Biotech Daily

Wednesday July 23, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BIOTRON UP 24%, ALCHEMIA DOWN 5%**

*** BIOTRON 'BIT225 REDUCES IMMUNE IMPAIRMENT, COGNITION POTENTIAL'**

*** ANTISENSE CLOSES ATL1102 STEM CELL MOBILIZATION PROGRAM**

*** MACQUARIE UNIVERSITY JOINS IMPEDIMED L-DEX LYMPHOEDEMA TRIAL**

*** DORSAVI HAILS FIRST US VIPERFORM DIAGNOSTIC SALE**

*** CLINICAL GENOMICS COLOVANTAGE BOWEL CANCER TEST TRIAL**

*** FISHER FUNDS BELOW 5% IN NANOSONICS**

*** PRIMA CEO MARC VOIGT STARTS ON $278k**

MARKET REPORT

The Australian stock market was up 0.6 percent on Wednesday July 23, 2014 with the S&P ASX 200 up 33.4 points to 5,576.7 points.

Nineteen of the Biotech Daily Top 40 stocks were up, eight fell, nine traded unchanged and four were untraded.

Biotron was the best, climbing as much as 52.4 percent to 16 cents before closing up 2.5 cents or 23.8 percent to 13 cents with 11.9 million shares traded, followed by Starpharma up 12 cents or 16.4 percent to 85 cents with 9.1 million shares traded and Oncosil up 14.3 percent to 12 cents with 1.1 million shares traded.

Patrys climbed 7.7 percent; Analytica, Anteo, Clinuvel and Pharmaxis were up more than five percent; Admedus was up four percent; Cellmid improved 3.45 percent; Acrux, Atcor, Circadian, Mesoblast, Prima and Universal Biosensors rose more than two percent; Neuren was up 1.05 percent; with Benitec, Cochlear, Resmed and Sirtex up by less than one percent.

Alchemia led the falls, down three cents or 4.8 percent to 60 cents with 335,150 shares traded.

Nanosonics lost 3.3 percent; Genetic Technologies shed 2.9 percent; Ellex, Impedimed and Viralytics were down more than one percent; with CSL, Osprey and Medical Developments down by less than one percent.

BIOTRON

Biotron says that data from its trial of BIT225 for HIV shows the drug can reverse HIV-induced impairment of the immune system, with implications for neurological dysfunction.

Biotron chief executive officer Dr Michelle Miller told Biotech Daily that following last year's initial results, showing that BIT225 reduced virus burden in monocyte reservoirs and had a potential role in the eradication strategy of HIV-1, the company further investigated samples for biomarker activity (BD: Dec 5, 2013).

Dr Miller said that BIT225 reduced the biomarker sCD163 which was associated with macrophage activity.

Dr Miller said that having reservoirs in the body with HIV meant that "the immune system was continuously switched on and hence deteriorating".

Biotron said that in a presentation to the AIDS 2014 conference in Melbourne the further investigation showed that blood samples taken from HIV-infected patients treated for 10 days with BIT225 showed a significant reduction in levels of the inflammatory marker sCD163, which was a marker of immune activation associated with macrophage cells.

The company said that at the end of treatment the sCD163 biomarker returned to pre-treatment levels, in contrast to samples from placebo-treated controls in which levels of sCD163 remained unchanged throughout the study.

Biotron said that HIV infection caused immune activation and inflammation, which were associated with adverse outcomes in patients, including accelerated aging and neurological dysfunction.

The company said that the previously released data from the 21-patient trial showed that BIT225 reduced virus levels in reservoir precursor cells known as monocytes, which turned into macrophages in tissues, where they acted as long-term reservoirs of virus that was not cleared by current antiretroviral drugs.

Biotron said that the presence of these pools of virus, which were below the limit of detection of standard assays, put continual pressure on the immune system, resulting in ongoing immune activation.

Biotron senior virologist and presentation co-author Dr John Wilkinson said that the aim of drug treatment for HIV was not only to reduce virus levels, but also to dampen down the associated immune activation.

