# Biotech Daily

Wednesday December 9, 2009

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: PHYLOGICA UP 8%; PATRYS DOWN 11%**

*** CHEMGENEX'S OMAPRO EFFECTIVE IN SECOND PHASE II/III CML TRIAL**

*** ASX APPROVES CBIO LISTING; IPO EXTENDED**

*** BIONOMICS 2nd PHASE II BNC105 TRIAL FOR MESOTHELIOMA**

*** CLINUVEL'S AFAMELANOTIDE 'HELPS GI CANCER TREATMENT'**

*** BIOTRON REQUESTS CAPITAL RAISING TRADING HALT**

*** SUPREME COURT APPROVES CYTOPIA TORONTO TAKEOVER MEETING**

*** PALLANE ISSUES $400k NOTE; PURSUES DIABETES DRUG**

*** KARMELSONIX RAISES $4.5m**

## MARKET REPORT

The Australian stock market fell 0.7 percent on Wednesday December 9, 2009 with the S&P ASX 200 down 32.7 points to 4637.9 points.

Six of the Biotech Daily Top 40 stocks were up, 18 fell, 11 traded unchanged and five were untraded.

Phylogica was best, up one cent or 8.3 percent to 13 cents with 230,000 shares traded.

LBT and Novogen climbed five percent or more; Universal Biosensors was up 4,5 percent; Clinuvel was up 3.45 percent; Genera rose 1.3 percent; with Cochlear and Resmed up by less than one percent.

Patrys led the falls, down 1.5 cents or 11.1 percent to 12 cents with 54,000 shares traded, followed by Alchemia down 9.7 percent to 65 cents with 120,825 shares traded.

Phosphagenics lost 7.7 percent; Genetic Technologies was down 6.98 percent; Prana was down 5.9 percent; Antisense, Benitec and Viralytics fell more than four percent; Avexa, Chemgenex, Pharmaxis and Prima were down more than three percent; Biota, CSL, Mesoblast and Starpharma shed more than two percent; with Acrux, Cellestis and Psivida down less than one percent.

## CHEMGENEX

Chemgenex says a second phase II/III trial of Omapro for chronic myeloid leukemia has shown high levels of efficacy for patients who have failed two tyrosine kinase inhibitors.

On Monday December 7, 2009, Chemgenex announced an 86 percent complete haematological response for the 49 chronic phase patients in its 81 patient trial of Omapro (omacetaxine mepesuccinate) for chronic myeloid leukemia patients with the Bcr-Abl T315I mutation. The 42 patients with a complete haematological response had a median duration of nine months.

Today's data from a phase II/III trial of 89 patients resistant or intolerant to two or more tyrosine kinase inhibitors showing that of the 44 patients in chronic phase, 82 percent (36 patients) had a complete haematological response for a median period of 4.8 months.

The data was presented at the American Society of Hematology meeting in New Orleans by the deputy chair of leukemia at the University of Texas MD Anderson Cancer Center Dr Jorge Cortes, an investigator for Chemgenex's phase II/III trials of omacetaxine.

Chemgenex said Dr Cortes concluded that Omapro was "a new potential therapy" for patients with multi-tyrosine kinase inhibitors resistant chronic myeloid leukemia.

The company said that of the 89 patients in the trial, 44 were in chronic phase, 25 were in accelerated phase and 20 were in blast phase.

Among the 44 in chronic phase 82 percent (36 patients) had a complete haematologic response with a median response duration of 4.8 months, a cytogenetic response rate of 27 percent (12 patients) and 23 percent (10 patients) had a major cytogenetic response.

Among the 25 accelerated phase patients, 80 percent (20 patients) had an overall haematologic response, with 52 percent (13 patients) achieving a complete haematological response with a median duration of 3.1 months.

Of the 20 blast phase patients 50 percent had an overall haematologic response, with 35 percent (seven patients) achieving a complete haematological response with median duration 2.5 months.

The company said that the investigators reported that omacetaxine was safe for self-administration, was well tolerated and that reversible and manageable myelo-suppression was the most common side effect.

Chemgenex chief executive officer Dr Greg Collier said that Omapro "continues to show that it may provide clinical benefit for CML patients who have developed resistance to currently approved therapies independent of the T315I point mutation".

Chemgenex chief operating officer Dr James Campbell told Biotech Daily that the data sets of both trials were completely separate with no overlap, meaning that Chemgenex had phase II/III safety and efficacy data on 170 chronic myeloid leukemia patients.

Chemgenex fell three cents or three percent to 96 cents.

## CBIO

CBio says the ASX has given "conditional listing approval" and the initial public offering has been extended to January 29, 2009 (BD: Nov 11, 2009).

CBio chairman Stephen Jones said the pre-condition to listing was "a key milestone in this offer process and a positive for all shareholders".

A company executive told Biotech Daily the conditions were "certain standard conditions imposed by ASX as part of any listing".

