antibody derived from IMP731 and both IMP731 and GSK2831781 were designed to specifically deplete potentially pathogenic, recently activated LAG-3 expressing T-cells which were enriched at the disease site in T-cell driven immuno-inflammatory disorders, while sparing other T-cells which might be necessary for other functions.
Prima said that Glaxosmithkline had dosed the first subject in its phase I, first-in-human clinical trial of GSK2831781 for the treatment of the autoimmune disease plaque psoriasis.
Prima chief executive officer Marc Voigt said that the start of the phase I trial was a significant milestone.
“The first subject dosing in the phase I trial triggers an undisclosed single digit million dollar financial milestone payment to Immutep,” Mr Voigt said.
“The partnership with GSK gives rise to significant further potential milestone payments as well as additional royalties,” Mr Voig said.
He said that Glaxosmithkline had responsibility for all development and associated costs for GSK2831781 and that Immutep had received an upfront payment and potential future milestones worth up to GBP64 million ($A121.8 million) and was eligible for single-digit, tiered royalties if all objectives were achieved.
Prima said that the first milestone payment from Glaxosmithkline triggered a milestone payment to the sellers of Immutep, as part consideration for the acquisition.
The company said that Glaxosmithkline’s 63-subject, double-blind, phase I trial would investigate the safety, tolerability and pharmacokinetics of GSK2831781 for plaque psoriasis.
Prima was up 0.2 cents or 6.1 percent to 3.5 cents with 2.8 million shares traded.

PSIVIDA

Psivida says that Finland and Luxembourg have granted marketing authorization for Iluvien for vision impairment associated with chronic diabetic macular oedema.
Psivida said that 15 European Union countries had approved the Alimera Sciences-licenced Iluvien, with two more EU approvals pending.
The company said that Iluvien was expected to begin US sales by April, 2015, where it was indicated for diabetic macular oedema patients previously treated with a course of corticosteroids who did not have a clinically significant rise in intraocular pressure, a broader indication than that approved for Europe.
Psivida chief executive officer Dr Paul Ashton said the company was “pleased with the marketing approvals for Iluvien in the EU and we very much look forward to its introduction in the US”.
“We are entitled to 20 percent of net profits from sales of Iluvien by its licencee on a country-by-country, quarter-by-quarter basis,” Dr Ashton said.
“Iluvien provides retinal doctors a new treatment to help patients with [diabetic macular oedema], which can often cause significant vision loss and greatly affect quality of life for patients,” Dr Ashton said.
Psivida was up 11 cents or 2.2 percent to $5.10.

FEDERAL GOVERNMENT

The Federal Government has awarded four biotechnology companies including Sirtex and Immuron, up to $50,000 each in its Research Connections' program.

A media release from the Federal Industry and Science Minister Ian Macfarlane said the grants were part of "the Government's $484.2 million Entrepreneurs' Infrastructure Program".

The media release said that Sirtex would work receive $49,886.50 to work with the University of Sydney on a $99,773 project to diversify into new treatments based on early-stage research developed from its liver cancer treatment, through the optimization and application of ultra-small super-para-magnetic iron oxide nano-particles for cell tracking.

"Research Connections helps small and medium business collaborate with researchers to develop new ideas with commercial potential and is an essential element of helping Australian industry to become more productive and competitive," Mr Macfarlane said.

"Research Connections facilitators are assisting businesses like Sirtex identify critical and strategic research needs and opportunities, then provide pathways for researcher-business cooperation and engagement on new products and processes," Mr Macfarlane said.

"Sirtex has a track record in innovation through its world-leading technology that delivers radiation therapy for terminally ill liver cancer patients," Mr Macfarlane said.

"While it isn't a cure for cancer, its small-particle technology extends lives through increasing tumor shrinkage and remission in patients," Mr Macfarlane said.

"Research has raised the possibility of applying this nano-particle technology to treating brain cancer, in ophthalmology and in stem cell science," Mr Macfarlane said.

Sirtex head of research and development Dr Steve Jones said that Research Connections assistance would offset concerns about the early-stage, high-risk nature of the research.

"The funding through Research Connections will help get our research moving forward, and that is extremely useful for us, because it's one thing having this fantastic product, but another to have a commercially viable application for it," Dr Jones said.

"We have quite an extensive R&D program, and we collaborate as much as possible with external universities and high profile research organizations rather than trying to do everything in-house," Dr Jones said.

Sirtex spokesman Tom Duthy told Biotech Daily the project was separate to the company's work on SIR-Spheres microspheres for liver cancer.

Mr Duthy said that Sirtex was investigating the utility of incorporating magnetic non-particles for potential uses in imaging or the treatment of particular cancers, such as brain cancer.

The Federal Government said that Immuron would receive $50,000 to work with Monash University on a $103,101 project on non-antibiotic strategies to manage the incidence, severity and recurrence of Clostridium difficile gut disease.

Former Xceed Capital subsidiary Boron Molecular was awarded $50,000 for a $149,656 program with the Commonwealth Scientific and Industrial Research Organisation on flow technology for large scale synthesis of pinacolborane, a building block in the manufacture of boronic acids.

In 2011 Xceed Capital sold Boron Molecular to the Melbourne-based Welvic for $1.5 million (BD: Jan 16, Feb 9, 2011).

