



# Biotech Daily

Tuesday November 10, 2009

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: UNIVERSAL BIO UP 15%; USCOM DOWN 6%**
- \* **GSK DETAILS ONCOLOGY PIPELINE, LUNG CANCER VACCINE**
- \* **REGULATORY CLEARANCE EARNS UNIVERSAL BIOSENSORS \$17m**
- \* **FDA ACCEPTS CHEMGENEX OMAPRO NDA, REVIEW IN 6 MONTHS**
- \* **UNILIFE OVERSUBSCRIBED PLAN RAISES \$21.5m**
- \* **CYTOPIA'S CYT997 SHOWS 'PROFOUND' VASCULAR DISRUPTION IN MICE**
- \* **COMPUMEDICS GERMANY WINS \$200,000 INNOVATION GRANT**
- \* **CLINUVEL EPP PHASE III TRIAL ON TARGET FOR DECEMBER CLOSE**
- \* **PROGEN-MEDIGEN LEGAL STOUSH ADJOURNED TO NOVEMBER 13**
- \* **BAM CAPITAL REDUCES 1% IN PRANA**
- \* **BIOPROSPECT APPOINTS SOLAGRAN'S CHARLES PELLEGRINO M-D**

## MARKET REPORT

The Australian stock market climbed 1.3 percent on Tuesday November 10, 2009 with the S&P ASX 200 up 58.7 points to 4,733.6 points. Eighteen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and four were untraded.

Universal Biosensors was best, up 26 cents or 15.12 percent to \$1.98 with 238,184 shares traded, followed by Labtech up 11.5 percent to 14.5 cents.

Tissue Therapies climbed 7.1 percent; Antisense was up 6.6 percent; Bionomics was up 5.7 percent; Mesoblast and Phylogica were up more than four percent; Cellestis was up 3.1 percent; Acrux, Avexa, Circadian, Compumedics, Nanosonics and Sunshine Heart rose more than two percent; with CSL, Living Cell and Sirtex up more than one percent.

Uscom led the falls for the second day in a row, down four cents or 5.7 percent to 66 cents with 1,300 shares traded followed by Tyrian down 5.3 cents to 1.8 cents.

Genetic Technologies and Viralytics lost more than three percent; Novogen shed 2.75 percent; with Biota, Clinuvel and Genera down more than one percent.

## GLAXOSMITHKLINE

Glaxosmithkline says it has more than 40 phase I, II and III clinical trials underway in Australia, with 22 focused on oncology, including a therapeutic lung cancer vaccine. In a briefing and teleconference on Glaxosmithkline's oncology research and development pipeline the company said it had a dedicated phase I/II clinical trial facility at Sydney's Prince of Wales Hospital.

The briefing was presented by Glaxosmithkline's oncology's medical advisor Dr Alan Paul and the Royal Prince Alfred Hospital's Prof Michael Boyer, a lead investigator in the therapeutic lung cancer vaccine being trialed by Glaxosmithkline.

The vaccine has been designed for patients who have had lung cancer and is intended to prevent the recurrence of the cancer.

Dr Paul said lung cancer killed more Australians than any other cancer despite success in reducing smoking rates. He said that if all people smoking tobacco stopped the rates of lung cancer would drop over time by 90 percent.

Dr Paul said along with lung cancer, Australia had high mortality rates from prostate, colorectal, breast cancer and melanomas, killing about 50,000 Australians this year. He said the direct health care cost of cancer in Australia was more than \$3.8 billion a year. He said that non-small cell lung cancers were the most common form of lung cancer with an incidence of about 7,300 cases in Australia, of the total of 9,180 cases.

Dr Paul said that if treated early there was an 80 percent survival rate.

He said that Glaxosmithkline was working not only to treat cancer but also provided supportive care through treating side effects of chemotherapy and was working to prevent cancer with the company marketing two nicotine patch brands.

Glaxosmithkline also has a cervical cancer vaccine on the market Cervarix.

