Biotech Daily

Thursday June 17, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN:**
- UNIVERSAL BIOSENSORS UP 10%, LIVING CELL DOWN 8%

*** TISSUE THERAPIES 'EXCEPTIONAL VITROGRO WOUND CARE RESULTS'**

*** BENITEC HIV STEM CELL TRIAL SAFE, FEASIBLE; 2nd TRIAL BEGINS**

*** BIO SA $240k GRANT FOR CALZADA'S NOVOSKIN COLLABORATION**

*** FERMISCAN DEED OF COMPANY ARRANGEMENT FALLS OVER**

*** ORBIS TAKES 14% OF CHEMGENEX**

*** CELTIC CAPITAL, JASON PETERSON TAKE 10% OF HELICON**

*** QUEENSLAND'S PETER BEATTIE JOINS MEDICAL RESEARCH FUND**

MARKET REPORT

The Australian stock market fell 0.7 percent on Thursday June 17, 2010 with the S&P ASX 200 down 31.7 points to 4527.3 points.

Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and nine were untraded.

Universal Biosensors was best, up 15 cents or 10.3 percent to $1.60 with 71,600 shares traded.

Cathrx and Tissue Therapies climbed more than eight percent; Viralytics was up 7.3 percent; Heartware was up 4.8 percent; Cellestis and Clinuvel rose more than two percent; with Acrux, CSL, Mesoblast, Nanosonics, Pharmaxis and Starpharma up less than one percent.

Living Cell led the falls, down two cents or eight percent to 23 cents with 179,000 shares traded.

Benitec, Optiscan and Virax lost five percent or more; Circadian and Genera fell more than four percent; Prana was down 3.1 percent; Novogen shed 2.9 percent, with Alchemia, Bionomics and Chemgenex down more than one percent.

TISSUE THERAPIES

Tissue Therapies says it has "further exceptional clinical results" from five venous ulcer patients treated with its Vitrogro wound care product.

Tissue Therapies said that of the five patients treated for 24 days at the Vascular Research Laboratory in Western Australia under the care of Prof Michael Stacey, two had 100 percent wound healing after no response to 19 months and 27 months of expert care, respectively, while a third patient had 75 percent healed after no response to two months of expert care.

The company said that of the 17 Australian venous ulcer patients treated with Vitrogro three were completely healed within 24 days and the average reduction in venous ulcer size was 39.2 percent with statistically significance of $p < 0.005$.

Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that all the patients treated with Vitrogro in Australia and in the earlier trial in Canada had improved with none deteriorating and none remaining unchanged.

"It's quite exceptional, particularly in 24 days of treatment," Dr Mercer said.

"All patients are improving and no patients are getting worse," he said.

Dr Mercer said that some Canadian patients showed no significant decrease in wound area, but clinical observation had shown the ulcers were healing from the base.

Dr Mercer said the European venous ulcer trial was expected to begin in August 2010 and would further examine the wound base repair capability of Vitrogro.

He said the trial of treatment for 12 weeks was expected to be completed in December 2010 with results "early in the New Year".

In the media release to the ASX Dr Mercer said that "to understand how exceptional these results are, it is important to bear in mind that up to 50 percent of diabetic and venous ulcers remain unhealed after 20 weeks of expert treatment".

"In addition, 10 medically complex, hard to heal venous, diabetic and pressure ulcer patients in Canada also showed excellent results from their treatment with Vitrogro, as has already been reported," Dr Mercer said (BD: Nov 18, 2009).

Tissue Therapies said that the first of the Canadian patients had a diabetic ulcer on his right foot that had not responded to expert care for more than two years and foot amputation was recommended.

The company said the patient's ulcer healed 29 percent in six weeks with a small weekly application of Vitrogro and he still had his foot.

Tissue therapies said that all patients in the Australian and Canadian clinical trials were categorized as "hard to heal" and the only change to their expert treatment was the addition of one low dose application of Vitrogro once a week in the Canada trial and twice a week in the Australian trial.

Dr Mercer said that expert clinical review of the results from both the Canadian and Australian Vitrogro trials also commented on the fact that all patients in both studies demonstrated ulcer healing, completely or at least partially.

"This is exceptional, perhaps unprecedented," Dr Mercer said.

"It is routine in the treatment of these chronic wounds for the ulcers of some patients to increase in size – this was not the case with Vitrogro," Dr Mercer said.

Dr Mercer said that a review of the commercial scale manufacturing of Vitrogro in Belgium confirmed that it was on time and budget.

