Biotech Daily

Tuesday September 27, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: SUNSHINE HEART UP 16%; BIOTA DOWN 4%**

*** PATRYS 10-YEAR DATA BACKS PAT-SC1 FOR GASTRIC CANCER**

*** CSL: SANDOZ CAN'T MEET GLOBAL BENZYLPENICILLIN DEMAND**

*** SUNSHINE HEART: 'MOST IMPROVE' IN 20-PATIENT CARDIAC TRIAL**

*** MESOBLAST SIGNS MANUFACTURING DEAL WITH LONZA**

*** HEALTHLINX SELLS 500 OVPLEX TESTS IN SINGAPORE**

*** AGENIX FILES MANUFACTURING PATENT FOR AGX-1009 HEP B DRUG**

MARKET REPORT

The Australian stock market climbed 3.64 percent on Tuesday September 27, 2011 with the S&P ASX200 up 140.7 points to 4,004.6 points.

Seventeen the Biotech Daily Top 40 stocks were up, six fell, 10 traded unchanged and seven were untraded.

Sunshine Heart was best, up 0.6 cents or 16.2 percent to 4.3 cents with 600,697 shares traded, followed by Acrux up 9.7 percent to $3.18 with 880,667 shares traded.

Clinuvel, Prana and Prima climbed more than six percent; Benitec, Cellmid and Phylogica were up more than five percent; Alchemia, Genetic Technologies and Phosphagenics were up more than three percent; Mesoblast, Nanosonics, Sirtex and Viralytics rose two percent or more; with Heartware, QRX and Resmed up more than one percent.

Biota led the falls, down three cents or 3.6 percent to 80 cents with 409,059 shares traded, followed by Anteo down 3.2 percent to 6.1 cents with 853,846 shares traded.

Optiscan, Reva and Tissue Therapies lost more than one percent; with Cochlear, CSL and Starpharma down by less than one percent.

PATRYS

Patrys says it has positive results from a 10 year follow-up of gastric cancer patients who were treated with its anticancer compound PAT-SC1.

Patrys said that between 1997 and 2001, 51 patients with CD55-positive gastric cancer were treated 48 hours prior to surgery to remove the primary tumor, with a single intravenous low dose of PAT- SC1, the first of its immunoglobulin M (IgM) antibodies to be used in a clinical trial.

The company said that of the 51 patients treated, 35 of them had no evidence of metastatic disease at operation and were classified as having R0 stage disease and did not receive any additional treatment such as radiotherapy or chemotherapy.

Patrys said the survival of the patients had been followed over time and compared to a historic control group of patients with R0 stage gastric cancer who did not receive PAT-SC1 before surgery.

The company said that 10 year follow-up data was available on 30 of the patients and 55 percent were still alive, compared to 30 percent of the control group, indicating that treating gastric cancer patients with PAT-SC1 confers a significant survival benefit.

Patrys chief executive officer Dr Marie Roskrow said the survival data was “very exciting given that these patients only received a single low dose of PAT-SC1 and that gastric cancer is a notoriously difficult disease to treat with an overall low survival rate”.

“I believe these results provide convincing proof of concept data which will add significantly to the attractiveness of this product to potential licencing partners,” Dr Roskrow said.

Patrys said it intended to licence PAT-SC1 in 2012.

The company said PAT-SC1 acted by binding to the CD55 protein on the surface of gastric cancer cells but not on the surface of healthy cells, thereby allowing it to kill the cancer cells while sparing the healthy cells.

Patrys said that gastric cancer could develop in any part of the stomach and spread throughout the stomach and to other organs; particularly the oesophagus, lungs, lymph nodes and liver, causing about 800,000 deaths a year.

The company said surgery was the most common treatment and was often the only hope of cure for stomach cancer.

Patrys was unchanged at 5.5 cents with 1.4 million shares traded.

CSL

CSL says Sandoz GMBH is unable to meet global hospital demand for benzylpenicillin which is on restricted supply in Australia and New Zealand until December 2011.

CSL public affairs director Sharon McHale told Biotech Daily that CSL was the Australian distributor for the supplier, the Novartis-owned and Austria-based Sandoz which was unable to fulfill orders on time.

CSL said that benzylpenicillin marketed as Benpen was a narrow spectrum intravenous penicillin used in the treatment of serious infections including wound infections, sepsis and meningitis.

CSL Biotherapies medical director Dr Alan Paul said CSL recognized the significance of the shortage and was working with Sandoz to expedite supplies.

CSL said it would identify and implement additional contingencies to support future supply of Benpen.

CSL fell two cents or 0.1 percent to $29.00 with two million shares traded.

SUNSHINE HEART

Sunshine Heart principal investigator and Ohio Medical Centre's director of cardiovascular medicine Dr William Abraham is in Australia presenting 'top-line' trial data.

Last week, Sunshine Heart published Dr Abraham's pilot trial of the C-Pulse aorta cuff pump results, saying that two patients improved to the point that they did not require the device, due to the absence of heart failure symptoms and there were positive indicators for the device, including the overall reduction in patient medication (BD: Sep 22, 2011).

Sunshine Heart did not provide detailed results, which had been intended to be presented at the American Heart Failure Society meeting last week and said the results would be presented at the Transcatheter Cardiovascular Therapeutics meeting in San Francisco on November 8, 2011.

The lack of detail has been attributed as the primary cause of the share price falling from 4.7 cents to a low of 4.2 cents on the day and 3.7 cents in following days.

Last week Sunshine Heart chief executive officer Dave Rosa told Biotech Daily that most of the 20-patients in its pilot trial of the C-Pulse aorta cuff pump improved heart failure categories, with one patient disconnected after the six month follow-up and the second patient after 11 months on therapy.