"BIT225 can potentially target both sides of the problem, resulting in reduction of virus and a normal functioning immune system," Dr Wilkinson said.

Biotron said that targeting the virus within monocyte and macrophage cells was central to preventing the ongoing cycle of infection and re-infection of T-cells with HIV in infected patients.

This company said the trial was the first demonstration of the feasibility of such an approach.

Biotron said that the BIT225 trial was conducted on 21 patients at an international clinical trial unit in Bangkok, Thailand.

The company said that patients enrolled in the study were HIV-infected, with high levels of virus and good CD4+ T cell counts and none of the patients previously received treatment with anti-retroviral drugs.

Biotron said that patients received either 400mg BIT225 twice daily or placebo for 10 days.

Dr Miller told Biotech Daily that the next trial of BIT225 for HIV would "look at establishing a clinical outcome for patients".

Biotron climbed as much as 5.5 cents or 52.4 percent to 16 cents before closing up 2.5 cents or 23.8 percent to 13 cents with 11.9 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says its 10-patient trial of ATL1102 for stem cell mobilization did not increase the release of CD34+ stem cells to a level relevant for a commercial product.
Antisense said that it had closed the “relatively low cost” stem cell mobilization program, which had “no bearing on [its] development plans in relation to ATL1102 for multiple sclerosis where the drug [had] been shown to significantly reduce brain lesions”.
The company said that the randomized, open-label, proof-of-concept study in 10 healthy volunteers was designed to assess the effect of ATL1102 on the release of haematopoietic stem cells (CD34+) into the blood when dosed alone and in combination with the existing mobilization therapy, granulocyte colony stimulating factor (GCSF).
Antisense said that there was an acknowledged clinical need for increasing mobilization levels in combination with G-CSF beyond those achieved by G-CSF alone.
The company said that ATL1102 in combination with G-CSF did not appear to increase the release of CD34+ stem cells beyond that achieved with G-CSF alone and when ATL1102 was dosed as a monotherapy the number of CD34+ stem cells in the blood increased, but not to a level sufficient to be a commercially desirable product.
The company said the trial “was a relatively low cost trial and eligible for the 45 percent [Research and Development] Tax Incentive refund”.
Antisense said it was the first occasion in humans that the effects of ATL1102 on CD34+ stem cell release had been assessed over a short, five-day, dosing period, with the ATL1102 dosing schedule designed to fit in with current G-CSF dosing practice.
The company said that it was possible that ATL1102 could have achieved greater CD34+ cell release if it was dosed for a longer duration.
Antisense said it was assessing with clinical experts the potential feasibility, including from a safety and tolerability perspective and commercial viability of longer dosing regimens of ATL1102, but was “not planning to move forward” with the clinical development of ATL1102 in the stem cell mobilization indication as originally envisaged as a five day use in combination with GCSF.
The company said it planned to meet the US Food and Drug Administration by October 2014 to discuss the design of the phase IIb trial of ATL1102 for multiple sclerosis.
Antisense chief executive officer Mark Diamond said that the stem cell mobilization trial was designed “with a clear therapeutic goal to provide clinical proof of concept to support the ongoing development of the drug in this specific application”.
“While this goal was not met in this trial, we were able to reach this decision point quickly and at relatively low expense,” Mr Diamond said. “In the short term, with respect to ATL1102, we remain focussed on the ongoing development in the [multiple sclerosis indication where we have already demonstrated potent clinical activity.”
Antisense was unchanged at 13 cents with 1.7 million shares traded.

IMPEDIMED

Impedimed says that Sydney’s Macquarie University Cancer Institute would be the Australian site for its 1100-patient, five year, international, post-approval clinical study.
Impedimed said that the study would objectively establish the clinical utility of its L-Dex device for the early detection of lymphoedema, post breast cancer (BD: Jun 26, 2014).
The company said that interim data from the trial would be used as it sought coverage from private health insurers in the US and the inclusion of major cancer centres would also drive market adoption as the current procedural terminology category 1 code came into effect on January 1, 2015.
Impedimed fell half a cent or 1.8 percent to 27 cents.

