Biotech Daily

Thursday June 23, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: VIRALYTICS UP 20%, OPTISCAN DOWN 17%**

*** GSK CLOSES AUSTRALIA ALLIANCES UNIT, NOT R&D**

*** CLINUVEL EARNS $1m FROM SCENESSE ITALIAN SPECIAL ACCESS**

*** BIONOMICS BNC105 CANCER DOSE-RANGING TRIAL PUBLISHED**

*** PROGEN: MEDIGEN READY FOR PHASE III PI-88 LIVER CANCER TRIAL**

*** AVITA PLACEMENT, SHARE PLAN EGM SEES LOW VOTE, DISSENT**

*** ONYX TAKES 14% OF FERMISCAN**

MARKET REPORT

The Australian stock market fell 0.71 percent on Thursday June 23, 2011 with the S&P ASX 200 down 32.1 points to 4,500.5 points.

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

Viralytics was the best, up 1.4 cents or 20 percent to 8.4 cents with 25.7 million shares traded, followed by Tissue Therapies up 11.9 percent to 61 cents.

Phosphagenics climbed four percent; Prima and Sunshine Heart were up more than three percent; Anteo and Patrys rose more than two percent; with Heartware, Nanosonics and Starpharma up more than one percent.

Optiscan led the falls, down one cent or 17.2 percent to 4.8 cents with 163,440 shares traded, followed by Compumedics down 14.7 percent to 8.1 cents with 22,545 shares traded and Genera down 10.5 percent to 17 cents with 71,100 shares traded.

Benitec and Impedimed lost more than six percent; Pharmaxis fell 5.5 percent; Cellmid was down 4.2 percent; Biota, Cochlear and Resmed were down more than three percent; Alchemia, Mesoblast and QRX shed more than two percent; with Bionomics, Circadian and Phylogica down more than one percent.

GLAXOSMITHKLINE

Glaxosmithkline has closed its research and development alliances unit, which was headed by Dr Ashley Bates.

Glaxosmithkline director of healthcare environment David Herd told Biotech Daily that the company's research and development program continues, but would be the responsibility of "global colleagues".

Mr Herd said the phase I trials unit in Sydney continued unaffected along with research and development and trial facilities for vaccines and pharmaceuticals in Australia and New Zealand and the on-going association with Monash University in Melbourne.

Mr Herd said there would be "a much greater focus [on alliances] with our global colleagues" and the company had research facilities across the world including in China, Spain, the UK and US.

Mr Herd agreed that the role of head of research and development alliances had been removed, but said alliance companies would speak more directly with the decision makers about their programs.

Mr Herd said that the first point of contact for Australian and New Zealand companies wanting to discuss research and development or commercialization would be medical director Dr Camilla Chong.

"The decisions where the research is done are being made directly," Mr Herd said.

"We are very much heavily involved in Australian and New Zealand research and development," Mr Herd said.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has recorded its first $1 million in sales of Scenesse to 40 erythropoietic protoporphyria patients in Italy.

Clinuvel said Scenesse (afamelanotide) was made available in Italy under a special access scheme 11 months ago for the genetic disorder designated as an orphan disease.

The company said that throughout the treatment period all patients had been followed up by erythropoietic protoporphyria (EPP) specialists and no serious drug-related adverse events had been recorded.

Clinuvel said the drug was reimbursed by the Italian health system and the company intended expanding its use.

The company said that erythropoietic protoporphyria was characterized by severe phototoxicity of the skin resulting in intolerable pain, swelling and scarring, usually of the exposed areas such as the face, hands and feet.

Clinuvel said patients were often forced to lead an indoors existence, severely affecting their quality of life, with about 10,000 people globally affected and about 4,000 in Europe.

Clinuvel chief scientific officer Dr Hank Agersborg said the company was "deeply affected and motivated by the numerous reports from patients expressing how the drug is changing their existence and facilitates a pain free outdoor life".

"It is now apparent that we have made the correct clinical and regulatory choices to set a precedent of how Scenesse is best utilized clinically," Dr Agersborg said.

Clinuvel chief executive officer Dr Philippe Wolgen said that despite the initial success, "we remain vigilant in continuously analyzing the effects of repeated dosing of the drug and, most importantly, the safety of our patients".

"The transition from research to initial revenue is significant in today's markets," Dr Wolgen said. "This earnings call five years after starting the program is an additional benchmark for all who follow the company's evolution," Dr Wolgen said.

Clinuvel fell one cent or 0.6 percent to $1.70.

BIONOMICS

Bionomics says its phase I BNC-105P dose-ranging trial data has been published in the journal Clinical Cancer Research supporting the 16mg/m2 dose (BD: Jun 7, 2010).

The trial evaluated BNC105 in patients with a range of advanced solid tumors for whom standard therapy had failed or did not exist.

The article, coauthored by Bionomics drug development director Dr David Bibby, is entitled 'Clinical, Pharmacodynamic and Pharmacokinetic Evaluation of BNC105P: a Phase I Trial of a Novel Vascular Disrupting Agent and Inhibitor of Cancer Cell Proliferation' and is available at: http://clincancerres.aacrjournals.org/content/early/2011/06/18/1078-0432.CCR-11-0937.abstract.