He said that a planning day in London in preparation for the European Union clinical trial confirmed that all regulatory and approval procedures were "progressing well for completion of this human trial of Vitrogro as planned by the end of December 2010".

Tissue Therapies climbed as much as 3.5 cents or 20.6 percent to 20.5 cents before closing up 1.5 cents or 8.8 percent to 18.5 cents with 1.85 million shares traded.

BENITEC

Benitec says its pilot phase I trial of a triple vector RNA therapy to suppress HIV in AIDS-related lymphoma patients is safe and feasible.

Benitec said the results of the trial in collaboration with California's City of Hope medical centre supported the development of an RNA-based cell therapy platform for HIV.

The paper, entitled 'RNA-based Gene Therapy for HIV Using Lentiviral Vector-Modified CD34+ Cells in Patients Undergoing Autologous Stem Cell Transplantation for AIDS-Related Lymphoma' was published in Science Translational Medicine.

An abstract is available at: http://stm.sciencemag.org/content/2/36/36ra43.abstract.

Benitec said the study recruited five patients with AIDS-related lymphoma, four of whose blood stem cells were harvested, transfected with the triple vector RNA therapeutic and then reinfused back into the patients.

Benitec said the study showed that the genetic treatment was successful, and three of the patients were still expressing the therapeutic molecules in their blood cells at 18 months, with one doing so at 24 months.

The company said the was "a landmark" and was the first clinical trial in HIV-infected humans using lentiviral vector transduction of human stem cells.

Benitec said it was the first trial to use a DNA directed RNA interference (ddRNAi) trigger known as a short hairpin RNA (shRNA) in human blood cells derived from ex-vivo gene-modified blood stem cells and it was the first trial to use a triple gene therapy combination.

Benitec said that in cell culture studies this triple vector showed almost complete inhibition of HIV growth.

The company said the key findings included the primary aim that the process of isolation of CD34+ blood stem cells, their genetic modification using a lentivirus vector expressing multiple anti-HIV RNAs and autologous infusion was safe and feasible.

Of the measurable transgenes, expression of the small interfering RNA (siRNA) and ribozyme persisted for at least 18 months post-infusion, representing an initial milestone in the development of genetic therapy for HIV infection using stem cells, the company said.

Benitec said the trial resulted in the development of several key methods for trials such as this at the City of Hope including manufacturing procedures, release criteria, in vitro correlative assays of cell function and analytical tools.

The company said there was a low level frequency of transduced peripheral blood cells, consistent with the low number of infused gene-modified stem cells.

The triple vector used in this trial (rHIV7-shI-TAR-CCR5RZ) encoded three forms of anti-HIV RNA including a shRNA targeted to HIV-1 tat/rev, a protein involved in the replication of the virus in human T cells; a decoy containing the HIV trans-acting response element (TAR), which binds and sequesters trans-activator of transcription (Tat). The decoy also inhibits HIV replication via a different mechanism to the shRNA construct, and a ribozyme (CCR5RZ) that targets the host cell CCR5 protein, which is a key molecule that HIV uses to bind to and enter human T cells.

Benitec chief executive officer Dr Peter French said the results were significant because it was the first human clinical trial of his company's ddRANi technology.

City of Hope principal onvestigator Dr John Zaia said the results "demonstrate that Benitec's technology, coupled with two other proprietary anti-HIV RNA constructs, has the potential to provide a novel therapy for HIV".

Benitec said it had begun recruitment in a second phase I clinical trial at the City of Hope using the same triple vector to transfect T cells in HIV/AIDS patients who have failed highly active antiretroviral therapy (HAART) therapy (BD: Apr 12, 2010).

Benitec fell 0.2 cents or 5.6 percent to 3.4 cents with two million shares traded.

CALZADA

Calzada's Novoskin joint venture has been awarded $240,000 by the South Australian bioscience industry development organization, Bio Innovation SA.

Calzada said Novoskin was a joint venture company focused on developing an innovative treatment for serious burns, has been awarded a grant for approximately $240,000 Novoskin is 80 percent owned by Calzada's wholly-owned subsidiary Polynovo Biomaterials and 20 percent by Skin Pty Ltd a company associated with Adelaide burns surgeon Prof John Greenwood.

The grant is for the "Development of a Biodegradable Temporizing Matrix and Composite Cultured Skin" with the funding primarily being provided to partly fund two animal trials to assess the biodegradable temporizing matrix and composite cultured skin products.

Calzada said Polynovo's the Novosorb biodegradable matrix could form the basis of a two-stage burn treatment strategy, with an initial non-cellular biodegradable temporizing matrix to stabilize the wound bed, followed by the application of cultured skin substitute.

