Biotech Daily

Tuesday June 8, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: SUNSHINE HEART UP 9%, GENETIC TECH DOWN 10%**

*** MAURICE BLACKBURN STARTS AUSTRALIAN GENE PATENTS TEST CASE**

*** SIRTEX ASIAN TRIAL SHOWS EXTENDED BENEFIT**

*** SIGNOSTICS HANDHELD ULTRASOUND WINS DESIGN AWARDS**

*** MODEL BACKS GENETIC TECHNOLOGIES' BREVAGEN TEST**

*** DR JULIA ARCHBOLD WINS $16k VICTORIA PREMIER'S PRIZE**

*** GENESIS LOSES DIRECTOR JIM MCLEAN**

*** IM MEDICAL EXTENDS NEGOTIATIONS HALT TO SUSPENSION**

MARKET REPORT

The Australian stock market rebounded 1.3 percent on Tuesday June 8, 2010 with the S&P ASX 200 up 55.3 points to 4381.2 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and five were untraded.

Sunshine Heart was best, up 0.3 cents or 9.1 percent to 3.6 cents with 110,000 shares traded.

Clinuvel and Phylogica climbed more than six percent; Bionomics was up 5.2 percent; Cellestis was up 4.8 percent; Compumedics, Prima, Tissue Therapies and Universal Biosensors were up more than three percent; with Acrux, CSL, Mesoblast, Sirtex and Virax up more than one percent.

Genetic Technologies led the falls, down 0.4 cents or 9.8 percent to 3.7 cents with 615,400 shares traded, followed by Novogen down 1.5 cents or 6.8 percent to 20.5 cents with 4,100 shares traded.

Cathrx and Impedimed lost more than five percent; Chemgenex fell 4.9 percent; Phosphagenics and Resmed were down more then three percent; Psivida and Viralytics shed more than two percent; with LBT and Starpharma down more than one percent.

GENETIC TECHNOLOGIES, MAURICE BLACKBURN

Law firm Maurice Blackburn, consumer organization Cancer Voices Australia and a breast cancer patient have begun legal action over a patent covering human genetic material.

Maurice Blackburn principal Rebecca Gilsenan is leading the case and told Biotech Daily the challenge was against three claims in the BRCA1 patent, owned by Myriad Genetics and licenced from Myriad by the Melbourne-based Genetic Technologies.

Ms Gilsenan said the matter was filed with the Federal Court's New South Wales registry today and expected a directions hearing in about four weeks.

Ms Gilsenan said the US gene patenting case went beyond the gene and technology patents and included constitutional issues and declared the patent invalid.

Genetic Technologies chief executive officer Dr Paul MacLeman told Biotech Daily that his company did not want a legal fight over gene patenting.

"We have a licence and provide the best service [for breast cancer BRCA1 gene testing]," Dr MacLeman said.

"We had to take a licence, but we're not the patent owner," Dr MacLeman said.

"We're not enforcing the patent. I don't know why we're involved in this case," he said.

In March, Dr MacLeman told Biotech Daily that his company licenced the patents for gene testing for breast and ovarian cancer from the US-based Myriad Genetics which was sued in the US District Court in New York by the American Civil Liberties Union over the patents (BD: Mar 30, 2010).

The widely reported finding said genes were not patentable as they were part of nature and not inventions.

Dr MacLeman's predecessor as chief executive officer at Genetic Technologies Michael Ohanessian wanted to recover costs from institutions performing the tests, but the company's founder and major shareholder Dr Mervyn Jacobson reversed the decision (BD: Jun 11, Dec 2, 2008).

A media release from Maurice Blackburn said it would argue that Patent 686,004 held by companies including Myriad Genetics and Genetic Technologies was invalid.

The media release said that in March, the Federal District Court in New York ruled that patents were improperly granted to Myriad Genetics on two human genes, including BRCA1.

Maurice Blackburn said the Australian test case was supported by patent law expert Dr Luigi Palombi from Australian National University and Sydney University and would be run on a pro bono basis by Maurice Blackburn partner Rebecca Gilsenan and barristers David Catterns and Peter Cashman.

Ms Gilsenan said there was "a philosophical and ethical issue about the commercialization of the human body".

