Biotech Daily

Thursday June 11, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN; PHOSPHAGENICS UP 11%, GENERA DOWN 9%**

*** BIOTA HUMAN RHINOVIRUS CHALLENGE SHOWS PROOF-OF-CONCEPT**

*** CHEMGENEX DRUG EXTENDS CML PATIENTS' LIVES; MECHANISM**

*** FERMISCAN APPEALS SUPREME COURT DECISION ON INVENTOR**

*** VIRAX LICENCEE TRANSGENE FDA-APPROVED PHASE III CANCER TRIAL**

*** CEPHALON HAS 89% OF ARANA; 1% TO COMPULSORY ACQUSITION**

*** HALCYGEN RELEASES 22m ESCROW SHARES**

*** EASTLAND APPOINTS MICHAEL STEWART DIRECTOR**

*** NEURODISCOVERY LOSES DIRECTOR DR TONY EVANS**

*** BIO-MELBOURNE WORKSHOPS DRUG DEVELOPMENT PROGRAMS**

MARKET REPORT

The Australian stock market climbed 0.6 percent on Thursday June 11, 2009 with the S&P ASX 200 index up 22.8 points to 4,047.2 points.

Eleven of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and six were untraded.

Phosphagenics was best, up 1.5 cents or 10.7 percent to 15.5 cents with 292,500 shares traded, followed by Genetic Technologies up 9.2 percent to 7.1 cents.

Pharmaxis climbed 7.6 percent; Alchemia, Avexa, Biota and Circadian were up four percent or more; Chemgenex rose 2.7 percent; Clinuvel, Cochlear and Heartware were up more than one percent; with Psivida up 0.89 percent.

Genera led the falls, down five cents or 9.1 percent to 50 cents with 54,727 shares traded.

Tissue Therapies and Viralytics lost more than five percent; Acrux fell 4.76 percent; Universal Biosensors was down 3.1 percent; Bionomics, Cellestis, Novogen, Polartechnics and Progen shed more than two percent; with CSL and Starpharma down more than one percent.

BIOTA

Biota says a phase IIa challenge study of BTA798 for human rhinovirus has shown proof-of-concept in humans and reduced the incidence and severity of the infection.

Biota said the proof-of-concept study of the BTA798 orally-active inhibitor of human rhinovirus (HRV) was an early clinical trial to establish preliminary evidence of efficacy in a small number of subjects.

The company said rhinovirus infection was usually transient and mild in otherwise healthy individuals, but was frequently associated with potentially serious complications in people with asthma, cystic fibrosis, chronic obstructive pulmonary disease or those with a compromised immune function, such as transplant patients.

Biota's product development vice president Dr Jane Ryan said "that efficacy was shown so convincingly in such a small cohort is surprising".

Dr Ryan said the trial brought the company "closer to realizing our plans for an effective HRV treatment in high risk patients".

Biota said the trial was a double-blind challenge study designed to evaluate BTA798 for the prevention of HRV infection in healthy male subjects who had no evidence of immunity to the HRV study virus.

The company said that prior to being exposed to an experimental rhinovirus infection, volunteers were administered either placebo or one of three dose levels of BTA798.

The study used the incidence of confirmed HRV infection and the incidence of upper respiratory illness in the four groups as the primary endpoints, with measures of viral count, symptom improvement, safety and pharmacokinetics as secondary endpoints.

The study was designed to enrol up to four groups of volunteers, each with about 60 subjects.

Analysis of the first group of 41 subjects provided positive efficacy data and adequately confirmed proof-of concept.

The ultimate small study size was limited by the availability of volunteers without prior immunity to HRV and costs were reduced to approximately $4.0 million, significantly less than budgeted.

Biota said BTA798 was shown to reduce the incidence and severity of HRV infection when compared to placebo and these benefits were dose-proportional.

Compared with subjects who received placebo, subjects who received the highest dose of BTA798 showed a statistically significant lower peak viral level equivalent to a 97 percent difference between the groups (p=0.0311) as well as a lower total amount of virus which is equivalent to a greater than 99 percent difference between the groups (p=0.0170).

