Biotech Daily

Wednesday February 4, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRANA UP 19%, TISSUE THERAPIES DOWN 12%**

*** CYNATA, UWA COLLABORATE ON STEM CELLS FOR LUNG FIBROSIS**

*** PATRYS: 'PAT-SM6 SAFE, TOLERABLE FOR MULTIPLE MYELOMA'**

*** TISSUE THERAPIES PLACES $4m, RIGHTS ISSUE FOR $3.7m MORE**

*** GENETIC TECHNOLOGIES MEETS 1st NASDAQ RULE, EXTENSION**

*** HUNTER HALL TAKES MORE PROFIT TO 8% IN SIRTEX**

*** SIENNA APPOINTS DR CLIFF HOLLOWAY INTERIM CEO**

MARKET REPORT

The Australian stock market was up 1.22 percent on Wednesday February 4, 2015 with the S&P ASX 200 up 69.9 points to 5,777.3 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and two were untraded.

Prana was the best, up 3.5 cents or 18.9 percent to 22 cents with 770,592 shares traded.

Admedus and Genetic Technologies climbed more than nine percent; Avita and Medical Developments were up more than six percent; Anteo, Circadian, Clinuvel, Ellex, IDT and Neuren were up more than three percent; Bionomics, Cochlear and Starpharma rose more than two percent; Acrux and Phosphagenics were up more than one percent; with CSL, Mesoblast and Sirtex up by less than one percent.

Tissue Therapies led the falls, down 3.5 cents or 12.1 percent to 25.5 cents with 1.0 million shares traded, followed by Patrys down 11.8 percent to 1.5 cents with 4.6 million shares traded.

GI Dynamics fell 7.8 percent; Living Cell lost 6.7 percent; Antisense and Optiscan fell more than four percent; Impedimed was down 3.2 percent; Atcor shed two percent; Alchemia and Osprey were down more than one percent; with Benitec and Resmed down by less than one percent.

CYNATA THERAPEUTICS

Cynata says it has begun a study to test the therapeutic efficacy of its Cymerus mesenchymal stem cells in an animal model of lung fibrosis.

Cynata said that the study would be performed within the University of Western Australia's Centre for Cell Therapy and Regenerative Medicine with researchers who had expertise in lung fibrosis and regenerative medicine.

The company said that the Centre's director Prof Geoff Laurent would take primary responsibility for the study and described Prof Laurent as "a world authority in extracellular matrix regulation and lung fibrosis, having made major contributions to these fields ... [with] more than 300 publications in this and related areas".

Cynata said that the lead investigator of the study was cell biologist Dr Cecilia Prêle.

The company said that the study was intended to provide further proof-of-concept data on its Cymerus mesenchymal stem cells.

Cynata said that lung fibrosis occurred in a range of disorders characterized by excessive deposition of extracellular matrix proteins within the pulmonary interstitium, leading to impaired gas transfer and a loss of lung function.

The company said that in the lung, fibrosis might be caused by known insults such as asbestos or radiation exposure but could develop in the absence of a known stimulus, such as in idiopathic pulmonary fibrosis.

Cynata said that to date, no treatment has been shown to be effective for idiopathic pulmonary fibrosis and on average patients survived for only three to five years after diagnosis.

The company said that the development of more efficient therapeutic approaches was urgently required to suppress and reverse the fibrotic response.

Cynata said that all adult tissues, including the lung, had some capacity to self-repair or regenerate through the replication and differentiation of stem cells resident within these organs and while lung resident stem cells were a candidate cell therapy for lung diseases, knowledge of the biology of these cells was limited.

The company said that there was interest in the therapeutic potential of exogenous cells, particularly mesenchymal stem cells for lung diseases and many studies provided evidence that mesenchymal stem cells could be used for lung diseases including fibrosis.

Cynata said that most of the studies used bone marrow-derived stem cells although several studies had used cells from other sources.

Prof Laurent said that "while adult tissues represent a useful source of [mesenchymal stem cells] there are also significant limitations with this approach".

"In particular, it is known that as a stem cell matures, it gradually loses its versatility," Prof Laurent said.

"The range of tissues into which it can differentiate becomes restricted and its expansion capability is diminished," Prof Laurent said.

"This study will examine the potential of [mesenchymal stem cells] derived using Cymerus technology, to prevent and reverse fibrosis in an animal model of lung fibrosis," Prof Laurent said.

"It is important to achieve economic manufacture of relevant quantities of very pure and well-characterized [mesenchymal stem cells] at a commercial scale to use in medicine and this is why we are partnering with Cynata on this project," Prof Laurent said.

Cynata chief executive officer Dr Ross Macdonald said that the partnership with the University of Western Australia built on the company's relationship with Grey Innovation in the development of a nebulizer technology to efficiently deliver stem cells to the lung.

Cynata was unchanged at 36 cents.

