Biotech Daily

Monday August 16, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LIVING CELL UP 8%; VIRAX DOWN 60%**

*** VIRAX HIV VACCINE FAILS PHASE I/IIa TRIAL; DATA REVIEW UNDERWAY**

*** VIRAX ACTIVELY LOOKING AT NEW IMMUNOTHERAPY PROGRAM**

*** STARPHARMA BEGINS PHASE II BACTERIAL VAGINOSIS VIVAGEL TRIAL**

*** PHYLOGICA SAYS $109m MEDIMMUNE DEAL 'IMMINENT'**

*** MESOBLAST, FDA CLOSE TO PHASE III BONE MARROW TRIAL DESIGN**

*** CAPITAL GROUP CLIENTS REDUCE TO 7% OF COCHLEAR**

*** FERMISCAN BACK TO THE BREAST CANCER DETECTION FUTURE**

MARKET REPORT

The Australian stock market fell 0.47 percent on Monday August 16, 2010 with the S&P ASX 200 down 21.1 points to 4438.5 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, three traded unchanged and seven were untraded. All three Big Caps fell.

Living Cell was best, up 1.5 cents or 7.9 percent to 20.5 cents with 46,878 shares traded followed by Bone up 6.1 percent to seven cents with 30,000 shares traded.

Clinuvel climbed 4.55 percent; Circadian and Genetic Technologies were up more than three percent; Optiscan, Psivida and Tissue Therapies rose more than two percent; with Acrux and Biota up more than one percent.

Virax led the falls, down 5.4 cents or 60 percent to 3.6 cents with 14.7 million shares traded, followed by Sunshine Heart down 18.75 percent to 2.6 cents with 82,910 shares traded and Phosphagenics down 14.8 percent to 9.8 cents with 305,077 shares traded.

Antisense and Novogen lost more than six percent; LBT was down 5.6 percent; Chemgenex, Heartware, Impedimed, Patrys and QRX fell more than four percent; Viralytics shed 2.9 percent; with Alchemia, Cochlear, Prima and Resmed down more than one percent.

VIRAX

Virax says its therapeutic vaccine for HIV, VIR201, has not met its primary or secondary endpoints in its 131-patient, South African, phase I/IIa trial.

Virax chief executive officer Dr Larry Ward told Biotech Daily that the company would review the data closely before making a final decision about the program.

“There was an interesting drop in viral count that needs further investigation,” Dr Ward said.

“We need to analyze the data more significantly before making that final decision, but we won’t be spending any more money on it,” Dr Ward said.

“HIV plus vaccine equals high technical risk,” Dr Ward said, agreeing that government funds for this type of trial would be appropriate, but in their absence he sought non-dilutive funds from the mining companies that supported the trial.

In its media release, Virax said 65 of the 131 patients were undergoing antiretroviral treatment and 66 patients were naïve to antiretroviral treatment (ART) treatment.

The company said the primary immunological endpoint of the trial was T-cell immune response via Elispot assay and the secondary immunological endpoint was the measurement of antibody isotype responses (IgG1, IgG2 and IgG3).

The effects of VIR201 vaccination on HIV viral load in the ART naïve group and CD4 count were also measured as secondary efficacy endpoints, the company said.

Virax said VIR201 failed to elicit a statistically significant increase in immune response relative to the control group in both T-cell assay (Elispot) and assays of antibody isotype.

The company said the effect of viral load was measured as time-weighted, mean change from baseline to the end of the trial (pVL).

Virax said that ART-naïve patients receiving VIR201 had a 0.61 log reduction relative to placebo in pVL (p=.0934).

The company said that the reduction in viral load was more pronounced soon after the first vaccination and the VIR201 group had a statistically significant 1.49 log reduction relative to placebo (p=0.0001) one week after the first vaccination with VIR201.

Dr Ward told Biotech Daily that there was “some very interesting viral load data in the ART naïve group that needs to be analyzed in more detail”.