Biota said BTA798 was generally well-tolerated with adverse events observed in both placebo and drug groups.

Due to the small sample size, no conclusive difference between the groups could be established but enhanced safety monitoring will be incorporated in the design of future studies, the company said.

Pharmacokinetic data indicated that mean plasma levels of BTA798 increased predictably across the three doses, similar to the observations from the previous phase I studies.

Biota said it had informed the UK Medicines and Healthcare Products Regulatory Agency of its intention to conclude the study.

Future studies will be developed to confirm efficacy and safety in patient groups with naturally acquired HRV infection, where appropriate risk/benefits can be established.

Clinical plans will be discussed in detail with regulatory agencies before the end of 2009.

Biota has confirmed its intention to license the global rights to the HRV program and is actively seeking commercial partners.

Biota climbed six cents or 4.96 percent to $1.27.

CHEMGENEX

Chemgenex says omacetaxine extends the lives of its target patients with chronic myeloid leukemia and is in the process of identifying the drug's mechanism of action.

The deputy chair of leukemia at the University of Texas MD Anderson Cancer Center Dr Jorge Cortes said data presented at an American Society of Hematology conference last year, but not yet published, indicated omacetaxine was significantly extending patient life.

Dr Cortes, an investigator for Chemgenex's phase II/III trial of omacetaxine for chronic myeloid leukemia patients with the T315I mutation, said the unpublished data showed that half the chronic phase patients with the mutation not treated with omacetaxine died in 20 months. He said half the accelerated phase patients died in 12 months and half the blast phase patients died in two months.

By comparison, data presented this week at the European Hematology Association meeting in Berlin and published in a webcast teleconference today showed a 90 percent chance of patients taking omacetaxine in the chronic phase surviving for 30 months, the median survival rate for patients in accelerated phase was 18.75 months and in blast phase patients 1.81 months.

The Chemgenex presentation showed that 100 percent of 30 chronic myeloid leukemia patients with resistance to two or more tyrosine kinase inhibitors survived to 18 months.

The data showed that of 40 patients with the T315I mutation, 85 percent had a compete haematologic response leaving them effectively asymptomatic and six patients had a major cytogenetic response, effectively clearing any detectable signs of the leukemia.

Chemgenex chief executive officer Dr Greg Collier said there was in vitro evidence that one of the mechanisms of action was through omacetaxine killing leukemic stem cells.

Dr Collier said omacetaxine was a first-in-class cetaxine that specifically binds to the A-site cleft inhibiting protein translation and selectively reduced the levels of short lived onco-proteins up-regulated in leukemic cells, reducing cyclin-D1, Mcl-1 and c-Myc.

Chemgenex was up 1.5 cents or 2.7 percent to 57 cents.

FERMISCAN

Fermiscan says it will appeal the May 29, 2009 New South Wales Supreme Court judgment dismissing its action against its technology's inventor Prof Veronica James.

Fermiscan confirmed today that on May 29 Justice Robert McDougall dismissed the company's claims against Prof James and ordered the company pay legal costs estimated at about $1.4 million (BD: June 5, 2009).

Fermiscan alleged that Prof James' for using fingernails and skin instead of hair to detect breast cancer infringed the 1998 patent the company bought from Prof James.

Fermiscan said it would appeal to the Full Court of the New South Wales Supreme Court.

On April 30, 2009 Fermiscan told the ASX it had a cash burn of $1,746,000 for the three months to March 31, 2009 with $5,585,000 cash available.

The company has not made a statement about the impact of legal costs on its accounts.

Fermiscan chief executive officer David Young was not available to speak with Biotech Daily today.

Regarding the proposed merger, Polartechnics and Fermiscan said on April 17, 2009 that they expected the bidder's and target's statement would be dispatched by mid-May 2009".

On May 22, 2009 they said that the statements were "still in the process of being finalized and the bidder's statement will be released to Fermiscan shareholders before June 17, 2009, which is the required statutory timeframe" (BD: Apr 17, May 22, 2009).

Fermiscan fell one cent to 6.7 percent to 14 cents.

