Biotech Daily

Thursday February 4, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: VIRALYTICS UP 11%; AVEXA DOWN 6%**

*** AVEXA'S PHASE III HIV TRIAL: NON-SIGNIFICANT ATC BENEFIT**

*** WEHI LEADS RESEARCH ON MALARIA PARASITE PROTEIN TARGET**

*** GTG'S DR MERVYN JACOBSON, TAMARA NEWING COMMITTED TO TRIAL**

*** GENESIS SHARE PLAN TO RAISE $485k**

*** KINETIC CEASES SUBSTANTIAL IN NANOSONICS**

MARKET REPORT

The Australian stock market fell 0.6 percent on Thursday February 4, 2010 with the S&P ASX 200 down 26.3 points to 4621.6 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and four were untraded.

Viralytics was best climbing 11.3 percent to 5.9 cents with 2.7 million shares traded, followed by Prana up 7.1 percent to 15 cents.

Cathrx climbed 5.7 percent; Cellmid and Heartware were up more than three percent; Alchemia, Biota, Cellestis, Clinuvel, Impedimed, Living Cell and Phosphagenics rose more than two percent; with Pharmaxis and Resmed up more than one percent.

Avexa led the falls, down one cent or 6.45 percent to 14.5 cents with 22.4 million shares traded.

Antisense and Phylogica fell more than four percent with the former trading 27.5 million shares; Nanosonics, Prima and QRX were down more than three percent; Acrux, Benitec, Novogen, Sirtex, Starpharma and Tissue Therapies shed more than two percent; with Bionomics, Chemgenex, LBT, Mesoblast and Psivida down more than one percent.

AVEXA

Avexa says 24 week data from its phase III HIV trial showed a non-significant positive clinical benefit for apricitabine compared to the standard of care.

Avexa said a greater percentage of patients on apricitabine (ATC) reached “undetectable” viral loads of less than 50 copies per millilitre than patients on 3TC.

In a table with the announcement, Avexa said 53 percent of patients on ATC reached this level compared to 51 percent on 3TC.

Avexa’s chief scientific officer Dr Jonathan Coates, the inventor of both 3TC and ATC, told Biotech Daily that “about 75 patients” were in each arm indicating that about 40 patients on ATC and 38 patients on 3TC had undetectable viral loads.

Avexa has not previously disclosed the number of patients in the trial, originally expected to reach 900 patients (BD: Nov 24, 2008)

In 2009, Avexa said there would be “at least 50 patients” in each arm of the then three arm trial comparing 3TC to 800mg ATC and 1200mg ATC. The trial was reduced to two arms with 1200mg patients transferred to 800mg when the company found there was little clinical difference, but marketing advantages for the lower dose (BD: Jun 4, 2009).

The company stopped the trial in October 2009 following discussions with the FDA with chief executive officer Dr Julian Chick saying that, “the fastest route to registration is to stop the study and look at the data” (BD: Oct 2, 2009).

Today Avexa said the data “was not statistically significant because the trial was stopped early and fewer patients were enrolled than originally projected”.

Avexa said it hoped to present a more detailed analysis by April 2010 and expected “a strong trend in favor of ATC”.

Dr Coates said the ‘less than 50 copies per millilitre’ standard might not tell the whole story of the viral load difference. He hypothesized that ATC could reduce the viral load much further than 50 copies, while 3TC might reduce it to just below 50 copies.

Dr Coates said that more encouraging was the data on patients not returning to higher viral loads, along with increased CD4 cell number increases and the percentage of patients with progression of HIV over the 24 week period.

Dr Coates said CD4 cells (a subset of T-cells) were part of the body’s defence system and were killed by the human-immunodeficiency virus. He said the average 98 CD4 cells/microlitres increase for the ATC group compared favorably to the 73 CD4 cells/microlitres for the 3TC group.

“A 25-cell difference is meaningful, if not statistically significant,” Dr Coates said. “In terms of HIV, a 50-cell difference is historically believed to be significant. A person with X CD4 cells will be more liable to a certain set of diseases than a person with X+50 cells.”

In its media release, Avexa said the percentage of patients on ATC with progression of disease over the 24 week period was 3.8 percent (about three patients) compared to 16.2 percent (about 12 patients) in the 3TC arm.

“This data gives me confidence that ATC is better than 3TC,” Dr Coates said.

