Biotech Daily

Wednesday September 28, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: QRX UP 13%; IMPEDIMED DOWN 5%**

*** ALCHEMIA CLAIMS EARLY SMALL CELL LUNG CANCER HYACT EFFICACY**

*** ALLIED HEALTH REQUESTS CAPITAL RAISING HALT**

*** WEHI: 'HUMAN-LIKE WORM CELL DEATH MAY LEAD TO PARASITE DRUG'**

*** PHARMAXIS BRONCHITOL EUROPEAN APPEAL 'ON SCHEDULE'**

MARKET REPORT

The Australian stock market climbed 0.87 percent on Wednesday September 28, 2011 with the S&P ASX200 up 34.9 points to 4,039.5 points.

Thirteen the Biotech Daily Top 40 stocks were up, five fell, 13 traded unchanged and nine were untraded.

QRX was the best, up 14 cents or 13.0 percent to $1.22 with 221,254 shares traded, followed by Pharmaxis up 10.2 percent to 70.5 cents with 430,736 shares traded and Living Cell up 10 percent to 5.5 cents with 294,000 shares traded.

Alchemia climbed 9.4 percent; Viralytics was up 8.5 percent; Sunshine Heart rose 4.65 percent; Anteo was up 3.3 percent; Tissue Therapies rose 2.5 percent; Biota, Mesoblast and Resmed were up more than one percent; with Acrux, Psivida and Sirtex up by less than one percent.

Impedimed led the falls, down 2.5 cents or 5.3 percent to 45 cents with 22,000 shares traded.

Genetic Technologies lost three percent; Cochlear and Starpharma shed more than two percent; Patrys was down 1.8 percent; with CSL and Reva down by less than one percent.

ALCHEMIA

Alchemia says its first two small cell lung cancer patients in its phase II HA-irinotecan trial have responded rapidly, with substantial shrinkage of their tumors after 10 days.
Alchemia said the patients were the first two of 40-patients in its investigator-sponsored, phase II trial of hyaluronic acid irinotecan (HA-irinotecan) in small cell lung cancer at the Monash Cancer Centre in Victoria. (BD: Sep 9, 2011).
The principal investigator Dr Vinod Ganju said he was “excited by these early responses to treatment, mostly because of the speed of the tumor regressions”.
“Typically we would anticipate achieving a measurable response to therapy after one to two months of treatment but, in the case of the patients treated with HA-irinotecan, we could measure tumor shrinkage in a matter of days,” Dr Ganju said.
Alchemia chief scientific officer Prof Tracey Brown said the early responses were “extremely encouraging” but said the effectiveness of the treatment wouldill need to be confirmed with further patient data.
“The rapidity of the responses is consistent with results from preclinical studies of HA-irinotecan in lung cancer,” Prof Brown said.
Alchemia said the study was examining the effectiveness of HA-irinotecan, using Alchemia’s patented Hyact technology to target the anti-cancer drug irinotecan to the tumor, with patients randomized to receive either HA-irinotecan or irinotecan.
The company said the trial would assess safety and progression-free survival efficacy.
Alchemia said the study would assess the impact of the treatments on circulating tumor cells, the number of cancer cells detected in the blood, and certain cell populations such as cancer stem cells in the tumor.
Alchemia said the Hyact platform worked by delivering a higher concentration of the drug to the tumor and enhancing the uptake of the drug by cancer cells, by targeting the drug to the CD44 protein expressed at high levels by the cells in solid cancers such as breast, lung and colorectal.
The company said the technology had been shown to enhance the activity of a broad range of drugs across a number of preclinical models of different cancers.
Alchemia said an earlier phase II study in colorectal cancer with HA-irinotecan showed a statistically significant improvement in progression free survival compared with irinotecan of 20.8 weeks compared to 9.6 weeks ($p = 0.017$) (BD: Apr 26, May 29, 2007).
The company said recruitment to its pivotal phase III study in colorectal cancer was expected to begin in 2011.
Earlier this month Alchemia chief executive officer Dr Pete Smith said the cost of the phase II small cell lung cancer trial would be paid primarily by Monash Cancer Centre, with Alchemia covering the costs of the drug, data analysis and monitoring.
Alchemia was up three cents or 9.4 percent to 35 cents with 1.9 millions hares traded.

ALLIED HEALTHCARE GROUP

Allied Health has requested a trading halt “pending an announcement regarding a capital raising”.
Trading will resume on September 30, 2011 or on an earlier announcement.
Allied Health last traded at 3.2 cents.

WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have identified a programmed cell death pathway in parasitic worms that could lead to treatments for schistosomiasis.