Polartechnics fell 0.2 cents or 2.17 percent to nine cents.

VIRAX

Virax says the US Food and Drug Administration has approved Transgene's phase III trial of TG4010 for non-small-cell-lung cancer.

Virax said the Strasbourg-based Transgene had licenced its Co-X-Gene technology for TG4010 with milestone and royalty payments on Transgene achieving relevant development milestones and sale of product.

Virax said an end of phase II meeting with the FDA reviewed clinical results for TG4010 and agreed with Transgene's plan for a phase III study in combination with first line chemotherapy in patients with advanced non-small-cell-lung cancer and with a normal level of activated natural killer cells before treatment.

Transgene also reported additional clinical data that confirmed a six month survival benefit (17.1 months when receiving TG4010 and chemotherapy versus 11.3 months for chemotherapy alone) in patients with normal activated natural killer levels prior to treatment.

Virax chief executive officer Dr Larry Ward said the regulatory milestone with the FDA , the confirmation of survival benefit upon TG4010 treatment and the ability to identify patients who should respond to this therapy were significant steps towards TG4010 being approved for the treatment of advanced non-small-cell-lung cancer, a disease of unmet medical need.

"This makes TG4010 a very valuable product and attractive to potential pharmaceutical partners," Dr Ward said.

Dr Ward told Biotech Daily that Transgene has previously said it expected to do a deal with a major pharmaceutical company by the end of this month, at which point Virax would be entitled to a milestone payment.

Virax fell 0.3 cents or 8.8 percent to 3.1 cents.

ARANA

Cephalon International Holdings increased its substantial shareholding in Arana from 200,997,372 shares (88.15%) to 203,496,213 shares (89.24%) on June 10, 2009.

To begin compulsory acquisition of the remaining 10 percent of Arana, Cephalon needs less than one percent of investor acceptances in the three trading days, including today, to the close of the offer on June 15, 2009.

Arana was unchanged at $1.39.

HALCYGEN PHARMACEUTICALS

Halcygen says 22,295,000 shares will be released from escrow on June 29, 2009:

Halcygen said 76,099,000 shares would be available for trading following the release and there were no other shares in escrow.

A total of 6,250,000 options will also be released from escrow at the same time.

Halcygen was up one cent or 3.33 percent to 31 cents.

EASTLAND MEDICAL SYSTEMS

Eastland Medical has appointed Michael Stewart as a non-executive director.

Eastland said Mr Stewart had a broad corporate and management background and has been extensively involved in bilateral donor funded and World Bank co-financed aid projects in under-developed countries.

Eastland fell 0.6 cents or 17.1 percent to 2.9 cents.

NEURODISCOVERY

Neurodiscovery says Dr Tony Evans resigned as a director on June 10, 2009.
On June 9, Neurodiscovery announced the appointment of Harry Karelis as a director.
Neurodiscovery was untraded at 3.3 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its June 25, 2009 workshop will provide a practical insight into the planning and implementation of a drug development program.
The Bio-Melbourne Network says drug development is expensive and human resource intensive and "one of the greatest challenges … is creating a strategic drug development plan".
The organization said that methodologies used by large pharmaceutical companies to decrease the risk associated with the development process can be scaled and made appropriate for smaller companies.
Medicines Development principals Mark Sullivan and Dr Errol Malta will discuss the provision of optimal data for commercial objectives at the June Bio-Workshop.
Biota's business development vice-president Dr Leigh Farrell will present his experiences of the development process.
The workshop will cover the preparation of a development plan and target product profile, structure a project team, the selection of, and working with, service providers, simplifying clinical development and using project managers and other project management tools to keep the project closer to budget and timelines.
The Bio-Melbourne Network said understanding which people needed to be involved and when was critical and the cost of getting this wrong could be quite significant.
The June 25, 2009 Bio-Workshop will be held at Deacons, RACV Building, Level 15, 485 Bourke St, Melbourne with registration from 8:45am.
For further information go to www.biomelbourne.org, email npitcher@biomelbourne.org or call Nicole Pitcher on +613 9650 8800.