Biotech Daily

Tuesday May 6, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ATCOR UP 8%, BENITEC DOWN 9%**

*** FDA ALLOWS TEVA (CHEMGENEX) SYNRIBO FOR HOME USE**

*** GI DYNAMICS, GSK: 'BILE ACID ENDOBARRIER METHOD OF ACTION'**

*** CLINUVEL STARTS SINGAPORE PHASE II SCENESSE FOR VITILIGO TRIAL**

*** CIRCADIAN: 'OPT-302 INHIBITS WET AMD IN MICE'**

*** PSIVIDA'S TETHADUR SUSTAINED DELIVERY OF ANTIBODIES**

*** PRIMA PROVIDES OVARIAN, PANCREATIC CANCER TIMELINES**

*** ANTISENSE AIMS FOR NEW ATL1102 MS TRIAL IN 2015**

MARKET REPORT

The Australian stock market was up 0.35 percent on Tuesday May 6, 2014 with the S&P ASX 200 up 19.2 points to 5,481.4 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 10 fell, 11 traded unchanged and four were untraded. All three Big Caps were up.

Atcor was the best, up one cent or 8.3 percent to 13 cents with 81,296 shares traded.

Osprey climbed six percent; Circadian was up 5.9 percent; Acrux, Pharmaxis and Psivida rose more than four percent; Bionomics, Oncosil, Tissue Therapies and Viralytics were up more than three percent; Anteo and Sirtex rose more than two percent; CSL, Resmed and Starpharma were up more than one percent; with Cochlear, Mesoblast and Nanosonics up by less than one percent.

Benitec led the falls, down nine cents or 9.1 percent to 90 cents with 1.05 million shares traded.

Uscom lost 7.1 percent; Antisense and GI Dynamics fell more than three percent; Biotron, Living Cell and Optiscan shed more than two percent; with Alchemia, IDT and Phosphagenics down more than one percent.

TEVA PHARMACEUTICAL INDUSTRIES (FORMERLY CHEMGENEX, CEPHALON)

Teva says the US Food and Drug Administration has approved Synribo for subcutaneous injection, including home administration, and a related medication guide and instructions.
In February, the US Food and Drug Administration granted full approval for Synribo for injection for chronic myeloid leukemia (BD: Feb 14, 2014).
Chemgenex developed omacetaxine mepesuccinate, then known as Omapro, for chronic myeloid leukemia, until the company was acquired by Cephalon, shortly before Teva acquired Cephalon (BD: Oct 22, 2010; May 3, Jun 1, 2011).
In 2012, the FDA approved Synribo under an “accelerated approval program”, based on clinical data showing the drug had an effect on a surrogate endpoint that was reasonably likely to predict a clinical benefit to patients (BD: Dec 5, 2012).
Today, Teva said that the approval meant that physicians who treated adults with chronic or accelerated phase chronic myeloid leukemia, who were no longer responding to, or who could not tolerate, two or more tyrosine kinase inhibitors would have the option to allow their patients to administer Synribo therapy at home.
Teva said it was finalizing a comprehensive specialty pharmacy support program which will help facilitate successful home administration of Synribo.