Dr Paul said Glaxosmithkline had a range of program including targeting angiogenesis in early stage disease, with the company looking for the location of cell signaling in order to disrupt further metastases.

Dr Paul referred to several trials that had been discontinued due to safety or efficacy concerns, noting that Glaxosmithkline was aware of the difficulty of taking compounds through the clinic to market.

He said the company was recruiting women a 900-patient trial of a treatment for ovarian cancer across several sites in Australia and an indication that was very difficult to diagnose.

Dr Paul said the company was conducting a phase III adjuvant breast cancer trial with 8,000 patients, a phase III 600-patient first line metastatic breast cancer trial, a phase III renal cell carcinoma trial with 876 patients and a phase III soft tissue sarcoma trial.

He said Glaxosmithkline was also conducting the Magrit lung cancer vaccine trial - a double-blind, randomized, placebo-controlled phase III study to assess the efficacy a cancer-specific antigen (called MAGE-A3) combined with an immune reaction booster (called an adjuvant system) as adjuvant therapy in patients with resectable MAGE-A3 positive non-small cell lung cancer.

The trial has a target of 2270 patients in 30 countries with 12 sites in Australia.

He said the cancer immunotherapy trial intended "to educate our own immune system to fight cancer" using selectively targeted antigens that are expressed by cancer cells but not expressed by normal cells

Dr Paul said the immune system reacted towards the antigen in the therapy and attacks the cancer cells where the antigen is found.

He said the antigen-specific cancer immunotherapeutic was administered as a vaccine or series of vaccines.

Glaxosmithkline Australia is a subsidiary of Glaxosmithkline UK.

### UNIVERSAL BIOSENSORS

Lifescan has initial regulatory clearance to sell Universal Biosensors blood glucose monitoring product, triggering a \$US16 million (\$A17.2 million) milestone payment. Universal Biosensors chief executive officer Mark Morrisson told Biotech Daily that due to confidentiality arrangements with Johnson & Johnson subsidiary Lifescan he was not able to specify the geographical location of the approval for his company's glucose test. Mr Morrisson did say that companies do not go to regulatory approval without being ready to roll-out the product for sale.

Biotech Daily believes the regulatory approval is northern hemisphere and probably the US or European Union.

Mr Morrison said in a media release that the milestone from Lifescan was "a tremendous accomplishment for UBI technology".

The company said Lifescan would decide the timing of test's launch, but sales of the product would accompany inventory building prior to launch.

The company said it expected revenue of \$25 million in the first 12 months from regulatory approval from milestone payments, manufacturing charges and service fees.

Mr Morrison told Biotech Daily that the blood glucose testing kit was just the first of its products and the company had several diagnostic tests in development.

Universal Biosensors was up 26 cents or 15.1 percent to \$1.98.

### CHEMGENEX

The US Food and Drug Administration has accepted Chemgenex's new drug application for Omapro and granted priority review.

Chemgenex said the priority review for Omapro (omacetaxine mepesuccinate) for chronic myeloid leukemia patients who have failed treatment with imatinib and who have developed the Bcr-Abl T315I mutation means the FDA would take about six months to make its decision on approval for sale in the US.

The company said priority review designation was given to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists.

Chemgenex chief executive officer Dr Greg Collier said the priority review status "underscores the critical need for a treatment option for the CML T315I patient population".

"If approved, we plan to launch Omapro in the US as the first therapy specifically indicated for CML T315I patients," Dr Collier said.

Chemgenex jumped three cents at the open but closed unchanged at 88 cents with 1.6 million shares traded.

### UNILIFE MEDICAL SOLUTIONS

Unilife says its share plan "was significantly oversubscribed" and raised \$21.5 million.

Unilife said it received applications for 33.7 million shares with a value of \$28.7 million.

The company said it increased in the number of shares to be issued under the plan from 11,764,705 shares to raise \$10 million to 25.3 million shares to raise \$21.5 million - a pro-rata allotment to shareholders of 75 percent of applications.

