Biotech Daily

Wednesday June 24, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN:**

PHYLOGICA UP 9%, GENETIC TECHNO, SUNSHINE HEART DOWN 17%

*** NEW ZEALAND APPROVES LIVING CELL'S DIABETES PIG CELL TRIAL**

*** MESOBLAST CLAIMS EARLY BONE MARROW TRANSPLANT SUCCESS**

*** STIRLING REQUESTS 'MAJOR PHARMA ACQUISITION' TRADING HALT**

MARKET REPORT

The Australian stock market climbed 0.27 percent on Wednesday June 24, 2009 with the S&P ASX 200 index up 10.1 points to 3,807.0 points.

Eight of the Biotech Daily Top 40 stocks were up, 19 fell, 11 traded unchanged and two were untraded.

Phylogica was best, up 0.4 cents or 8.7 percent to five cents with 13,700 shares traded, followed by Viralytics up 8.6 percent to 3.8 cents.

Biota climbed 7.2 percent; Tissue Therapies was up 6.25 percent; Chemgenex and Peplin rose more than two percent; CSL and Impedimed were up more than one percent; with Acrux and Resmed up by less than one percent.

Genetic Technologies and Sunshine Heart led the falls, both down one cent or 16.67 percent to five cents with 109,440 and 60,300 shares traded, respectively, followed by Cytopia and Tyrian both down 10.0 percent to 7.2 cents and 2.7 cents, respectively.

Nanosonics lost 8.3 percent; Benitec fell 6.9 percent; Polartechnics was down 5.15 percent; Avexa and Progen fell more than four percent; Clinuvel, Mesoblast, Novogen and Sirtex were down more than three percent; Prana and Psivida shed more than two percent; Alchemia and Pharmaxis were down more than one percent; with Circadian, Cochlear and Genera down by less than one percent.

LIVING CELL TECHNOLOGIES

New Zealand's Minister of Health, Tony Ryall, has authorized Living Cell's phase I/IIa clinical trial of Diabecell for insulin dependent diabetes.

Living Cell said the authorization confirmed the conditions announced last week (BD: Jun 19, 2009) for the developed world's first major xeno-transplant trial of porcine islets of Langerhans for type 1 diabetes.

Living Cell said the changes included limiting participation in the trial to patients with poorly controlled or brittle diabetes along with a number of procedural issues.

The company said that with the Middlemore Hospital clinical team conducting the trial, it had requested the regional ethics committee accept the required changes.

Living Cell chief executive officer Dr Paul Tan said the company was pleased the conditions had been finalized and the company expected to begin the trial "within the next two months with the acceptance of the changes by the Ethics Committee".

Living Cell founder and medical director Prof Bob Elliott said the New Zealand diabetes trial was "another major milestone".

"With two diabetes patients not requiring insulin following implants with encapsulated pig islet cells in our first study in Russia, we expect to see further benefit in more patients as we use higher doses of Diabecell in the New Zealand trial," Prof Elliott said.

The company said its Russian phase I/IIa clinical trial started with a low dose of Diabecell and preliminary data showed "sustained long term clinical benefit in patients treated with the Diabecell implant with no remarkable adverse events" (BD: May 5, 2009).

Living Cell said two of seven patients given implants no longer required insulin injections.

The company said the New Zealand trial would extend the phase I/IIa clinical data with eight patients, four of whom would receive double the initial dose used in Russia followed by four patients to receive triple the dose.

The clinical director and diabetes physician at Auckland's Middlemore Hospital, Dr John Baker, who will be conducting the trial said there were "many patients with poorly controlled diabetes who would qualify for this trial".

Dr Tan told Biotech Daily last week that there were about 200 type 1 diabetes patients who had made themselves available for the New Zealand trial of which 20 had already been screened.

Dr Tan said at that time that the first dosing was expected by September, 2009.

Living Cell said in today's media release to the ASX that Diabecell was designed to normalize blood glucose levels in type 1 diabetes sufferers through the injection of encapsulated porcine insulin-producing cells which can be administered without the need to use immunosuppressive drugs.

The company said type 1 diabetes occurred when the body's own immune system destroys the insulin-producing cells of the pancreas.

Five to 10 percent of the more than 200 million diabetics worldwide have insulin dependent type 1 diabetes.

Living Cell said type 1 diabetes was associated with kidney failure, blindness, nerve damage, life-threatening cardiovascular disease and limb amputations.

Current treatment options include multiple daily injections of insulin.

Living Cell was unchanged at 18 cents.

MESOBLAST

Five patients treated with Mesoblast's mesenchymal precursor cells in a US phase I/II bone marrow transplant trial had more rapid engraftment than historical control patients.
Mesoblast and Angioblast director Prof Silviu Itescu told Biotech Daily that engraftment meant the bone marrow was being accepted and not rejected by the patient and was functioning to create new white blood cells sufficient to protect the person from infection.
Prof Itescu said that reducing the time to engraftment, while the patient was without bone marrow and in hospital intensive care units, reduced the likelihood of infections and other complicating factors.
Mesoblast said in its media release to the ASX that up to 30 blood and bone marrow cancer patients, including leukemia patients, would receive bone marrow transplantation with haematopoietic stem and progenitor cells expanded by Mesoblast's allogeneic, or off-the-shelf mesenchymal precursor cells (MPCs).
The company said the phase I/II trial was being conducted by its US sister company Angioblast Systems at the University of Texas MD Anderson Cancer Center and was funded through a grant awarded by the US National Institutes of Health.
Mesoblast said "successful bone marrow reconstitution and engraftment was achieved in all five patients with haematologic malignancies who received MPC-expanded haematopoietic stem and progenitor cells from cord blood, with no cell-related adverse events".
"The median time to engraftment was 15 days, approximately two weeks faster than expected without MPC expansion," the company said.
Mesoblast said the mesenchymal precursor cells used in the trial were being developed under a US Food and Drug Administration orphan drug designation granted to Angioblast for expanding haematopoietic stem and progenitor cell numbers in patients with haematologic malignancies.
Prof Silviu Itescu said in the media release that the initial results "were extremely encouraging".
"By significantly reducing the time to engraftment and increasing the overall success rate of an allogeneic bone marrow transplant, this technology has the potential to lower the risk of infections, bleeding, and death in critically ill patients with haematologic malignancies following chemotherapy," Prof Itescu said.
Mesoblast said that "in view of the important nature of the unmet medical need" it would seek FDA clearance to begin an accelerated phase III program if subsequent patients showed enhanced bone marrow engraftment potential.
Prof Itescu said an accelerated program "would represent a significantly shortened timetable to product commercialization".
Mesoblast fell three cents or 3.75 percent to 77 cents.

STIRLING PRODUCTS

Stirling has requested a trading halt pending an announcement "in relation to a major pharmaceutical business acquisition".
Trading will resume on June 26, 2009 or on an earlier announcement.
Stirling last traded at 1.8 cents.