DORSAVI

Dorsavi says it has begun sales of its Viperform wearable motion analysis device for athletes in the US, following its US Food and Drug Administration in April 2014.

Dorsavi said that Viperform's sensors provided analysis and bio-feedback on movement and muscle activity to a computer, tablet or small recording device.

Dorsavi said that Viperform was available from Metro Orthopaedics and Sports Therapy, in Silver Spring, Maryland and the company's consultant Dr Mehul Desai would work with athletic trainers and physical therapists to maximize athletes' potential and use the Viperform data for research projects.

"Increasingly in our healthcare environment we seek means by which to measure function objectively, and to some extent our inability do so in the past has limited the opportunity to customize treatment measures for patients," Dr Desai said. "Viperform provides objective information to the clinician who will then gain the opportunity to integrate this data and personalize care for their patient."

Dorsavi chief executive officer Andrew Ronchi said the company had a strong US sales team in the clinical and sports area and the appointments were "paying off following the sale of Viperform to Metro Orthopaedics and Sports Therapy".

Dorsavi fell half a cent or 1.1 percent to 45 cents.

CLINICAL GENOMICS

Clinical Genomics says it will begin a pilot trial of its Colovantage Plasma blood test for bowel cancer (BD: May 26, 2014).

Clinical Genomics said that the test was developed with the Commonwealth Scientific and Industrial Research Organisation and the Adelaide-based Flinders Centre for Innovation in Cancer and the roll-out was supported by regional health insurer Westfund Health reimbursing the cost of the test for eligible members.

The company said that colorectal surgeon and Bowel Cancer Australia spokesman Prof Graham Newstead welcomed the pilot project for the new test.

"This is as an important development in bowel cancer screening," Prof .Newstead said. "A continuing focus on the stool test first with the option of a blood test for those who would not otherwise screen has the potential to see more Australians participate in screening and more lives being saved," Prof Newstead said.

Clinical Genomics chief executive officer Dr Larry LaPointe said the trial in the Blue Mountains, west of Sydney was "an opportunity to access a new option in bowel cancer screening".

"The Blue Mountains has been chosen because it has a supportive local health insurer, accessible pathology services and a strong network of local primary healthcare providers," Dr LaPointe said. "It's important to note, however, that the test is primarily intended for people who cannot, or will not, carry out recommended screening with a faecal immunochemical test, that is the stool test."

"So the message for local residents is that the stool test is the best place to start for people aged 50 or over who are due for screening," Dr LaPointe said. "Then the blood test is for those people who can't or won't screen with a faecal test".

Clinical Genomics said that the blood test was based on two genes that leaked into the blood and early clinical studies showed the test could detect 65 percent of bowel cancer cases, increasing to 73 percent for more advanced cancers.

The company said that Westfund Health would supplement existing screening in the Blue Mountains by supporting Colovantage Plasma blood test.

Clinical Genomics is a private company.

NANOSONICS

Fisher Funds Management and associates have reduced their substantial shareholding in Nanosonics 13,290,531 shares (5.03%) to 12,890,531 shares (4.88%).
The Auckland, New Zealand-based Fisher Funds said it sold the 400,000 shares on July 22, 2014 for $299,100 or 74.8 cents a share.
Nanosonics fell 2.5 cents or 3.3 percent to 74 cents.

PRIMA BIOMED

Prima says that Berlin-based chief executive officer Marc Voigt will be paid a base salary of EUR195,000 ($A278,373) a year as well as performance inicentives.
Prima said that Mr Voigt would be entitled to up to $500,000 in shares as a long term incentive an additional equity-based short term incentive and an annual cash bonus of up to EUR15,000.
Prima was up 0.1 cents or 2.4 percent to 4.2 cents with 2.2 million shares traded.