Biotech Daily

Tuesday May 24, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ADMEDUS UP 8%, ANTISENSE DOWN 12%**

*** INNATE 11-MONTHS FOR MIS416 RESULTS, FINDING MS ENDPOINTS**

*** REVA TO LAUNCH FANTOM STENT BY JULY 2017, CASH-TIGHT**

*** WEHI, QIMR TO 'SWITCH ON' NATURAL KILLER CELLS FOR CANCER**

*** CLARITY RAISES $2m FOR SARTATE NEUROENDOCRINE TUMOR TRIAL**

*** FDA APPROVES CSL FLUCELVAX QUADRIVALENT 'FLU VACCINE**

*** GSK $80k RESEARCH EXCELLENCE NOMINATIONS OPEN**

*** D3 APPOINTS DR SANELA BILIC, DR TIFFANY LIN TO CLINICAL TEAM**

*** BRETT CROWLEY REPLACES USCOM CO SEC CATHERINE OFFICER**

MARKET REPORT

The Australian stock market fell 0.44 percent on Tuesday May 24, 2016 with the ASX200 down 23.3 points to 5,295.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and two were untraded. All three Big Caps were up.

Admedus was the best, up 2.5 cents or 8.3 percent to 32.5 cents with 624,729 shares traded.

Actinogen and Uscom climbed more than four percent; IDT and Pro Medicus were up more than three percent; Prima, Psivida and Viralytics rose more than two percent; Cochlear, Impedimed, Neuren and Prana were up more than one percent; with CSL, Medical Developments, Resmed and Starpharma up by less than one percent.

Antisense led the falls on a 'company strategy update', down 0.6 cents or 12.2 percent to 4.3 cents, with 100,000 shares traded.

Biotron and Oncosil lost more than six percent; Avita and Universal Biosensors fell more than five percent; Ellex, Genetic Technologies and Orthocell fell more than four percent; Clinuvel was down three percent; Anteo and Opthea shed more than two percent; Acrux, Mesoblast, Polynovo and Reva were down more than one percent; with Nanosonics and Sirtex down by less than one percent.

INNATE IMMUNOTHERAPEUTICS

Innate chief executive officer Simon Wilkinson says there has been strong demand for the compassionate use of MIS416 for secondary progressive multiple sclerosis.

Last month, Innate said that it had completed enrolment in its 93 patient phase IIb, randomized, placebo-controlled trial of MIS416 for secondary progressive multiple sclerosis, with nine of the 13 patients who completed the study requesting support from their physicians for post-study access to MIS416 (BD: Apr 13, 2016).

Today, Mr Wilkinson told Biotech Daily that he expected the last patient to complete their 12-month dosing in April 2017, with a study report expected in September 2017.

He said that the company was conducting efficacy assessment every three months, from baseline, from before the start of dosing to the last dose at 12 months.

Mr Wilkinson said there was increasing interest in the company as it awaited the results from the two-to-one randomized trial.

“Completing enrolment has heightened awareness and we are responding by meeting investors and brokers to update them where we are at,” Mr Wilkinson said.

“There is a very clear timetable and there is on-going very strong big pharma interest,” Mr Wilkinson said.

“If we get a good result from the trial we have a high degree of confidence there will be a transaction by the end of next year, either an outright sale of the company or a partnership for a phase III trial,” Mr Wilkinson said.

Mr Wilkinson said that in 2014 Servier paid $US47 million for an option for the non-US rights to a company that conducted an 11-patient trial.

He said that 75 percent of the multiple sclerosis market was in the US and the market for secondary progressive multiple sclerosis was estimated at $US4 billion with no drug approved for the indication.

Mr Wilkinson said that there was great difficulty defining an efficacy endpoint and there was “no accepted, validated, primary endpoint for a phase II approval trial”.

He said that the currently used ‘extended disability severity score’ could provide the same number for a patient who had improved, because there was a loading on the ability to walk, with one patient having a marked decrease in disability, gaining strength and movement in her hands, but because she could not walk the score remained the same.

He said that Innate had been invited to join that Multiple Sclerosis Outcome Assessment Consortium which included the US Food and Drug Administration, European Medicines Agency, the US Multiple Sclerosis Association, the Critical Path Institute and representatives of major pharmaceutical companies.

“We’ve been invited to join because we have a phase II trial where we can measure improvement rather than just disease progression,” Mr Wilkinson said.

He said the company was investigating a range of neuro-muscular changes that could be clinically measured including hand strength and function, eyesight, walking speed and cognition processing speed, which was especially important for hand-eye co-ordination for mobility.

“We are increasingly confident that things that we are measuring will throw up endpoints that the FDA and/or our partners will like as endpoints for a phase III trial,” Mr Wilkinson said.

Mr Wilkinson said that the trial’s final data was not necessarily a binary event and that if a subset of patients on MIS416 showed improvement, rather than just a slowing of progression, MIS416 could still be approved or partnered, as there were no treatments available for secondary progressive multiple sclerosis.

