Biotech Daily

Thursday May 15, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS UP: STARPHARMA UP 13%; OPTISCAN DOWN 12%**

*** NEUREN ON TRACK WITH PHASE III GLYPROMATE TRIAL**

*** PROGEN TRIALS POLYAMINE ANALOG FOR CANCER**

*** RESEARCHERS SAY PANDEMIC STOCKPILES NEED (BIOTA'S) RELENZA**

*** IMUGENE CLAIMS POULTRY COCCIDIOSIS VACCINE TRIAL 'SUCCESS'**

*** USCOM SELLS 3 MONITORS TO BIRMINGHAM ICU PROGRAM**

MARKET REPORT

The Australian stock market climbed 0.4 percent on Thursday May 15, 2008 with the All Ordinaries up 24.6 points to 5,964.9 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and one was untraded.

Starpharma was best, up four cents or 12.7 percent to 35.5 cents on small volumes, followed by Prana up three cents or 7.23 percent to 44.5 cents and CSL up $2.65 or 6.68 percent to $42.33 with 2.1 million shares traded.

Biota and Novogen climbed more than six percent; Psivida was up five percent; Antisense and Neuren were up more than four percent; Cellestis, Cochlear and Tissue Therapies were up more than three percent; Agenix, Alchemia, Arana, and Phylogica rose more than two percent; with Acrux, Chemgenex, Peplin and Progen up more than one percent.

Optiscan led the falls down 3.5 cents or 12.07 percent to 25.5 cents on small volumes, followed by Portland down half a cent or 10 percent to 4.5 cents.

Heartware lost 9.32 percent; Circadian, Mesoblast and Proteome shed more than seven percent; Bionomics and Cytopia were down more than six percent; Phosphagenics lost 3.33 percent; Benitec, Stem Cell and Ventracor shed more than two percent; with Living Cell and Pharmaxis down more than one percent.

NEUREN

Neuren says a US data safety monitoring committee review of data from the first 100 patients in its Glypromate phase III trial has recommended the trial continue.
Neurologist and chairman of the independent committee Prof Graeme Hankey said that a detailed review of patient data showed "no difference in adverse events or other measures of safety between the treated and untreated patient populations", Neuren said.
Neuren chief executive officer Dr Parmjot Bains said 250 patients had been recruited into the phase III trial and the trial was "on track for completion of enrolment this year".
Neuren said Glypromate was being developed to reduce cognitive impairment following cardiac surgery with cardiopulmonary bypass which affects up to 70 percent of patients.
The company said about one-third of patients exhibited cognitive impairment three months after surgery.
More than one million cardiac bypass procedures are performed worldwide annually but there is no treatment approved to reduce or prevent cognitive impairment.
Neuren said the data safety monitoring committee would review patient data again at 300 completed patients in the third quarter of 2008.
In 2007 Neuren filed an investigational new drug application and the US Food and Drug Administration has confirmed the trial as a major efficacy or pivotal study.
As a result, only one additional phase III trial would be required for registration.
Neuren was up half a cent or 4.76 percent to 11 cents.

PROGEN

Progen has resumed patient enrolment in the phase I dose-escalation study of its recently acquired polyamine analog, PG-11047 for patients with advanced cancer.
Progen said PG-11047 (formerly CGC-11047) was the lead compound in its polyamine program following the Cellgate acquisition (see Biotech Daily; February 4, 2008).
The first patient has been enrolled at the University of Chicago.
The trial is exploring the potential of PG-11047 as a single anti-cancer agent and is designed to assess the agent's maximum tolerated dose.
Under Cellgate, the trial recruited 31 patients and had shown little evidence of toxicity, while using significantly higher doses than most previous studies of polyamine compounds.
Progen chief executive officer Justus Homburg said that since the acquisition of Cellgate, the company had assessing its portfolio of clinical and pre-clinical compounds.
"Our re-initiation of PG-11047 in phase I clinical development is the first step in driving potential value from our expanded portfolio of first-in-class oncology therapies," he said.
Progen said data from the trial would be used in parallel with a separate PG-11047 study assessing it in combination with other marketed anti-cancer drugs as the basis for determining potential phase II development.
Progen expects the study to produce data within the next 12 months.
Progen said PG-11047 was a polyamine analog which modified the production of natural polyamines, a class of chemical which are involved in regulation of cell growth.
They are overproduced in many cancers and PG-11047 is believed to restore polyamine reduction to natural levels.
Despite being the focus of scientific interest for many years, this mechanism is unique, and if successful, PG-11047 could become a first-in-class oncology product, Progen said.
Progen said PG-11047 had been shown to have anti-tumor activity in animal models, combined with a good safety profile.
Progen climbed 2.5 cents or 1.85 percent to $1.38.

BIOTA, GLAXOSMITHKLINE

A paper published in the journal Nature says influenza pandemic stockpiles should include Biota's Relenza (zanamivir).

