



Biotech Daily

Wednesday December 4, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: PRIMA UP 6%, ANTEO DOWN 13%**

- * **MESOBLAST STEM CELLS 'SAFE, SOME EFFICACY' IN TYPE 2 DIABETES**

- * **BLUECHIIP ADDS 10 TRIAL SITES, TALKS TO ASIAN DISTRIBUTORS**

- * **LIVING CELL TELLS ASX: 'SATURDAY NEWS PUBLISHED ON MONDAY'**

MARKET REPORT

The Australian stock market climbed 0.34 percent on Wednesday December 4, 2013 with the S&P ASX 200 up 17.7 points to 5,273.8 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and two were untraded.

Prima was the best, up 0.3 cents or 6.4 percent to five cents, with 10.7 million shares traded.

Clinuvel, Neuren, Patrys and Pharmaxis climbed four percent or more; Admedus, Atcor and Benitec were up three percent or more; Tissue Therapies rose 2.2 percent; Alchemia, Cochlear, Living Cell and Osprey were up more than one percent; with QRX and Sirtex up by less than one percent.

Anteo led the falls, down 2.5 cents or 13.2 percent to 16.5 cents with 13.0 million shares traded, followed by Phylogica down 0.2 cents or 10.5 percent to 1.7 cents with 161,500 shares traded.

Reva lost 8.2 percent; Circadian and Universal Biosensors were down more than six percent; Psivida fell 5.4 percent; Genetic Technologies fell 4.6 percent; Impedimed and Starpharma were down more than three percent; Acrux and GI Dynamics shed more than two percent; Avita, Bionomics and Resmed were down more than one percent; with CSL, Mesoblast and Prana down by less than one percent.

MESOBLAST

Mesoblast says its 61-patient phase II trial of mesenchymal precursor cells shows the cells are safe, tolerable and can reduce blood sugar levels in type 2 diabetes patients. Mesoblast said that a single intravenous infusion of mesenchymal precursor cells (MPCs) showed an improvement in glycaemic control as evidenced by reduction in haemoglobin A1c or HbA1c.

The company said that the phase II randomized, single-blind, placebo-controlled, dose escalation trial was conducted across 18 sites in the US evaluating the effects of a single intravenous infusion of 300,000 MPCs/kg, 1.0 million MPCs/kg or 2.0 million MPCs/kg or placebo over 12 weeks in 61 patients with a mean diabetes duration of 10 years.

Mesoblast said that the mesenchymal precursor cells were safe and well tolerated with no treatment-related adverse events, meeting the trial's primary endpoint.

The company said that following a single intravenous infusion, overall HbA1c levels were reduced over the 12-week study period when compared to placebo.

Mesoblast said that the highest dose showed the greatest overall reduction in HbA1c, with a peak decrease of 0.4 percent at eight weeks compared with placebo ($p < 0.05$), and a decrease of 0.3 percent at 12 weeks.

Yesterday, GI Dynamics said its Endobarrier duodenal-jejunal liner "showed a significant reduction in blood glucose levels reducing HbA1c by 1.3 percent from baseline, with more than half (52%) of diabetic patients achieving healthy blood glucose levels (HbA1C less than or equal to 7.0%) during the treatment period" (BD: Dec 3, 2013).

GI Dynamics has not disclosed what happens with patients' HbA1c level or weight control once the Endobarrier is removed.

The US National Institutes of Health website said that a normal level of HbA1c was 5.6 percent or lower with 5.7 percent to 6.4 percent described as "pre-diabetes" and 6.5 percent or above diagnosed as "diabetes".

Today, Mesoblast said that in the less well-controlled subjects, as defined by a baseline HbA1c greater than 8.0 percent, a 0.6 percent decrease in HbA1c was seen at eight weeks in the high dose cohort compared with placebo.

The company said that in those with a baseline HbA1c less than 8.0 percent, a target of HbA1c less than 7.0 percent at week 12 was achieved in 63 percent or five of eight high-dose treated subjects compared with none of seven placebo controls ($p < 0.05$).

Mesoblast chief executive Prof Silviu Itescu said the company was "very pleased and encouraged by these top-line results".

"In this phase II trial, a single injection of Mesoblast's MPCs was well tolerated and showed evidence of improved glycaemic control in type 2 diabetes, a chronic inflammatory disease affecting multiple organs," Prof Itescu said.

"This is an important first step in developing an MPC-based immunomodulatory therapy for the treatment of type 2 diabetes and its complications," Prof Itescu said.

Mesoblast said that there were more than 347 million people worldwide with diabetes and the number is likely to more than double by 2030 without intervention.

The company said that in the US alone, 18.8 million people suffering from type 2 diabetes in 2011.

Mesoblast said that according to the US Food and Drug Administration Guidance for Industry 2008, HbA1c was the primary endpoint of choice for glycaemic control in subjects with type 2 diabetes.

Mesoblast fell three cents or 0.5 percent to \$6.16 with 538,244 shares traded.

BLUECHIIP

Bluechiip says it has 10 new trial and validation sites in progress or about to begin in the US, Europe and Australia and is in discussion with potential Asian distributors.

Bluechiip said that Asia was “the fastest growing region for bio-banking”.

Bluechiip chairman Iain Kirkwood said that the company had “progressed discussions with distributors in three different Asian territories, China, Korea and Malaysia, and expect to form partnerships with these parties over the coming months”.

“Building our sales order book is our number one priority both in regions where we have already engaged distributors such as North America and now Europe and Asia Pacific,” Mr Kirkwood said.

“We are very aware that this process has taken much longer than we anticipated but we have addressed this and are now allocating additional resources to execute this strategy,” Mr Kirkwood said.

Bluechiip said it was manufacturing two new products a cryovial and a polycarbonate cassette canister, which could be sold as a stand-alone consumable product.

The company said that it continued to work closely with Micronic America and its sub-distributors Nova Biostorage Plus, E&K Scientific and USA Scientific in the US and MJS Biolynx in Canada.

Bluechiip was up one cent or 9.1 percent to 12 cents.

LIVING CELL TECHNOLOGIES

Living Cell has told the ASX that it received data safety monitoring board advice on Saturday November 23, and published it on Monday November 25, 2013.

The ASX said the announcement entitled ‘NTCell clinical trial: Recruitment of further patients approved’ was released on its announcements platform at 9.54am on November 25, 2013 and asked the company if the board decision would be information that a reasonable person would expect to have a material effect on the price or value of its securities and if so “when did the company first become aware of the DSMB decision”?

Living Cell said it believed the information would be material and it first became aware of the decision on Saturday November 23, 2013.

“The information was not released to the market on Saturday, 23, or Sunday, 24

November as the ASX announcements platform was closed at that time,” Living Cell said.

“An announcement was made before trading commenced on Monday, November 25,” the company said.

Living Cell was up 0.1 cents or one percent to 10 cents.