Avexa said that at 24 weeks, ATC improved the overall clinical effectiveness of HIV therapy compared to the best available standard of care and was “extremely safe and well tolerated, with no serious adverse events reported”.

“These results highlight the ability of ATC to maintain suppression of patients’ viral loads while increasing CD4 cell numbers, resulting in a clear clinical benefit to the patients,” Dr Coates said. “This data indicates that ATC could be a significant clinical addition to the drugs currently available including the new classes of HIV integrase and CCR5 inhibitors plus the new generation of non-nucleoside reverse transcriptase inhibitors and protease inhibitors.”

Avexa fell one cent or 6.45 percent to 14.5 cents with 22.4 million shares traded.

WEHI, LICR, BURNET, DEAKIN

Walter and Eliza Hall Institute researchers have identified “a clear target” in the malaria parasite that will help it develop a new class of anti-malarial drugs.

A WEHI media release said a key protein called Plasmepsin V was used by the malaria parasite Plasmodium falciparum to transform human red blood cells and ensure its own survival.

WEHI said that its staff along with researchers from the Ludwig Institute for Cancer Research, the Burnet Institute and Deakin University had identified the Plasmepsin V protein as essential for effector proteins to be exported into the red blood cell.

The Institute said the most lethal form of malaria was caused by the parasite Plasmodium falciparum, which invades red blood cells and drastically modifies them so it can survive.

The head of the Walter and Eliza Hall Institute’s infection and immunity division Prof Alan Cowman said the parasite remodels the red blood cells by exporting hundreds of effector proteins into the cytoplasm of the red blood cell.

“These are key virulence proteins that allow the parasite to survive in the human and hide from the human immune system,” Prof Cowman said.

“There has to be a mechanism that allows these effector proteins to be exported but until now we haven’t known what it is,” Prof Cowman said.

The researchers identified the Plasmepsin V protein as being essential for effector proteins to be exported into the red blood cell.

The research article, entitled ‘An aspartyl protease directs malaria effector proteins to the host cell’ was published in Nature today (Issue 463, pp627-631) and an abstract is at http://www.nature.com/nature/journal/v463/n7281/full/nature08728.html.

Prof Cowman said experimentation had shown that the action of Plasmepsin V on the effector proteins was the first step in priming the proteins to be exported beyond the parasite’s membrane into the red blood cell cytoplasm.

“Plasmepsin V is responsible for determining that all the hundreds of effector proteins are exported,” Prof Cowman said.

“If we could find drugs to block Plasmepsin V the malaria parasite would die,” he said.

Prof Cowman said because Plasmepsin V was a protease it was an attractive drug target.

“Drugs that target proteases have been very effective in combating HIV so, by analogy, drugs that impede the function of Plasmepsin V should also show promise,” Prof Cowman said.

WEHI said that each year more than 400 million people contract malaria and more than one million people, mostly children, die from the disease.

The research was funded by the US National Institutes of Health, the Australian National Health and Medical Research Council and the Maryland-based Howard Hughes Medical Institute.

GENETIC TECHNOLOGIES

Genetic Technologies founder Dr Mervyn Jacobson and his daughter Tamara Newing have been committed to stand trial on a total of 672 counts of market manipulation.

Genetic Technologies major shareholder and former chief executive officer Dr Jacobson has been charged with 319 counts of market manipulation and Ms Newing has been charged with 353 counts on the same charge (BD: Feb 1, 2010).

Officers of the court said that magistrate Phillip Goldberg directed that Dr Jacobson and Ms Newing appear at the County Court on April 15, 2010.

Bail was granted.

Genetic Technologies was unchanged at four cents.

GENESIS RESEARCH AND DEVELOPMENT

Genesis hopes to raise up to $NZ611,365 ($A484,567) through the issue of up to 10,189,422 shares at six New Zealand cents a share .
Shareholders eligible at the record date of February 12, 2010 would be able to apply for parcels of shares from $1,000 to $15,000.
Genesis said the share plan would close on March 10, 2010.
The company said the plan was to allow shareholders to buy shares without brokerage fees and to provide funds for ongoing operations.
Genesis was unchanged at six cents.

NANOSONICS

Kinetic Investment Partners has ceased its substantial shareholding in Nanosonics, reducing its holding below the five percent level.
Kinetic's most recent substantial shareholder notice on December 12, 2009 showed the company held 5.12 percent of Nanosonics.
Kinetic is part of Challenger Financial Services.
Nanosonics fell two cents or 3.42 percent to 56.5 cents.