The company said that a supplementary prospectus was lodged with the Australian Securities and Investments Commission on December 7, 2009 extending the initial public offer to January 29, 2010.

CBio is a public unlisted company hoping to raise up to $30 million at $1.00 a share.

## BIONOMICS

Bionomics says it will conduct a phase II clinical trial of its BNC105 anti-cancer drug on 60 mesothelioma patients at up to 12 Australian centres.

Bionomics announced a US phase II renal cancer trial earlier this year and said the mesothelioma trial was the second phase II clinical trial of BNC105, a novel anti-cancer agent which is both a vascular disrupting agent and an inhibitor of cancer cell proliferation.

The company said the phase II trials followed a successful BNC105 phase I trial in patients with advanced cancers at four Melbourne hospitals.

In May, Bionomics said its phase I dose escalation trial of BNC105 showed safety, tolerability and some efficacy (BD: May 29, 2009).

In that announcement Bionomics said two of nine treated patients had stable disease and received additional cycles of treatment and one patient with mesothelioma treated with 8.4 $mg/m^2$ had stable disease up to week 22 of treatment.

The company said mesothelioma was a cancer, usually caused by exposure to asbestos, in which malignant cells developed in the protective lining that covers most internal organs with the most common site the outer lining of the lungs and internal chest wall.

Most people who develop mesothelioma had jobs where they have been exposed to asbestos dust fibres and there had been cases where people washing the clothes of others have suffered mesothelioma.

Despite treatment, mainly with chemotherapy and radiation therapy, the disease usually had a poor prognosis, Bionomics said.

Bionomics said it had “rapidly reached a number of clinical milestones for BNC105” including blood levels consistent with vascular disrupting agents and anti-tumor activity; evidence of vascular disrupting activity confirmed by tumor imaging; a mesothelioma patient enrolled in the trial achieved stable disease where cancer progression was halted; no complicating side-effects; data suggests BNC105 has more than a 10-fold therapeutic window compared to a leading competitor in cancer patients.

Bionomics chief executive officer Dr Deborah Rathjen said the drug was “very promising so far and the company is quickly moving to phase II trials”.

“We are expecting to report interim results of this trial in patients with mesothelioma in early 2011,” Dr Rathjen said.

“This condition has virtually no effective treatments after first line chemotherapy and patients typically have a life expectancy of less than one year,” Dr Rathjen said.

“The long latency means that we are still to see the peak incidence of mesothelioma over the next decade,” she said.

Bionomics said that in 2005 there were 597 new cases of mesothelioma diagnosed in Australia and in 2006 there were 486 deaths attributed to mesothelioma. It is a usually fatal cancer which typically occurs 20 to 40 years after exposure to asbestos.

Bionomics said the phase II trial of BNC105P as a second line chemotherapy for advanced malignant pleural mesothelioma was a single arm, unblinded study for patients with mesothelioma who have progressed on platinum and pemetrexed chemotherapy. The company said BNC105 would be administered on days one and eight of 21 day cycles. Treatment will continue until disease progression with a primary objective to determine the tumor response rate and secondary endpoints including progression-free survival, quality of life, overall survival and treatment duration.

Bionomics said the Australasian Lung Cancer Trials Group and the National Health and Medical Research Council Clinical Trials Centre had been contracted to conduct the trial.

Dr Rathjen told Biotech Daily that the second phase II trial was “rounding off what’s been a tremendous year for the company with our capital raisngs and clinical milestones”.

Bionomics was unchanged at 36 cents.

## CLINUVEL PHARMACEUTICALS

Clinuvel says its afamelanotide being developed for sun sensitivity is effective for patients in systemic photodynamic therapy for certain gastro-intestinal cancers

Clinuvel said a 16 patient phase II trial showed that a single 16mg dose of afamelanotide improved the quality of life and phototoxicity in patients undergoing systemic photodynamic therapy in four clinics in France.

The company said nine patients were administered afamelanotide and seven patients received placebo as a subcutaneous implant at the same time as the photosensitising agent Photofrin was administered intravenously to enhance and accelerate tumor treatment by laser illumination.

Clinuvel said that in patients with advanced stage bile duct cancer, the treatment is reported to extend average life expectancy from 98 to 498 days, but for up to 90 days following treatment, patients must avoid sunlight and artificial lights or risk phototoxic reactions including intense pain and second degree burns.

Post-operative analysis at seven and 12 days revealed a positive trend to tolerate ambient light at standardized exposure by seven out of nine patients (77%) receiving afamelanotide.

The company said that in patients on the active drug, a significant improvement in quality of life assessment was demonstrated at 60 days of treatment (p=0.02).

Clinuvel said that observations from all physicians and reports from patients supported and encouraged further use of afamelanotide in photodynamic therapy (PDT) cancer trials and no significant drug-related adverse events were reported.