Today, Dr Abraham provided slightly more detail, telling a Bell Potter investor briefing in Melbourne that there were two patients in New York Heart Association class IV heart failure, the most severe form of heart failure and 18 patients in class III.

Dr Abraham said one stage III and one stage IV patient improved to the point that they were reclassified as asymptomatic stage I and disconnected from the device driver.

Dr Abraham said that unlike ventricular assist devices, the disconnected C-Pulse system can remain inside the patient and if required be reconnected.

Dr Abraham said that in heart failure patients, the disease progresses with up to 15 percent of patients dying one-year after diagnosis and 50 percent dying in five years.

He said non-progression of disease was "a good outcome", so to have only one patient die from a non-device related event and all others to either remain stable or improve showed the benefit of the C-Pulse device.

Dr Abraham said other improvements were measured by quality of life scores, six-minute walk times, ejection fractions and reductions in drugs, especially anti-clotting agents.

Dr Abraham said that apart from the one death from a sternal infection, there were no neurological events, myocardial infarctions and the six drive-line exit site infections were treated with antibiotics.

Mr Rosa demonstrated a new exit site apparatus locking the driver tube to an ostomy base-plate but said the company was intending to eliminate external drive lines with a fully implantable device.

Mr Rosa said the company expected to recruit 270 patients into a pivotal randomized trial beginning in 2012 and taking two years to recruit at up to 30 North American centres.

Mr Rosa said that with a one year follow-up results would be expected in 2015 and the trial would cost about $US30 million.

Dr Abraham said the cost of heart failure was $US56 billion, with a high rate of hospital readmissions and 33 percent of hospitalized patients dead in 12 months.

Dr Abrahams said the C-Pulse device was ideally suited to stage III patients who were symptomatic with minimal exertion, compared to stage IV patients who were symptomatic at rest and stage II patients who were symptomatic with moderate exertion.

He said that as a cardiologist, he would not recommend the nine percent risk of thrombosis associated with a ventricular assist device, for a stage III patient, which a stage IV patient had no choice, but the C-Pulse was well-suited for stage III patients.

Sunshine Heart was up 0.6 cents or 16.2 percent to 4.3 cents.

MESOBLAST

Mesoblast says the Lonza Group will conduct the clinical and long-term commercial production of its off-the-shelf or allogeneic adult stem cell products.
Mesoblast said the alliance with the Basel Switzerland-based would provide significant commercial advantages, including certainty of capacity to meet long-term global supply of its proprietary mesenchymal precursor cell products.
The company said Lonza would supply Mesoblast's clinical and long-term commercial mesenchymal precursor cell product needs with Mesoblast able to trigger a process requiring Lonza to construct a manufacturing facility exclusively for its products and in return, Mesoblast would purchase agreed quantities of products.
Mesoblast said it could exercise its right to buy the manufacturing facility at a pre-agreed purchase price two years after the facility received approval.
The company said it would have exclusive access to Lonza's cell therapy facilities in Singapore for the manufacture of allogeneic cell therapy products, subject to certain exceptions and Lonza would use its intellectual property to facilitate reductions in Mesoblast's manufacturing costs and enable development of second generation products.
Mesoblast chief executive Prof Silviu Itescu said that access to Lonza's manufacturing capabilities would give his company significant commercial advantages globally.
"It is in line with our growth strategy to deliver the highest quality and most effective cell therapy products worldwide," Prof Itescu said.
Lonza chief executive officer Stefan Borgas said cell therapy was expected "to become a major growth industry with the potential to mirror the growth … in monoclonal antibodies".
Mesoblast was up 20 cents or 2.6 percent to $7.80.

AGENIX

Agenix says it has filed an international 'method of manufacture' patent application under the Patent Cooperation Treaty for its hepatitis B drug AGX-1009.
Agenix said the application covered the manufacturing process of a compound that used the same active ingredient, tenofovir, used in the US Food and Drug Administration-approved drug marketed by Gilead under the trade name Viread.
The company said the patent international application aimed to provide further long-term protection for the company's platform hepatitis B drug compounds until 2030.
Agenix said it already had a registered patent to protect the AGX-1009 compound in China through to 2026.
The company said that like Viread, AGX-1009 was a 'prodrug' of Tenofovir and Gilead's prodrug of Tenofovir was approved for treatment of hepatitis B in the US in 2008 and in numerous countries globally but was not approved in China.
Agenix said that both drugs contained tenofovir and both worked by blocking an enzyme the hepatitis virus needs to replicate, but had different molecular side chains to activate tenofovir.
Agenix said it would initiate a phase I human safety trial of AGX-1009 in 2012 and the clinical trial application would be made with assistance from the Institute of Medicinal Biotechnology of the Chinese Academy of Medical Sciences in Beijing, from whom Agenix purchased the original compound patent.
The company said AGX-1009 was one of several new drug candidates supported by the Chinese Government's State Special Funds for new drugs which aimed to expedite new mass market therapies for major diseases in China.
Agenix said Gilead's version is expected to be released on the Chinese market in 2014.
Agenix was untraded at 1.1 cents.

HEALTHLINX

Healthlinx says that sales of Ovplex in Singapore for the first 12 months since its September 2010 launch exceeded 500 units, more than the budgeted 300 units. Healthlinx chief executive officer Nick Gatsios told Biotech Daily that the tests sold for about $S190 ($A149) each and he expected about $20,000 in royalties from total sales. Healthlinx was up 0.2 cents or 10.5 percent to 2.1 cents.