Innate was unchanged at 25 cents.

REVA MEDICAL

Reva says it expects to launch its Fantom bio-resorbable stent in Europe by July 2017 and has sufficient cash to fund activities until April 2017.

In Melbourne meeting investors following the publishing of positive data from its Fantom II trial Reva chief executive officer Dr Regina Groves said that Boston Scientific had two distribution options, with the first option to be triggered by a geographic approval and a second option a whole of world distribution deal.

Last week, Reva's six-month follow-up results from its first 117 patient cohort in its Fantom II trial, showed a 1.7 percent rate of major adverse cardiac events and a "low" late lumen loss with a mean in-segment loss of 0.21mm (BD: May 18, 2016).

Today, Dr Groves said the company had set a major adverse cardiac events target of below 5.0 percent and was "very pleased" with the results.

Dr Groves said that Boston Scientific would have 90 days from European approval to decide whether to take up the option and further 90 days to negotiate the terms.

Dr Groves said that Boston scientific could expedite the process if it wanted.

She said that Reva expected to file for Conformité Européenne (CE) mark by October 2016 and be granted CE mark by the end of 2016.

Dr Groves said that the company was spending about $US6 million per quarter, had $US22.1 million at March 31, 2016 and had previously said it would need to raise capital but at this stage there were no firm plans.

Dr Groves said that the agreement with Boston Scientific included the condition that Reva would receive 50 percent of the average price of the coronary stents.

Modelling by stockbrokers Morgans senior analyst Derek Jellinek put the likely procedure cost of each Fantom stent at about $US1,200, with an estimate that following scale-up they could be produced for about $250.

Dr Groves said that one of the key Fantom stent advantage over other bio-resorbable stents was that it was visible under x-ray due to the combination of iodine in the polymer, which was intellectual property licenced by Reva from the New Brunswick, New Jersey-based Rutgers University.

Dr Groves said that the Fantom polymer was more pliable than the competitor plastic stents and was easier for cardiac surgeons to use.

Dr Groves said that she hoped to begin a dialogue with the US Food and Drug Administration in July or August of this year, with a 2,000 patient US trial costing about $US80 million and taking four years.

She said that the coronary stent market was worth $US4 billion a year with bio-resorbables taking a small percentage share of the five million stents a year.

Dr Groves said that there was a two percent per annum adverse event rate with metal stents, which did not occur with bio-resorbable stents.

She said that one of the reasons for the slow take-up of the Abbott Absorb stent was "bad training advice" not to re-expand the stent post-dilation, whereas the Reva Fantom could be more easily inflated once in place and the more supple polymer was less likely to have structural issues during the placement and balloon inflation period.

Dr Groves said that Reva had a number of options to consider, including whether to undertake its own distribution in Europe, should Boston Scientific not produce an acceptable agreement.

She said that Reva could partner with one of the major cardiac companies for a pivotal US trial and there was the possibility that a competitor might want to buy the entire company.

Reva's annual general meeting will be held in Sydney on Thursday.

Reva fell 1.5 cents or 1.3 percent to $1.17.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that with the Queensland Institute of Medical Research it is investigating ways to switch-on 'natural killer' cells.

WEHI said that natural killer cells detected and destroyed deviant cells before they could develop into tumors or before infection spread.

The Institute said that the research identified a protein 'brake' within natural killer cells that controlled their ability to destroy target tumor cells and showed that when the brake was removed in a mouse model, the natural killer (NK) cells were better able to protect the body against metastatic melanoma.

The article, entitled 'CIS is a potent checkpoint in NK cell–mediated tumor immunity' was published in the journal Nature Immunology and an abstract is available at: http://www.nature.com/ni/journal/vaop/ncurrent/full/ni.3470.html.

The article co-authored by Dr Sandra Nicholson and Dr Nicholas Huntington said that the detection of aberrant cells by natural killer cells was "controlled by the integration of signals from activating and inhibitory ligands and from cytokines such as IL-15".

"We identified cytokine-inducible SH2-containing protein, or CIS encoded by Cish, as a critical negative regulator of IL-15 signalling in NK cells," the abstract said.

"Our data uncover a potent intracellular checkpoint in NK cell–mediated tumor immunity and suggest possibilities for new cancer immunotherapies directed at blocking CIS function," the abstract said.

Dr Nicholson said that natural killer cells were "a key part of our immune system that locate other cells posing a danger to health either because they are infected or because they are becoming a cancer cell".

"However, it is known that abnormal cells sometimes escape the immune system and develop into a cancer," Dr Nicholson said.

WEHI said that Dr Nicholson and Dr Huntington's research had shown that an inhibitor protein made inside the natural killer cells limited the ability of the natural killer cell to respond to IL-15 and kill cancer cells, and that by identifying for the first time how the protein inhibited natural killer cell responses, the researchers hoped that a drug could be developed that would improve the natural killer cells' response to the growth factor and help patients fight cancer with their own immune system.