The Institute said that Dr Erinna Lee and Dr Doug Fairlie from its structural biology division were studying apoptosis or programmed cell death in human cells and began studying the process in schistosomes, parasitic fluke worms responsible for the deadly disease schistosomiasis.

Dr Lee said that the group had shown that, unexpectedly, the cell death machinery in fluke worms was “remarkably similar” to the cell death pathway in human cells.

“We found that schistosomes have a complex cell death mechanism that relied on a delicate balancing act of pro-survival and pro-death molecules, just like in humans,” Dr Lee said. “Using the Australian Synchrotron, we also determined that the three-dimensional structure of a key schistosome cell death molecule was very similar to the protein which controls the process in humans.”

“This structure is important because it will potentially guide future efforts to design drugs that target the schistosome cell death pathway,” Dr Lee said.

The research was published in the Proceedings of the National Academy of Sciences in an article entitled ‘Discovery and molecular characterization of a Bcl-2–regulated cell death pathway in schistosomes’.

An abstract is at http://www.pnas.org/content/early/2011/03/24/1100652108.short.

The Institute said that more than 700 million people were at risk of schistosomiasis and 200 million people were currently infected, 85 percent of whom live in Africa and about 200,000 people die from the disease each year.

WEHI said the parasitic schistosome flat worm was carried by freshwater snails in contaminated water systems and caused damage to the spleen, liver and other organs.

Dr Fairlie said that there was only one drug widely used for treating schistosomiasis and concerns about the potential for drug resistance have increased the urgency for new drug targets and treatments.

“Schistosomiasis ranks with malaria as a major source of human disease,” Dr Fairlie said. “More than 2 billion people globally are at risk of parasitic worm infection and we need to invest in the development of new drugs and vaccines, particularly as there are very few options currently available,” Dr Fairlie said.

The Institute said that in the 1980s its scientists and others discovered that defects in the cell death pathway were associated with cancer development.

Dr Lee said the team was exploring the possibility that so-called BH3 mimetic compounds such as ABT-737, discovered by Abbott Laboratories, could also have a niche application for the treatment of parasitic worm diseases such as schistosomiasis.

The Institute said that BH3 mimetics targeted the cell death pathway in humans and were being trialed as anti-cancer agents (BD: Jul 19, 2011).

“We have found that a BH3-mimetic compound called ABT-737 binds to at least one schistosome pro-survival protein, suggesting it is feasible that BH3-like molecules could also be developed for treating schistosomiasis, and potentially other parasitic worm infections,” Dr Lee said.

WEHU said that there wasa lot to be understood about the cell death process in fluke worms before the discovery led to new treatments for parasitic worm diseases,

“Though we have found that this cell death pathway exists in the parasite, we don’t yet know how important it is for the survival of the worm, or what the effect of drugs targeting the pathway will be,” Dr Fairlie said. “But we are excited about the possibility of developing an entirely new treatment strategy for schistosomiasis, which is a significant disease burden in developing countries.”

PHARMAXIS

Pharmaxis says the re-examination of its European Bronchitol marketing application for cystic fibrosis is on schedule.

Earlier this year, the European Medicines Agency's Committee for Medicinal Products for Human Use rejected the application for the use of Bronchitol to treat cystic fibrosis and Pharmaxis appealed against the decision (BD: May 25; Jun 24, 27; Jul 5, 2011).

Today, Pharmaxis said the Committee adopted a list of questions to be considered by the ad hoc scientific advisory group which included clinicians and cystic fibrosis experts.

The company said it would present to the scientific advisory group in early October and the scientific advisory group would make its recommendations to the Committee.

Pharmaxis said an opinion on the re-examination was due to be reached by the Committee at its meeting to be held October 17-20, 2011.

Pharmaxis chief executive officer Dr Alan Robertson said that Bronchitol "operates higher on the patho-physiological cascade than any approved medicine for cystic fibrosis and represents an exciting new treatment option".

"Re-hydration of the surface lining of the lung is an important clinical goal and leads to a reduction of mucus accumulation, improved mucus clearance and a reduction in the incidence of pulmonary exacerbations," Dr Robertson said.

"In two phase III clinical trials, Bronchitol has been shown to improve lung function - the loss of which ultimately leads to the early death of people with cystic fibrosis," Dr Robertson said.

In one of the trials Bronchitol narrowly failed to meet the primary endpoint with a significance level of $p = 0.059$ despite improving lung function (BD: Jun 22, 23, 2010).

"We look forward to working with the [Committee] over the coming weeks with the goal of making Bronchitol available to patients in Europe with cystic fibrosis," Dr Robertson said.

Pharmaxis said that Bronchitol had orphan drug designation from the European Medicines Agency and was approved for marketing in Australia.

Pharmaxis was up 6.5 cents or 10.2 percent to 70.5 cents.