The abstract concluded that BNC105P had a favorable toxicity profile at the recommended dose of 16mg/m2 and was associated with pharmacodynamic changes consistent with its known mechanism of action.

The abstract said the trial also evaluated the safety and toxicity profile, pharmacokinetic and pharmacodynamic effects of BNC105P, which was an inhibitor of tubulin polymerization that has vascular disrupting and anti-proliferative effects.

The abstract said BNC105P was administered as a 10 minute infusion on days one and eight of a 21-day cycle in a first-in-human phase I study.

A dynamic accelerated dose titration method was used for dose escalation.

Plasma concentrations of BNC105P (phosphate prodrug) and BNC105 (active agent) were determined.

The abstract said that pharmacodynamic assessments were performed using dynamic contrast enhanced magnetic resonance imaging and analysis of a blood-borne biomarker.

The abstract said that 21 subjects with advanced solid tumors were enrolled on six dose levels, ranging from 2.1 mg/m2 to 18.9 mg/m2 and the recommended dose level was 16 mg/m2 and was well tolerated.

Pharmacodymanically active plasma levels were obtained with a dose dependant reduction in the levels of polymerized tubulin (on-target action) being observed.

The abstract said that dynamic contrast enhanced magnetic resonance imaging indicated blood flow changes in the tumor lesions of a number of subjects.

Bionomics said the trial was conducted in Australia under an investigational new drug application from the US Food and Drug Administration.

Bionomics said that the reduction in both tumor blood flow and tubulin polymerization observed following treatment of cancer patients with BNC105 is consistent with the mechanism of action of BNC105.

The company said BNC105 was a dual-action tumor vascular disrupting agent and cancer cytotoxic causing tumor blood vessels to collapse and kills cancer cells directly by binding to tubulin.

Bionomics said the observation of tubulin polymerization changes at 16mg/m2 suggested that BNC105 attained blood exposure levels that were high enough to disrupt its intended molecular target, consistent with the very high level of specificity for tumor blood vessels shown by BNC105 in preclinical studies.

The Peter MacCallum Cancer Centre's head of the department of medical oncology at Dr Danny Rischin said BNC105 had a favorable toxicity profile at the recommended dose.

"In this trial we were able to demonstrate for the first time that levels of tubulin polymerization in cells isolated from cancer patients correlated with the dose of a [vascular disrupting agent], using an assay developed by Bionomics," Dr Rischin said.

Bionomics fell one cent or 1.7 percent to 57 cents.

PROGEN PHARMACEUTICALS

Progen says Medigen will undertake a phase III trial of PI-88 in the adjuvant treatment of subjects with hepatitis virus-related hepatocellular carcinoma after surgical resection
Progen said it licenced PI-88 to Medigen Biotechnology Corp on an exclusive worldwide basis for oncology indications in June 2010 (BD: Jun 30, 2010).
Progen said the randomised, double blinded, placebo controlled, parallel group, international, multicentre trial would be known as the Patron trial and had been approved by the Taiwanese Food and Drug Administration.
The company said Medigen had completed a Taiwan investigator meeting with more than 20 investigators participating and had submitted the protocol to both the Korean and Chinese regulatory authorities.
Progen said that the European Medicines Agency had approved orphan medicinal products designation for PI-88 for heptocellular carcinoma.
Progen said its contract manufacturing subsidiary, Pharmasynth had manufactured and coordinated the preparation of the clinical trial drug supplies, which had been sent to Medigen's clinical research organisation for distribution to the clinical trial sites in readiness for the enrolment of the first cohort of patients.
Progen said that as Medigen made progress developing PI-88, it benefited through milestone payments and contract manufacturing services provided by Pharmasynth.
Progen said the next milestone payment was payable when the first patient is treated, which was expected by October 2011.
Progen was up 6.5 cents or 27.7 percent to 30 cents.

AVITA MEDICAL

Avita says that fewer than 30 million shares of the 120,175,260 shares on offer voted on extraordinary general meeting resolutions for stock issues to raise funds for the company.
Seven of the nine resolutions saw significant dissent with the closest vote supporting the placement of 80,000,000 shares with 10,282,726 proxy votes (70.7%) in favor and 4,267,443 proxy votes (29.3%) against.
Other resolutions facing significant oppositions were placements of 2,000,000 shares at 10 cents each to director Dalton Gooding; 3,500,000 shares to director Ian Macpherson and 1,300,000 shares to chief executive officer Dr William Dolphin
The placement of 100,000 shares to Dr Fiona Wood was passed more easily with 23,862,464 proxy votes in favor and 1,124,681 proxy votes against.
The share purchase plan was passed unopposed, but resolutions relating to further share and option issues were passed with significant opposition.
Avita was unchanged at 12 cents.

FERMISCAN

Onyx Capital has increased its substantial shareholding in Fermiscan from 74,500,000 shares (12.8%) to 82,350,000 shares (14.1%).
The Collins Street Melbourne-based Onyx said it acquired the 7,850,000 shares in an on-market transfer and purchase for $63,075 or an average price of 0.8 cents a share.
Fermiscan was up 0.1 cents or 14.3 percent to 0.8 cents.