He said that a potential application of a therapeutic HIV vaccine was to be able to vaccinate individuals soon after primary infection, to lower the HIV viral load, which would decrease the rate of deterioration of the immune system which was often measured based on the level of a particular type of immune cell (CD4).

In countries such as South Africa, the CD4 cell level is also a major trigger for patients being put on ART treatment, Dr Ward said.

“Thus a successful therapeutic vaccine, by lowering viral load, will lengthen the time between infection and need to start ART,” he said.

One week after the first vaccination there was a 1.49 log (approximately 30-fold) difference between VIR201 arm and placebo and across the length of the trial the average decrease in viral load was 0.6 log (about four-fold) between VIR201 and placebo groups.

Further analysis at the individual patient level is required to better understand what is going in terms of the time course and length of viral load suppression and if the patients are responding as a homogeneous group, Dr Ward said.

In the previous Australian treatment interruption trials it was clear some patients were responsive while VIR201 had no effect on others.

The company said it was reviewing and further evaluating the trial results and would further update shareholders in due course.

Virax fell 5.4 cents or 60 percent to 3.6 cents with 14.7 million shares traded.

VIRAX

Virax said it wanted “to undertake a suitable value accretive corporate transaction to further expand its product and technology portfolios”.
The company said it had been “very active in this area in recent months and is in advanced discussions with a large international immunotherapeutic company regarding a significant clinical program that has the potential to add significant value for shareholders” and would announce results of these discussions and seek shareholder approval and support through a capital raising.
Dr Ward told Biotech Daily that the program was not an HIV immunotherapy and was not necessarily for an infectious disease.
Virax said a key technology asset was its Co-X-Gene licenced to France’s Transgene in two cancer vaccine products. VIR201 also uses the Co-X-Gene technology with a fowlpox delivery system.

STARPHARMA

Starpharma has begun its phase IIa study of Vivagel for the treatment of bacterial vaginosis, following receipt of ethics approval.
Starpharma said in July 2010 that the US Food and Drug Administration had accepted and cleared its investigational new drug application for the study (BD: Jul 15, 2010).
The company said US clinical trial sites would be initiated this week and enrolment would begin immediately.
Starpharma said the clinical program would investigate the treatment of bacterial vaginosis with a once daily Vivagel treatment for seven days.
The company said the findings would guide further investigation of its use in both treatment and suppression of recurrence.
Starpharma said bacterial vaginosis was the most common vaginal infection worldwide, and the most common cause of vaginal irritation, discharge and malodor.
It is particularly prevalent in the US, where it affects an estimated one-third of the adult female population.
The condition is implicated in pelvic inflammatory disease and may also be associated with an increased risk of sexually transmitted infections, including HIV and pre-term birth, the company said.
Starpharma fell half a cent or 0.95 percent to 52 cents.

PHYLOGICA

Phylogica says the signing of formal documentation of a $109 million deal with Medimmune was “now imminent”
Phylogica announced a trading halt and later a suspension regarding the deal “with a large pharmaceutical and biotechnology group” earlier this month, but was unable to seal the deal prior to a media conference (BD: Aug 3, 4, 5, 2010).
The company said the deal related to a research partnership using its proprietary library of protein fragments or Phylomer peptides.
Phylogica said that details of the agreement would be released as soon as the formal documentation has been completed.
Phylogica was in a voluntary suspension and last traded at 8.4 cents.

MESOBLAST

Mesoblast says a meeting with the US Food and Drug Administration earlier this month has advanced its phase III bone-marrow transplant program.

Mesoblast said it proposed a phase III clinical trial whose design, size, duration, and primary endpoints were not disclosed in today's media release to the ASX.

The company said the design was based on results from the 25-patient pilot trial at the University of Texas MD Anderson Cancer Center compared with a registry of 300 patients collected by the Center for International Blood and Marrow Transplant Research.