GI DYNAMICS

GI Dynamics says a study with Glaxosmithkline showing its Endobarrier liner increases bile acids may point to its method of action for obesity and type 2 diabetes.
GI Dynamics said the study, entitled ‘Duodenal-jejunal Bypass Liner Increases Fasting and Postprandial Serum Levels of Bile Acids in Patients with Severe Obesity’ was presented at Digestive Disease Week in Chicago.
GI Dynamics chief medical officer Dr David Maggs said his company formed an association with Glaxosmithkline “to better understand the mechanism of action of the Endobarrier and related hormonal and metabolic changes”.
“The increased level of bile acids we observed suggest that there may be a similar mechanism of action associated with Endobarrier in the treatment of obesity and diabetes to that observed with gastric bypass,” Dr Maggs said.
“This mechanism may be the driver of the significant weight loss and glucose stabilization seen in patients treated with Endobarrier,” Dr Maggs said.
GI Dynamics said that increased post-operative levels of bile acids might be tied to the effectiveness of the common gastric bypass surgery, Roux-en-Y gastric bypass.
The company said that to better understand the method of action of the Endobarrier and how it might mimic Roux-en-Y gastric bypass, the study authors evaluated bile acid levels in 17 patients with severe obesity, with and without type 2 diabetes.
GI Dynamics said that the findings showed that after 52 weeks of treatment with Endobarrier, a 16 percent total body weight loss was accompanied by fasting total bile acid levels more than two-fold higher than those observed at baseline ($p < 0.05$); and following a standard test meal, nutrient-stimulated levels of total bile acids were also increased by 70 percent ($p < 0.05$).
Glaxosmithkline head of endocrine biology Dr Andrew Young said the findings “show that Endobarrier induced significant changes in the level of bile acids, which play a known role in the regulation of energy and glucose homeostasis”.
“These data offer the beginning of a mechanistic explanation for the robust effects on body weight seen with Endobarrier and support the continued investigation of Endobarrier in patients with type 2 diabetes and obesity,” Dr Young said.
GI Dynamics fell two cents or 3.8 percent to 51 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has begun recruitment in a 60-patient, Singapore phase II study of Scenesse (afamelanotide 16mg implant) for vitiligo.
Clinuvel said that the CUV103 study was a seven month, double-blind, placebo-controlled trial at Singapore's National Skin Centre and would evaluate Scenesse as a combination treatment with narrowband ultraviolet B phototherapy.
The company said that patients would be randomized into two treatment arms to receive either Scenesse or placebo implants every 28 days and all patients would be administered narrowband ultraviolet B phototherapy twice weekly.
Clinuvel said that assessment would include re-pigmentation, time to re-pigmentation, standardized digital photography, quality of life questionnaires and investigator and patient statements, with a three-month follow-up period to assess the maintenance, or stability, of pigmentation achieved.
Clinuvel said the study aimed to confirm results from an earlier, US phase IIa study of Scenesse in vitiligo, which showed that the combination of Scenesse and narrowband ultraviolet B phototherapy therapy provided greater and faster re-pigmentation in vitiligo patients compared to narrowband ultraviolet B phototherapy alone.
Clinuvel was unchanged at $1.60.

CIRCADIAN TECHNOLOGIES

Circadian says OPT-302, formerly VGX-300, inhibits hallmarks of wet age-related macular oedema progression in a laser-induced model of the disease in mice.
Circadian said that OPT-302 was soluble form of vascular endothelial growth factor receptor-3 being developed through wholly-owned subsidiary Opthea Pty Ltd.
The company said that data on age-related macular oedema (AMD) was presented at the Association for Research in Vision and Ophthalmology meeting in Orlando, Florida by collaborator Schepens Eye Research Institute's Dr Kameran Lashkari.
Circadian said that the poster presentation entitled 'VEGF-C and VEGF-D blockade by VGX-300 inhibits choroidal neovascularisation and leakage in a mouse model of wet AMD' showed that OPT-302 could inhibit the formation of wet age-related macular oedema lesions in mice when administered at the onset of the disease.
The company said that OPT-302 effectively reduced the size and leakage of vessels to a comparable extent as the marketed agent Eylea and reduced ocular inflammation.
Circadian said that Eylea had a distinct mechanism of action from OPT-302, blocking vascular endothelial growth factor-A (VEGF-A), but not VEGF-C and VEGF-D.
The company said that sales of Eylea in the US for the treatment of wet AMD, were $US1.4 billion in 2013.
Circadian said that wet AMD was the leading cause of blindness for people over the age of 50 years in the US and Europe and affected more than 1.5 million people globally, but more than 45 percent of patients had some degree of resistance to anti-VEGF-A therapy.
Dr Lashkari said that current therapies for wet AMD targetted VEGF-A but there was an unmet medical need for improved treatments.
"The current data indicates that VEGF-C is important in wet AMD and that administration of OPT-302 to mice with established lesions ... can reduce disease burden," Dr Lashkari said.
Circadian chief executive officer Dr Megan Baldwin said that OPT-302 had "the potential to improve vision in patients either when used alone, or as an adjunct therapy with existing anti-VEGF-A therapies and the company hoped to begin clinical trials by July 2015.
Circadian was up one cent or 5.9 percent to 18 cents.