Clinuvel's chief scientific officer Dr Hank Agersborg said the results were "meaningful as they statistically confirmed the benefits of the adjunctive use of afamelanotide in a small group of oncology and terminally ill patients".

"In the next few weeks we will decide on a further phase III trial in PDT," Dr Agersborg said.

"The particular choice for afamelanotide as an adjuvant photoprotective drug in gastro-intestinal cancer stems from the common biochemical pathways seen in both PDT and erythropoietic protoporphyria, a disease in which we are using afamelanotide in parallel advanced phase III trials," Dr Agersborg said.

Dr Agerborg said the results were of particular relevance because the regulatory agencies would accept the data from the PDT studies as supporting evidence for the erythropoietic protoporphyria (EPP) registration, currently in phase III trials with the first trial due to close this month and the confirmatory trial die to begin before June 2010 and be completed by the end of 2010.

"Therefore, the confirmation of safety and the improvement in quality of life in these light intolerant patients provides a substantial step toward the registration of afamelanotide for EPP," Dr Agersborg said.

Clinuvel was up one cent or 3.45 percent to 30 cents.

## BIOTRON

Biotron has requested a trading halt pending an announcement "regarding the underwriting of an option entitlement issue which may result in a material capital raising".

Trading will resume on December 11, 2009 or on an earlier announcement.

Biotron last traded at 10 cents.

## CYTOPIA

Cytopia says the Supreme Court of Victoria made orders yesterday to convene a shareholders meeting to vote on the proposed merger with Canada's YM Biosciences Inc.
Should shareholders approve the merger it would be through a scheme of arrangement exchanging 11.737 Cytopia shares for one YM Biosciences share (BD: Oct 6, 7, 2009).
Cytopia said the scheme meeting would be held at the offices of BDO Kendalls, Level 30, 525 Collins Street, Melbourne on January 12, 2010 at 10.30am and shareholders on the share register on January 10, 2010 could vote at the meeting.
Cytopia has posted an explanatory statement to the ASX including the independent expert's report and notice of meeting, the scheme booklet has been registered by the Australian Securities and Investments Commission and filed with the ASX and will be sent to shareholders next week. A copy is at the Cytopia website www.cytopia.com.au.
Cytopia chief executive officer Andrew Macdonald said the proposed merger had "the unanimous support of the Cytopia board, in the absence of a superior proposal".
"We believe that it will provide shareholders with the best opportunity available for the continued development and expansion of our lead programs, as well as exposure to a broader portfolio of potential cancer development therapies and geographic diversification," Mr Macdonald said.
Shareholder briefing sessions will also be held in Melbourne, Sydney and Brisbane, hosted by Mr Macdonald and Cytopia's drug development director Dr Gregg Smith.
The Melbourne briefing on December 18, 2009 will be at Austock Group, Level 1, 350 Collins Street, Melbourne at 9.30am.
The Sydney briefing will be on December 21 at the Portside Centre, Symantec House, Level 5, 207 Kent Street, Sydney at 9.30am and the Brisbane briefing will be held on the same day at Management House, Corner Boundary & Rosa Streets, Spring Hill, at 3pm.
Cytopia was up 0.3 cents or 3.5 percent to 8.9 cents.

## PALLANE MEDICAL

Pallane (formerly Dia-B Tech) says it has issued a convertible note for $400,000, which is not subject to the reinstatement of its securities to official quotation.
Pallane said the $400,000 would be used for operating costs and was in addition to a $370,899 tax refund for the 2009 financial year.
The company said it would raise an additional $600,000 through convertible notes in the next three months.
Pallane said further capital raisings would be conducted the shareholder approval and the company would apply research and development grants from the Federal Government in combination with research consultants appointed by the company.
Pallane said it would continue its discovery and development of pharmaceuticals, diagnostics and treatments for diabetes and related diseases, with Dia-B Tech's former lead compound ISF402 to improve blood glucose control in diabetes the major project.
ISF402 is a small, naturally occurring protein shown to enhance the effects of insulin (BD: May 3, 2007).
The company said it planned to take the project to phase II clinical trials and commercialization with major pharmaceutical groups.
Pallane said it intended to approach pharmaceutical partners who have previously reviewed the clinical data and would further develop and commercialize the project by exploring potential licencing deals and joint ventures.
Pallane has not traded on the ASX. Dia-B last traded at 1.7 cents prior to a 20-to-one consolidation.

KARMELSONIX

Karmelsonix has placed 112,500,000 shares at four cents a share and 56,250,000 options to professional and sophisticated raising $4.5 million.

Karmelsonix said the attaching options were exercisable at 7 cents each by July 31, 2011.

The company said 100 million shares would be issued under the approval received at the company's annual general meeting on November 12, 2009 with the balance being issued under the ASX 15 percent rule.

Karmelsonix fell 0.2 cents or four percent to 4.8 cents.