Last year, Mesoblast said that results from the first 18 bone marrow transplantation patients using umbilical cord blood expanded by allogeneic mesenchymal precursor cells showed the cells "expand haematopoietic stem cells in umbilical cord blood … 40-fold" (BD: Nov 6, 2009).

Last month, Mesoblast said that of the 25 patients transplanted with mesenchymal precursor cell-expanded haematopoietic progenitors from cord blood, "80 percent successfully achieved the key composite endpoint at 100 days of survival with sustained engraftment of both neutrophils and platelets" (BD: Jul 7, 2010).

Mesoblast compared it to the 38 percent rate for the composite endpoint achieved after transplantation with non-expanded cord blood in the US 300 patient registry.

The company said in July that four patients (16%) receiving expanded cord blood had developed severe graft-versus-host disease.

Today, Mesoblast said the FDA meeting was "very constructive, with the FDA providing the company with expected guidance on phase III primary endpoints and duration of patient follow-up".

The company said that to ensure full alignment on product approval requirements, it would seek a binding special protocol assessment from the FDA prior to commencing the trial.

Mesoblast said the special protocol assessment provided an agreement between the FDA and the company regarding the design, including size and clinical endpoints, of the pivotal trial to support an efficacy claim in a biologic licence application.

The company said that for the phase III program it would use its adult mesenchymal precursor cells under an orphan drug designation to expand unrelated donor haematopoietic stem and progenitor cell numbers for use in patients with haematologic malignancies.

Mesoblast said that more than 70 percent of patients who could use an unrelated-donor bone marrow transplant did not received one, because a fully-matched donor could not be found. The company said that perfect matching was required because of the high risk of the potentially life-threatening complication of severe graft-versus-host disease.

Mesoblast said its objective was to make available a source of unrelated donor bone marrow cells which could be used without full matching to effect rapid bone marrow reconstitution with a low risk of graft-versus-host disease.

The company said this would expand the use of bone marrow transplantation to all those in need of the procedure but who could not find a donor.

Mesoblast said it was "on-track to file an investigational new drug submission to the FDA to commence a phase III trial for its bone marrow transplant product by the end of this year" and had sufficient cash to fund the trial.

The company said orphan drug designation was reserved for therapies which were being developed for conditions affecting up to 200,000 patients annually in the US and allowed for an accelerated review process by the FDA, seven-year market exclusivity in the US on obtaining marketing authorization, tax benefits and exemption from user fees.

Mesoblast was up one cent or 0.5 percent to $1.92.

COCHLEAR

The US based Capital Group Companies has further reduced its substantial shareholding in Cochlear from 4,427,062 shares (7.83%) to 3,789,642 shares (6.70%).
Capital Group increased its holding in Cochlear to as much as to 7,322,475 shares (13.03%) on September 11, 2009, before beginning reductions in May (BD: May 11, 2010).
Capital Group said it did not own shares in Cochlear but held them on account for Capital Research and Management Company.
Capital Group said the 637,420 shares were sold at an average price of $70.266.
Capital Group's last acquisition of 604,101 Cochlear shares was at an average price of $59.057, with the previous 573,027 shares acquired for an average price of $55.486.
Cochlear fell 78 cents or 1.1 percent to $68.84.

FERMISCAN

Fermiscan says it has a heads of agreement to complete x-ray diffraction of hair tests for breast cancer.
The company has been in voluntary administration and has completed a deed of company arrangement (BD: Nov 18; Dec 15, 2009).
In May, Fermiscan's administrators Woodgate & Co sold the company's intellectual property and other assets for $250,000 to the Sydney Breast Clinic-related company SBC Research (BD: May 4, 2010).
Fermiscan director, former Polartechnics chief executive officer Ben Dillon, told Biotech Daily that the company had unfinished trials in Europe and there were exemptions for research as long as it was not for commercial purposes.
Mr Dillon said that if the company wanted to commercialize the test it would have to negotiate a licence with SBC Research.
Fermiscan last traded at three cents.