Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: PRANA UP 10%, GENERA DOWN 12%**

*** MESOBLAST STEM CELLS IN 'WORLD FIRST OSTEOARTHRITIS TRIAL'**

*** FDA ORPHAN STATUS FOR CHEMGENEX MDS INDICATION**

*** HALCYGEN COMPLETES THIRD US ANTI-FUNGAL TRIAL**

*** NEUREN PLEADS SCHULTZ TO ASX 250% SHARE PRICE RISE QUERY**

*** ITL'S CEO BRIAN ANDREWS STARTS ON $300k**

MARKET REPORT

The Australian stock market fell 3.1 percent on Tuesday January 20, 2009 with the S&P ASX 200 down 112.7 points to 3,476.6 points.

Six of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and 11 were untraded.

Prana was best, up three cents or 9.68 percent to 24 cents with 10,000 shares traded, followed by Biota up two cents or 4.88 percent to 43 cents.

Alchemia climbed 3.57 percent, with Cathrx, Circadian and up more than one percent.

Yesterday's best, Genera, led the falls, down three of its four cent gain or 11.54 percent to 23 cents with 10,000 shares traded, followed by Clinuvel down 10 percent to 22.5 cents and Polartechnics down 9.68 percent to 14 cents.

Avexa, Cellestis, Impedimed and Novogen lost more than eight percent; Starpharma shed 7.5 percent; Heartware was down five percent; Cochlear fell 4.84 percent; CSL was down three percent; Ventracor shed 2.67 percent; with Chemgenex, Mesoblast and Resmed down more than one percent.

MESOBLAST

Mesoblast says it has Australian ethics approval for the first human trial of adult stem cell treatment for prevention of knee osteoarthritis after an acute traumatic knee injury.

The randomized, placebo-controlled, phase II clinical trial design will evaluate whether Mesoblast's allogeneic, or off-the-shelf, adult stem cell product, Replicart, can slow or prevent the development of knee osteoarthritis after reconstruction of a ruptured anterior cruciate ligament.

The trial will enrol 24 patients aged between 18 and 40 years old who have undergone recent anterior cruciate ligament surgical reconstruction within six months of a traumatic knee injury.

Mesoblast's executive director Prof Silviu Itescu told Biotech Daily that the injury was frequently incurred by athletes, especially Australian Rules footballers and soccer players.

Prof Itescu said the injury was often sustained when the ligament was involved in a high-speed, twisting motion impact.

Patients will be randomized to receive either one of two doses of Replicart injected into the knee joint together with the gel-like molecule hyaluronan, or hyaluronan alone.

The trial's primary endpoint will be safety of the stem cell therapy at 12 months and its secondary endpoint prevention of cartilage loss and knee osteoarthritis during this period.

In earlier preclinical trials, a single injection of Mesoblast's allogeneic stem cells into the knee joint shortly after knee surgery resulted in sustained and significant protection of joint cartilage and reduced the severity of knee osteoarthritis.

The lead investigator, Dr Andrew Shimmin, an orthopaedic surgeon at the privately-run Melbourne Orthopaedic Research Foundation said that anterior cruciate ligament injury was "very common in our young active sporting population and unfortunately the injury is associated with the early development of arthritis despite modern reconstructive procedures".

"Little has changed in the prevention and treatment of arthritis over the past 50 years, so the application of Mesoblast's stem cell technology for reducing the progression of this degenerative process in the knee offers a new and exciting direction for the management of arthritis," Dr Shimmin said.

Prof Itescu said Mesoblast was developing a unique product for both protection and regeneration of knee cartilage in patients at risk of, and with, established osteoarthritis of the knee.

"Commencing this clinical trial in post-traumatic knee osteoarthritis is an important step towards accessing the huge commercial opportunity that exists today for Mesoblast in the osteoarthritis market," Prof Itescu added.

Mesoblast said a ruptured anterior cruciate ligament of the knee, was a common severe joint injury without a bone fracture, which occurs in a young active patient population.

The company said that up to 70 percent of these patients go on to develop osteoarthritis 15 to 20 years earlier than the general population regardless of whether they have had their knees reconstructed.

As there is no known treatment other than to relieve the pain, these patients face the prospect of a joint replacement at a young age.

In the US, osteoarthritis after a single acute traumatic incident comprises about 12 percent of all osteoarthritis cases with up to 300,000 new cases each year.

Mesoblast fell 1.5 cents or 1.71 percent to 86 cents.

CHEMGENEX

The US Food and Drug Administration has granted Chemgenex orphan drug designation for omacetaxine for myelodysplastic syndromes.

Chemgenex chief executive officer Dr Greg Collier told Biotech Daily that myelodysplastic syndromes (MDS) were unrelated to the company's lead indication for omacetaxine mepesuccinate, chronic myeloid leukemia and in particular patients with the T315I mutation who are resistant to Gleevec.

Dr Collier said older patients with myelodysplastic syndromes "drift into acute myeloid leukemia" so there was an overlap with acute myeloid leukemia (AML) which was previously the second indication for omacetaxine.

Dr Collier said a European trial of omacetaxine for acute myeloid leukemia was continuing, but myelodysplastic syndromes was "a quicker registration pathway than AML".