PATRYS

Patrys says the results from its phase I/IIa, open-label study for PAT-SM6 for patients with refractory or relapsed multiple myeloma has been published in the journal Haematologica.
Last year, Patrys said that four of 12 patients in the trial had stable disease with two patients stable for more than 130 days (BD: Mar 27, 2014).
Patrys said at that time that the final results showed that one patient who received 3mg/kg of PAT-SM6 was stable for 138 days before additional therapy was needed and another patient, who received 6mg/kg, was stable for 154 days and was therapy free at the time of publication in March 2014.
Today, Patrys said the article, entitled 'GRP78-directed Immunotherapy in relapsed or refractory multiple myeloma- results from a Phase I Trial with monoclonal IgM antibody PAT-SM6' was a summary of the results of four escalating intravenous infusion doses at 0.3mg/kg, 1mg/kg, 3mg/kg and 6mg/kg over two weeks, and an abstract was available at: http://www.haematologica.org/content/early/2015/01/26/haematol.2014.117945.
The company said that the primary objectives of the study, safety and tolerability had been supported with all doses administered found to be safe, well tolerated and the maximum tolerated dose not reached.
Patrys said that four of 12 patients had stable disease after PAT-SM6 treatment across the dose cohorts 1 mg/kg, 3 mg/kg and 6mg/kg and the results were comparable to other antibodies under clinical development for the treatment of multiple myeloma.
The company said that treatment of relapsed-refractory multiple myeloma was a therapeutic challenge, prompting a continued search for additional therapeutic options and the results reflected in-vivo activity in a difficult-to-treat patient population.
Patrys said that targeting GRP78, which was responsible for resistance in many cancers, highlighted the prospective role of PAT-SM6 in combination with the existing therapies to overcome tumor resistance.
The company said the favorable safety profiles made PAT-SM6 a candidate for possible synergistic results in combination with other therapies while maintaining low toxicity.
Patrys has planned a trial of PAT-SM6 in combination with carfilzomib and dexamethasone and said that Amgen subsidiary Onyx would provide carfilzomib but the study had been delayed (BD: Aug 25, Nov 7, 2014).
The company said Haematologica article included data on an observation regarding immune mechanisms of PAT-SM6 and a possible role in overcoming tumor resistance.
Patrys fell 0.2 cents or 11.8 percent to 1.5 cents with 4.6 million shares traded.

TISSUE THERAPIES

Tissue Therapies says it has raised $4.0 million in a placement at 21 cents a share and will offer a fully-underwritten one-for-15 non-renounceable rights offer for $3.7 million.
Tissue Therapies said that Morgans Corporate and Baillieu Holst were the joint lead managers and underwriters to the capital raising.
Tissue Therapies chief executive officer Dr Steven Mercer said that the European regulatory approval process had "exceeded the internal timelines and expectations".
"It has become apparent that the appropriate risk mitigation strategy is to uncouple FDA approvals and sales for a diabetic ulcer trial in the rest of the world from the CE mark process ... and the capital raising will support this objective," Dr Mercer said.
Tissue Therapies said that the record day for the rights issue would be February 10, the offer would open on February 11 and close on February 27, 2015.
Tissue Therapies fell 3.5 cents or 12.1 percent to 25.5 cents with 1.0 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has compiled with the Nasdaq share price requirement and has been given an extension to regain compliance with the equity requirement.
Genetic Technologies said its share price had fallen below the $US1.00 minimum and a consolidation had reset the ratio of one American depository receipt (ADR) to 30 Australian shares to one ADR to 150 Australian shares.
On the Nasdaq last night the company closed at $US3.09.
The company said that it had not maintained the $US2.5 million in stockholder equity for continued listing, but the Nasdaq had been granted an extension of time to May 4, 2015 to regain compliance.
Genetic Technologies said the Nasdaq rules only applied to US stock trading on the Nasdaq and not the trading on the ASX.
Genetic Technologies was up 0.2 cents or 9.1 percent to 2.4 cents with 16.15 million shares traded.

SIRTEX MEDICAL

Hunter Hall Investment Management has again reduced its substantial holding in Sirtex from 5,428,852 shares (9.60%) to 4,675,173 shares (8.27%).
Hunter Hall sold shares between October 31, 2014 and February 2, 2015, with the single largest sale of 101,403 shares for $2,794,912 or $27.56 a share.
Hunter Hall has been reducing its holding in Sirtex since May 2013 (BD: May 29, 2013).
Hunter Hall has been a long term shareholder in Sirtex and in 2009 increased to 16,684,884 shares (29.92%) when the company was at $2.35 a share (BD: Mar 5, 2009).
Sirtex was up 18 cents or 0.65 percent to $27.88 with 295,154 shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says that Dr Cliff Holloway has been appointed interim chief executive officer replacing Dr Kerry Hegarty from February 2, 2015.
Sienna said that Dr Holloway had held executive management and directorship positions in the bio-pharmaceutical and information and communications technology industries.
The company said that Dr Holloway was most recently chief executive officer of the public unlisted Immune System Therapeutics, which was developing biologic therapeutics for blood cancers and was currently the Australasian representative for health care and chemicals investment banking group Ferghana Partners and a director of investment fund Newstar Ventures.
Sienna said that Dr Holloway held a Bachelor of Pharmacy and a Doctorate of Philosophy from the University of Nottingham.
Sienna is a public unlisted company.