"This is about learning how to activate the NK cells of the individual patient and boost their immune system to tackle the disease," Dr Huntington said.

"We are hopeful our research will lead to new immunotherapies that supercharge the body's natural killer cells and maintain it in a highly active state to more efficiently and specifically fight cancer," Dr Huntington said.

CLARITY PHARMACEUTICALS

Clarity says it has raised $2 million for a phase IIa trial of its Sartate radio-biological for localized treatment of neuroendocrine tumors, with results expected by July 2016.

Clarity said that the funds would also "fast-track clinical trials of Sartate in neuro-blastoma, an aggressive childhood cancer, as well as other difficult-to-treat cancers".

The company said the capital raising had "strong support" from directors Dr Chris Roberts, Dr Alan Taylor and Dr Matt Harris, as well as from shareholders and collaborators including the Australian Nuclear Science and Technology Organisation, the University of Melbourne and ATP Innovations.

Clarity said that Sartate was the world's first use of copper radioisotopes for the diagnosis, dosimetry and treatment of cancer.

Clarity is a private company.

CSL SEQUIRUS

CSL says the US Food and Drug Administration has approved its Seqirus subsidiary's Flucelvax Quadrivalent influenza vaccine for people aged four years and older.
CSL said that Flucelvax Quadrivalen was the first four-strain, cell culture-derived, inactivated seasonal influenza vaccine and helped protect against the two influenza A viruses and two B viruses recommended by the World Health Organization and the US Food and Drug Administration for the current influenza season.
CSL Seqirus president Gordon Naylor said that as "the first and only cell culture-derived seasonal influenza vaccine in the US to offer four-strain 'flu protection for people aged four years and older, Flucelvax Quadrivalent will provide healthcare providers and their patients with an important option to further broaden their influenza coverage".
Mr Naylor said that Flucelvax Quadrivalent was produced at the company's cell culture influenza vaccine manufacturing facility in Holly Springs, North Carolina and was using the same full-scale cell culture manufacturing technology as its predecessor Flucelvax, which allowed the potential for rapidly increased production of influenza shots in response to outbreaks or pandemic.
CSL said that cell culture technology did not depend on eggs for manufacturing and the vaccine was produced in sterile bioreactors.
The company said that the change to using cells rather than eggs was the first major development in influenza vaccine manufacturing technology since vaccine production began in the 1930s.
CSL was up nine cents or 0.1 percent to $113.26 with 631,420 shares traded.

D3 MEDICINE

D3 says it has appointed Dr Sanela Bilic as its senior director of clinical pharmacology and Dr Tiffany Lin as its clinical pharmacologist.
D3 said that Dr Bilic worked for Novartis Pharmaceuticals for 13 years in translational clinical oncology and clinical pharmacology and was responsible for the non-clinical and clinical pharmacology sections of more than 16 investigational new drug applications.
The company said that Dr Lin had more than 10 years clinical pharmacology experience with Novartis, Bayer Healthcare and Hoffmann-La Roche.
D3 is a private company

USCOM

Uscom says that Brett Crowley will replace Catherine Officer as its company secretary.
Uscom said that Mr Crowley was a solicitor and a former Ernst & Young Hong Kong and Australia partner, and formerly was with KPMG Hong Kong and had worked in China establishing and managing joint venture companies, with more than 30 years' experience in advising companies on taxation, corporate strategy, international structuring, capital raising and commercial negotiations.
The company said that Mr Crowley had experience as a chairman, finance director and company secretary of ASX-listed companies and was a former senior legal member of the New South Wales Civil and Administrative Tribunal.
Uscom said the Ms Officer was leaving the company after three years to take up a new role with a not-for-profit organization.
Uscom was up one cent or 4.8 percent to 22 cents.

GLAXOSMITHKLINE

Glaxosmithkline says that nominations for its $80,000 Award for Research Excellence have opened and the closing date is July 4, 2016.

Glaxosmithkline said that the award began in 1980 to recognize “outstanding achievements in medical research and facilities career development with potential importance to human health and Australian research”.

Glaxosmithkline medical director Dr Andrew Weekes said that the award was “a flagship programme for GSK Australia and viewed as prestigious in the Australian research community”.

“It’s a privilege to be able to recognise advances in immunology, cancer, muscular disease and other areas,” Dr Weekes said.

“We always look forward to recognising the winner for their vision and dedication,” Dr Weekes said.

Glaxosmithkline said that successful applicants were generally mid-career researchers with a long-standing commitment to their field.

The company said that the winner would be announced on November 16, 2016 at the Annual Research Australia Awards, at the Sydney’s Westin Hotel.

For more information go to the GSK Award website at: http://bit.ly/1YUn1RL.