The Federal Government media release said that Marinova Pty Ltd would receive $50,000 for a $100,000 project with the University of Tasmania to evaluate the effectiveness of its Maritech Synergy algae extracts in normalizing the inflammation of the gut.

Details of the 10 recipients is available at www.business.gov.au/RCGrants.

VIRALYTICS

Viralytics says it has begun its phase I, UK clinical trial of Cavatak in up to 40 patients with non-muscle invasive bladder cancer, also known as superficial bladder cancer.
Viralytics said that the Cavatak in non-muscle invasive bladder cancer (Canon) study was a two-part, open-label, dose-escalation study.
The company said that the first stage of the trial would evaluate Cavatak delivered as a monotherapy via a catheter directly into the bladder and the second stage would examine Cavatak given in conjunction with mitomycin C by the same route of administration, with a goal of demonstrating safety and tolerability, and establishing a recommended phase II dosing regimen for the combination therapy.
The company said that Cavatak would be given prior to standard therapy, to patients who were scheduled to undergo trans-urethral resection to treat their disease.
Viralytics said that the trial was designed to evaluate the safety and tolerability of Cavatak administered alone directly into the bladder, as well as in combination with the standard chemotherapy, mitomycin C and assess the pharmacodynamics of Cavatak and document evidence of anti-tumor activity.
The company said that Cavatak was an investigational cancer immunotherapy based on the Coxsackievirus type A21 cold virus that had been shown to preferentially infect and attack cancer cells and in preclinical studies, Cavatak and mitomycin C synergistically increased cancer-killing activity in bladder cancer cell lines.
University of Surrey Cancer Research Institute director and principal investigator said Prof Hardev Pandha said there was “a real need for new therapies for bladder cancer that will improve the durability of response and reduce toxicities compared to current treatments”.
“Based on the promising preclinical performance of Cavatak in our studies, we are keen to explore this novel treatment in human trials,” Prof Pandha said.
Viralytics managing director Dr Malcolm McColl said that with the start of the trial the company had clinical trials underway “across a range of significant cancer indications and by several routes of administration”.
The company said that bladder cancer was the sixth most common cancer type in the US.
Viralytics fell one cent or 3.2 percent to 30.5 cents.

BRAIN RESOURCE

Brain Resource says that following a meeting with the US Food and Drug Administration it will be ready to complete its depression treatment test submission in “the coming months”.
Brain said it appeared to be in agreement with the FDA in regard to the outstanding statistical analysis issues, which were the focus of this meeting.
The company said the depression treatment test was the first to be submitted to the FDA and if cleared for marketing in the US, it would service a very large unmet need.
Brain said that depression was among the most costly burden on health budgets and workplace productivity, costing more than $100 billion.
The company said that medication was prescribed on a trial-and-error basis and the test was the first objective test to predict treatment response to escitalopram, sertraline and venlafaxine-XR, three of the most commonly used anti-depressant medications.
Brain said the computerized battery of tests assessed cognition and a predictor model that used the inputs to generate recommendations of likely or not likely to remit or no recommendation for each drug.
The company said that the clinically useful, minimal risk, low cost test was scalable to address the need in the 85 million a year US clinical visits for depression.
Brain Resource was up 6.5 cents or 30.2 percent to 28 cents.

USCOM

Uscom says the Chinese Food and Drug Administration has re-registered the Uscom 1A ultra-sonic cardiac output monitor, allowing its sale in China.

Uscom said the Uscom 1A previously had CFDA registration, but the new registration was attained under a process involving strict examination, resulting in the Uscom 1A being reclassified as a Class II device and the new registration valid for five years rather than the prior three years.

Uscom executive chairman Dr Rob Phillips said that the Chinese had been early users of Uscom technology, leading the way in adoption of advanced haemodynamics practices.

"We conduct education, training and certification courses throughout China and Chinese sales contribute a significant and growing component of our global revenue," Dr Phillips said.

Dr Phillips said the company was undertaking the approval process for the BP+ central blood pressure monitor so that distributor China Pioneer Pharma could begin BP+ sales.

Uscom was unchanged at 20 cents.

AUSBIOTECH, QUEENSLAND LIBERAL NATIONAL PARTY

With four days to the Queensland State Election, Ausbiotech says Premier Campbell Newman has promised a $90 million Research to Reality Fund if re-elected.

A Queensland Liberal National Party media officer confirmed to Biotech Daily that the policy to provide $90 million over three years was released on January 18, 2015.

The Ausbiotech media release said that the Queensland Government also announced a $500 million Entrepreneurial and Innovation Fund to provide long term-funding for innovation and start-up sector.

Ausbiotech said that the Fund would join the Federal Government's Medical Research Future Fund as long-sighted, nation-building asset for Australia's future.

Dr Anna Lavelle said that the industry organization "welcomes these outstanding and significant examples to support the growing emphasis on translating our world-class research into practical outcomes that improve economic productivity, create jobs and improve and extend the lives and wellbeing of Australians".

Ausbiotech said that while the details of the Medical Research Future Fund "are still in development, Ausbiotech has written to the Health Minister this week recommending that at least 10 percent of the principal be dedicated to a rolling Translational Biotech Fund, providing a consistent and predictable resource for earlier stage life science companies".

Biotech Daily has been told that to date no planning or work has been done to create the Medical Research Future Fund, which was dependent on the Federal Government's rejected Medicare levy.