Dr Collier said that previous studies had shown that existing drugs had a 12-18 percent efficacy rate for myelodysplastic syndromes but data on an earlier form of omacetaxine showed a 28 percent response rate.

In a media release to the ASX Chemgenex said orphan drug designation was intended to support the clinical development of new drugs in diseases affecting fewer than 200,000 people in the US.

The company said the FDA "often provides technical and financial assistance to expedite and optimize drug development and on approval, grants a seven year period of market exclusivity".

Chemgenex said myelodysplastic syndromes described a group of bone marrow disorders characterized by a defect in stem cells and is most common in elderly patients as they are more prone to bone marrow damage but it can occur in any age group.

About 15,000 people a year in the US are diagnosed with the syndromes or five in 100,000 a year, Chemgenex said.

In the media release Dr Collier said the orphan designation reflected "our corporate strategy of expanding the use of the drug to other haematological conditions where new treatment options are needed to improve patient outcomes". (See Marc Sinatra's Bioguide at http://www.biotechdaily.com.au/media/sinatra/Chemgenex%202008%20Update.pdf)

"Whilst expansion into MDS is integral to realizing the full commercial potential of omacetaxine, we remain focused on our primary objective of seeking regulatory approval for the drug in CML patients with the T315I mutation," Dr Collier said.

"The enrolment target for our registration-directed clinical trial for omacetaxine was achieved on schedule in December and we remain on track to complete the rolling [new drug application] submission to the FDA in mid 2009," Dr Collier said. The enrolment target is believed to be 40 to 50 patients.

In December Chemgenex said that clinical data from its phase II/III pivotal study in chronic myeloid leukemia patients who have the T315I mutation (BD: Dec 9, 2008) showed that 80 percent of 25 chronic phase chronic myeloid leukemia patients had a "complete haematological response".

The company said at that time that the data came from a total of 44 patients in its phase II/III trial of omacetaxine mepesuccinate for chronic myeloid leukemia patients with the T315I mutation.

Chemgenex said that despite "a growing number of treatment options for patients with MDS, current therapies still exhibit certain limitations". The company said bone marrow transplantation offered curative hope, but it was available to a very small segment of MDS patients due to factors such as age and finding matched donors.

Chemgenex fell half a cent or 1.09 percent to 45.5 cents.

HALCYGEN

Halcygen says it has completed recruitment and dosing of the third of three pivotal pharmacokinetic studies of its antifungal drug SUBA-itraconazole.

Halcygen said the US Food and Drug Administration approved trials are designed to compare Halcygen's SUBA-itraconazole and the market's leading product Johnson & Johnson's Sporanox (itraconazole).

Halcygen chief executive officer, Dr Roger Aston said the company had completed "the recruitment and treatments for the third key study aimed at evaluating the pharmacokinetics of different doses of our drug, so we remain well on track with our registration program".

"We have now successfully completed three consecutive US trials within six months which has prepared the ground for reverting to the US FDA for further guidance," Dr Aston said.

"During the next few weeks we will be reporting the implications of the outcomes of these three trials and our strategy to seek registration of SUBA-Itraconazole," he said.

Halcygen said it had clinically evaluated SUBA-itraconazole in five pharmacokinetic studies in Australia.

The company said those studies "demonstrated that Halcygen's formulation has significantly improved bioavailability or absorption by the gastrointestinal tract compared with the market leader, enabling the use of a lower dose of the drug" and the formulation provided for more stable blood levels, compared to Sporanox.

The company said the global market for itraconazole was more than $US600 million a year and it was targeting this market.

Halcygen was untraded at 19 cents.

NEUREN

Neuren has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 0.4 cents on January 12, 2009 to 1.4 cents on January 16, 2009, along with an increase in trading volume.

Neuren said it "intended providing an update to shareholders on it business plans in the coming weeks" but had brought this forward in response to the ASX query and requested a trading halt (BD: Jan 19, 2009) until January 21, 2009, when it expected to release the business plan.

"The company does not believe that the business plan information could be an explanation for the trading in the securities of the company on January 16, 2009," Neuren said.

"Due to the previously announced results for the Glypromate trial [BD: Jan 16, 2009] and the company's decision to discontinue development of Glypromate, there will be an impairment charge against the company's results to December 31, 2008 for the net book value of intellectual property related to Glypromate," Neuren told the ASX.

"Although the company is in the process of completing the financial statements for the year ended December 31, 2008 and has not yet quantified its operating loss for the year or quantified and determined the classification of the impairment charge which will be subject to audit, it is likely that the operating loss for the 2008 year will vary by more than 15 percent from the previous corresponding period due to this impairment charge.

"The company does not expect to record any material abnormal or extraordinary loss for the financial year ended December 31, 2008 except for the impairment charge noted above, if it is so classified," Neuren said.

Neuren last traded at 1.2 cents.

ITL

ITL's chief executive officer Brian Andrews total fixed remuneration will be $300,000 a year including superannuation, non-monetary benefits and Fringe Benefits Tax.

ITL said Mr Andrews will receive a short term incentive of up to 30 percent of the total fixed remuneration, subject to annual achievement of performance targets and other criteria.

The company said that as a long term incentive Mr Andrews had been granted 1,000,000 options with an exercise price is 20 cents, exercisable between January 13, 2012 and January 12, 2013.

ITL was up half a cent or 4.76 percent to 11 cents.