With commitments for \$32.1 million from institutional investors in the US and sophisticated and professional investors in Australia and the plan's \$21.5 million, the company has raised \$53.6 million.

Unilife was up four cents or 3.5 percent to \$1.175 with 1.1 million shares traded.

## CYTOPIA

Cytopia says preclinical mouse studies show its vascular disrupting agent CYT997 had "profound" effects with oral daily dosing.

Cytopia said the data would be presented at the Molecular Targets and Cancer Therapeutics Conference in Boston on November 16, 2009.

The company's research director Dr Chris Burns will present a poster entitled 'Antitumour activity of CYT997: a phase II vascular disrupting agent administered orally in combination with cisplatin in a colon adenocarcinoma xenograft model' which outlines data from preclinical studies with CYT997, "clearly demonstrating the profound vascular disrupting effects achieved through repeated oral daily dosing of the compound".

Cytopia said CYT997 was in a phase II clinical trial.

"This data demonstrates the broad potential utility of CYT997 as an anticancer agent," Dr Burns said.

"The ability to administer CYT997 orally differentiates it from other [vascular disrupting agents] in development and allows more flexible dosing regimes than agents which can only be administered intravenously," Dr Burns said.

Cytopia said "a large body of preclinical work on CYT997 has also been published in the November edition of the prestigious journal Molecular Cancer Therapeutics".

Cytopia was up 0.2 cents or 2.15 percent to 9.5 cents.

## COMPUMEDICS

Compumedics says its Singen, Germany-based Doppler technology business has been awarded an EUR120,000 (\$A200,000) grant from the German Federal Government.

Compumedics said the grant from the Zentrales Innovationsprogramm Mittelstand was awarded to develop an integrated ultrasound Doppler-system for flexible endoscopy.

Compumedics said the award was an additional milestone in its strategy and followed previously announced Germany contracts.

Compumedics Germany GmbH managing director Christoph Witte said the development of an integrated ultrasound-Doppler-system for flexible endoscopy was "a major step for the DWL business in extending its product portfolio".

Compumedics was up 0.5 cents or 2.86 percent to 18 cents.

## CLINUVEL

Clinuvel chief executive officer Dr Philippe Wolgen says his company's phase III trial of afamelanotide for erythropoietic protoporphyria is on target to close by the end of this year.

Dr Wolgen said in a paid-for interview Clinuvel would "achieve the main objective set by this management team and under my guidance four years ago: the successful completion of a phase III registration trial by December 2009".

"To find, convince, recruit and retain 101 patients with a rare disorder like porphyria to participate in a pan-European trial has been an enormous challenge out of Australia," Dr Wolgen said.

He said more than 600 implants had been administered and when he started four years ago "there were no data generated, let alone the ability to talk about a filing prospect".

Clinuvel is developing the photoprotective drug for a range of indications including polymorphic light eruption, photodynamic therapy side effects, actinic keratoses and solar urticaria.

Clinuvel fell half a cent or 1.7 percent to 29 cents.

### PROGEN

Progen says a Queensland Supreme Court hearing to adjourn resolutions on director elections has been adjourned to Friday November 13, 2009.

Progen is also seeking an alternative order postponing its annual general meeting until after the determination of legal proceedings relating to an alleged contravention of the Corporations Act (BD: Aug 4; Sep 15; Nov 2, 2009).

Progen was unchanged at 59 cents.

### PRANA BIOTECHNOLOGY

BAM Capital has reduced its substantial holding in Prana from 19,285,500 shares (8.28%) to 16,926,110 shares (7.26%) on October 9, 2009.

BAM Capital is associated with Hal Mintz and Ross Berman.

Prana was unchanged at 18 cents.

### BIOPROSPECT

Bioprospect has appointed Solagran employee and former director Charles Pellegrino as managing director.

Bioprospect was up 0.3 cents or 7.89 percent to 4.1 cents with 1.4 million shares traded.