Entitled 'Crystal structures of oseltamivir-resistant influenza virus neuraminidase mutants' and published online in Nature, the article says "neuraminidase mutants from H5N1-infected patients … are resistant to oseltamivir but still strongly inhibited by zanamivir".

The paper was published online on May 14, 2007 as a letter from Patrick J Collins et al of London's Medical Research Council-National Institute for Medical Research and the Interdisciplinary Centre for Human and Avian Influenza Research, School of Biology, University of St Andrews, Scotland.

The abstract to the paper says "the potential impact of pandemic influenza makes effective measures to limit the spread and morbidity of virus infection a public health priority".

"Antiviral drugs are seen as essential requirements for control of initial influenza outbreaks caused by a new virus, and in pre-pandemic plans there is a heavy reliance on drug stockpiles," the article says.

"The principal target for these drugs is a virus surface glycoprotein, neuraminidase, which facilitates the release of nascent virus and thus the spread of infection.

"Oseltamivir (Tamiflu) and zanamivir (Relenza) are two currently used neuraminidase inhibitors that were developed using knowledge of the enzyme structure.

"It has been proposed that the closer such inhibitors resemble the natural substrate, the less likely they are to select drug-resistant mutant viruses that retain viability. However, there have been reports of drug-resistant mutant selection in vitro and from infected humans.

"We report here the enzymatic properties and crystal structures of neuraminidase mutants from H5N1-infected patients that explain the molecular basis of resistance.

"Our results show that these mutants are resistant to oseltamivir but still strongly inhibited by zanamivir owing to an altered hydrophobic pocket in the active site of the enzyme required for oseltamivir binding.

"Together with recent reports of the viability and pathogenesis of H5N1 and H1N1 viruses with neuraminidases carrying these mutations, our results indicate that it would be prudent for pandemic stockpiles of oseltamivir to be augmented by additional antiviral drugs, including zanamivir," the abstract said.

Biota was up 6.5 cents or 6.5 percent to $1.065

IMUGENE

Imugene says its vaccine developed with the Israel-based Abic Biological Laboratories Teva "successfully induced protection against the major poultry disease coccidiosis".

Imugene said Abic presented a summary of the results of the recently completed coccidiosis disease poultry trial.

The trial tested a series of vaccine candidates constructed by Imugene in a research agreement with Abic.

Of the six variations of the vaccine candidates tested, there was a clear best performer which induced strong protection against the coccidiosis disease and lesions.

The vaccine also significantly reduced shedding of the protozoal parasite which is a major indicator for vaccine efficacy.

Imugene managing director Dr Warwick Lamb said "the success of the Imugene Abic collaboration to develop an orally delivered vaccine has exceeded our expectations in this first trial".

“The vaccine has surpassed the accepted commercial parameters for protection against this disease that affects all young chickens in both the chicken meat and egg production markets,” Dr Lamb said.
He said Imugene’s fowl adenoviral vector had “proven to be effective against a non-viral disease for the first time”.
“Coccidiosis is a protozoal parasite and we are delighted to have proven the FAV vector efficacy against a new class of infectious agent,” Dr Lamb said.
The trial was conducted by Abic in conjunction with the University of Technology Sydney and was designed to test several versions of vaccines using Imugene’s fowl adenoviral vector delivery system and Abic’s patented coccidian genetic material.
The delivery system enables the effective vaccine to be administered orally in water on a mass scale, such as the broiler sheds containing many thousands of chickens.
Dr Lamb said it was “the second successful vaccine trial of our expanding poultry disease vaccine range”.
“Following on from the trial success of our Avian Influenza vaccine and our in ovo and oral delivery successes, our laboratory has been very busy,” Dr Lamb said. “We have another four poultry vaccines nearing readiness for trials and this second trial success is very encouraging for the prospective vaccines moving into the trial phase,” Dr Lamb said.
“The next stages in the development of the vaccine will require optimization techniques to be applied and trialing to determine aspects such as minimum dose and optimum date of administration for protection,” Dr Lamb said.
Abic and Imugene are in discussions regarding the arrangements to undertake these necessary stages of development.
Imugene’s commercial strategy remains consistent and will be seeking to licence, on commercial terms, the non exclusive use of the fowl adenoviral vector to Abic to enable the Imugene Abic coccidiosis vaccine to be developed and marketed by Abic to broiler producers worldwide.
Imugene was unchanged at 10 cents.

USCOM

Uscom has sold three of its Uscom 1A devices to the Birmingham Hospital Trust to establish a nurse-led intensive care unit outreach program.
The ultra sonic cardiac output monitors are non-invasive measures of cardiac output.
Uscom said the nurse-led outreach programs were designed for rapid and cost-effective delivery of sophisticated intensive care unit care to general ward patients.
Uscom chief executive officer Paul Butler said it was “an important order … as it is an identified application with which we have been working and for multiple units into a hospital trust which has confidence that Uscom will improve care and reduce cost within their hospitals”.
Uscom climbed seven cents or 46.67 percent to 22 cents on small volumes.