PSIVIDA CORP

Psivida says the first peer-reviewed preclinical data demonstrates the use of its Bio-silicon Tethadur delivery technology to provide sustained release of Avastin.
Psivida said the data was presented at the Association for Research in Vision and Ophthalmology meeting in Orlando, Florida May 4 to 8, 2014 by researcher Dr Dinesh Nadarassan in a poster entitled 'Sustained Release of Bevacizumab (Avastin) from Biosilicon'.
Psivida said that the data from the study evaluating the effect of pore size in Tethadur on Avastin release over a period of three weeks concluded that long-term sustained release of antibodies such as Avastin was achievable with Tethadur and the release of the antibodies was controllable over a wide range by adjusting the pore size and surface area of Tethadur.
Psivida chief executive officer Dr Paul Ashton said that "the implications of the ability to control the duration of sustained delivery of antibodies through pore size are significant".
"By varying pore size, we believe the release rate of antibodies loaded into Tethadur can be controlled, which could permit sustained delivery of antibodies that currently must be delivered by frequent injections," Dr Ashton said.
"For example, Avastin and the two of the top-selling [vascular endothelial growth factor-F] ophthalmic drugs today are injected as frequently as once a month," Dr Ashton said.
Psivida said that Tethadur was designed to provide sustained delivery of large biologic molecules, including peptides, proteins and antibodies.
The company said that its Biosilicon technology used a fully-erodible, honeycomb structure of nano-porous, elemental silicon to provide sustained delivery of therapeutics.
Psivida was up 18 cents or 4.7 percent to $4.00.

PRIMA BIOMED

Prima expects to complete recruitment for its re-started European phase II CVac ovarian cancer trial by mid-2015 with results by the end of 2016.
In a quarterly investor teleconference, Prima chief executive officer Matt Lehman said that the original CAN-004 trial was stopped in 2013 and the amended trial would be known as CAN-004b.
Last year, Prima halted the trial and changed the primary endpoint from progression-free survival to overall survival (BD: Sep 19, Nov 7, 2013).
Today, Mr Lehman said the 210-patient trial would only recruit patients in Europe, whereas the original trial was Europe, Australia and the US.
Mr Lehman said that it would take about one year to recruit all the patients to the trial and full results should be available by the end of 2016.
He said that there would be interim reporting on the secondary endpoint of progression-free survival and earlier overall survival data.
Mr Lehman said that final progression-free survival data from the CAN-003 trial, which led to the change in endpoint for the CAN-004 trial would be presented at American Society of Clinical Oncology meeting in Chicago on May 31, 2014 and the abstract would be available in Australia on May 15, 2014.
Prima chief technical officer Dr Sharron Gargosky told the teleconference that the company had planned a separate 40-patient, single-arm, pilot trial of CVac for pancreatic cancer.
Dr Gargosky said that she expected to begin recruitment for the CAN-301 pancreatic cancer trial in July 2014.
Prima was unchanged at 3.6 cents with 1.4 million shares traded.

ANTISENSE THERAPEUTICS

Antisense hopes to have US Food and Drug Administration approval for a new phase IIb trial of ATL1102 for multiple sclerosis to begin in 2015.

Antisense managing director Mark Diamond told a brokers meeting today that the company had resolved toxicity issues that contributed led to Israel's Teva Pharmaceuticals handing back ATL1102, despite positive result in a 2010 phase II trial (BD: Jun 30, 2008; Mar 24, 2010).

Mr Diamond said that Antisense had completed a further round of toxicology studies and would approach the FDA by October 2014 to discuss a phase IIb trial.

He said that the company hoped to partner ATL1102 to fund the trial.

Mr Diamond said that the company's lead program was ATL1103 for acromegaly and that by demonstrating that the drug could reduce insulin-like growth factor-1 (IGF-1) in its current phase II trial ATL1103 would be expected to take a large share of the second line therapy market.

Mr Diamond said the existing drug for acromegaly, Somavert, required daily injections and was expensive compared to the ATL1103 once weekly regime.

Mr Diamond said that data available on four of 24 patients in the phase II trial showed that ATL1103 was meeting its primary endpoint of IGF-1 reduction.

He said that the company also hoped to partner ATL1103 for acromegaly to fund further trials.

Mr Diamond said that Antisense expected to take development of ATL1102 for stem cell mobilization "all the way" as the treatment was a relatively simple acute procedure.

Mr Diamond said that ATL1102 mobilized bone marrow CD34+ stem cells which could be collected in blood from a patient prior to chemotherapy for re-injection following chemotherapy to rebuild the immune system.

He said that a trial of ATL1102 for stem cell mobilization was underway with results expected in "mid-2014".

Antisense fell half a cent or 3.6 percent to 13.5 cents.