The company said Dr Greenwood had been working on a biodegradable polymer-based cultured skin since 2004, with the Novoskin joint venture established in 2006.

Calzada said that since 2007 the emphasis has been to optimize the required processes and product and to ensure that the biodegradable temporizing matrix could be manufactured efficiently and that the manufacturing process was scaleable and to ensure that procedures implemented would facilitate progress through the regulatory pathway.

The company said the group was ready to start two animal studies, the first starting at the end of June to assess the biodegradable temporizing matrix in a large wound in a pig model. The six month trial would treat large surgically created wounds in 24 pigs.

The aim is to test the efficacy of the treatments and to determine which form of the biodegradable temporizing matrix was most effective - a foam based structure or a fibrous mat with crisscrossed filaments.

Calzada said that following the pig study, the group would conduct a composite cultured skin study on 96 athymic mice to investigate full thickness wound repair.

At the same time, the group will commission the North American Medical Safety Agency to undertake toxicity, mutagenicity and carcinogenicity safety studies, the company said.

Calzada said the group expected to begin pilot human clinical trials within the next 18 months.

Calzada was up 0.1 cents or 3.85 percent to 2.7 cents.

FERMISCAN

Fermiscan director Ben Dillon says the deed of company arrangement was terminated on June 11, 2010.

Mr Dillon was appointed a director replacing Mark Fordree on June 7, 2010.

In March, administrators Woodgate & Co said a deed of company arrangement to extract value from the company's shell was executed on March 8, 2010 (BD: Mar 17, 2010).

Fermiscan failed to advance Prof Veronica James's hair x-ray diffraction test for breast cancer and lost its appeal to the New South Wales Supreme Court in its long running legal battle against Prof James (BD: Nov 11, 12, 2009).

The company also failed to complete a merger with Polartechnics, which contributed to Polartechnics going into voluntary liquidation (BD: Jul 16, 31, 2009).

The breast cancer test was sold to the Sydney Breast Clinic, which Fermiscan bought for $5.5 million and sold for $1 million (BD: Oct 2, 2009).

The company's status without a deed of company arrangement is uncertain.

Fermiscan was untraded at three cents.

CHEMGENEX

Orbis Investment Management increased its substantial shareholding in Chemgenex from 36,789,005 shares (12.99%) to 39,640,833 shares (13.99%).
Orbis said the 2,851,828 shares were acquired on between April 27 and June 15, 2010 for $979,281 or an average price of 34.3 cents a share.
Chemgenex fell half a cent or 1.6 percent to 30 cents.

HELICON GROUP

Jason Peterson has become a substantial shareholder in Helicon with a holding of 10,000,000 shares or 10.03 percent.
The ASX notice said Celtic Capital of Mt Pleasnat Western Australia paid $125,000 for the shares or 1.25 cents a share and Mr Peterson was the Celtic Capital's sole director.
Yesterday Helicon said it placed 13,001,277 shares to clients of CPS Securities at 1.25 cents a share raising $162,516 and hoped to raise $1,875,000 in a rights issue.
Helicon was untraded at two cents.

MEDICAL RESEARCH COMMERCIALISATION FUND

Former Queensland Premier Peter Beattie, has been appointed as a non-executive director of the $31.2 million Medical Research Commercialisation Fund.
The Medical Research Commercialisation Fund said in a media release that it was established in 2007 "as an innovative investment collaboration between Australia's leading medical research institutes and Statewide and Westscheme Superannuation funds".
The Medical Research Commercialisation Fund is managed by Brandon Capital Partners, to support development of the most promising medical discoveries in Australia.
Fund principal executive and Brandon Capital partner Dr Chris Nave told Biotech Daily that Osprey Medical was an example of the Fund's activities and was created from research at the then Baker Heart Institute (now Baker IDI Heart and Diabetes Institute) and had developed a catheter to remove toxic dyes used in angiograms.
Dr Nave said Mr Beattie was actively interested in the biotechnology sector which he had promoted both as Premier of Queensland and as Queensland's Trade Commissioner to North and South America.
"As Premier of Queensland Peter was a champion of commercializing promising new medical technologies," Dr Nave said in a media release. "He shares our passion for the industry and has strong commercial skills to match."
Mr Beattie said he was "a passionate supporter of Australian biotechnology for over a decade".
The Fund began operations with seven institutes and support from the Victorian and New South Wales Governments and members include 27 medical research institutes and hospitals in Victoria, New South Wales, Queensland and Western Australia, employing more than 6,000 researchers with more than $700 million in annual research expenditure.