"Beyond that, there is a practical concern - the patent owner has a right to prevent people from studying and testing for the gene mutation, so gene patents can stifle research, the development of treatments, and access to diagnostic testing," Ms Gilsenan said.

"Patents protect inventions, not discoveries," she said.

"What Myriad has done is discovered and isolated the gene from the human body," Ms Gilsenan said.

"We will argue that that does not and can not amount to a patentable invention," Ms Gilsenan said.

The law firm said that five to 10 percent of women with breast cancer had a known gene mutation and many others had a strong family history.

At least 20 percent of human genes were patented and the outcome of the test case would have implications for the status of other patents on other genetic material.

Genetic Technologies fell 0.4 cents or 9.8 percent to 3.7 cents.

SIRTEX MEDICAL

Sirtex says that its radioactive SIR-Spheres microspheres combined with a standard chemotherapy drug helped extend survival rates for inoperable liver cancer patients.

Sirtex said the results from an independent 35-patient, four country clinical trial was presented at the American Society of Clinical Oncology conference in Chicago and showed a median overall survival of 11.75 months for patients treated with a combination of SIR-Spheres microspheres and the current standard chemotherapy drug Sorafenib, marketed as Nexavar by Bayer-Schering, to treat primary liver cancer.

Singapore's Asia-Pacific Hepato-cellular Carcinoma Trials Group conducted the study designed to evaluate tumor response and overall survival in patients with inoperable liver cancer, including those with disease that has spread outside the liver, the company said.

Sirtex chief executive officer Gilman Wong said the study demonstrated that a combination of radioactive SIR-spheres microspheres and standard-of-care chemotherapy presented clear survival benefits in a hepato-cellular cancer patient population with limited treatment options available.

"We are very optimistic the survival benefit observed for this combination of therapies will be confirmed by the larger … phase III study which will soon begin recruiting patients in Europe," Mr Wong said.

Sirtex said the overall survival for patients with major vascular invasion and or extra-hepatic spread compared to those without was 8.75 months and 18.25 months, respectively, which compared favorably with an overall survival of 5.6 months and 14.3 months respectively in patients on Sorafenib alone in an earlier Asia-Pacific study.

Sirtex said the overall disease control rate was 79.5 percent with 35.5 per cent in this group reporting tumor response and 44 percent a stabilization of the disease.

Three patients who presented with unresectable disease had a sufficient reduction in tumor size to permit potentially curative therapy, including one who had a liver transplantation and two who received radio-frequency ablation.

Sirtex said patients in the advanced stages of liver cancer, particularly those with major vascular invasion in the liver and spread of disease outside the liver, were not candidates for surgery or transplantation, had a very poor prognosis and relatively low survival rates.

An abstract is at http://abstract.asco.org/AbstView_74_49939.html.

Sirtex was up seven cents or 1.4 percent to $5.01.

SIGNOSTICS

Signostics says its handheld ultrasound device has won two major awards at the 2010 Australian International Design Awards.

Signostics chief operating officer and a co-inventor of the pocket-sized Signos portable ultrasound system Stewart Bartlett told Biotech Daily that the wholly self-contained unit comprising a screen and probe cost less than $5,000 and had applications ranging from general practice to accident and emergency departments and for remote communities.

Mr Bartlett said the ultrasound's rechargeable lithium battery provided up to 80 minutes continuous operation, could be easily cleaned and the entire probe was waterproof.

Mr Bartlett said apart from general practice, the probe was targeted at respiratory physicians, palliative care staff for abdominal fluid drainage, physiotherapists, women's health specialists and in countries that can't afford stand-alone imaging systems.

The company's media release said that Signos won a design award in the medical and scientific category before winning the Powerhouse Museum design award, chosen from all finalists across all categories.

Signos is a public unlisted company.

GENETIC TECHNOLOGIES

Genetic Technologies says modeling shows that adding its Brevagen test for breast cancer to decision models improves clinical outcomes and is cost-effective.

Genetic Technologies says the pharmaco-economic data, modeled and compiled by the San Francisco-based Archimedes Inc was presented at the American Society of Clinical Oncology meeting in Chicago and supported its Brevagen breast cancer risk test.

The abstract is available at: http://abstract.asco.org/AbstView_74_42880.html.

Genetic Technologies said that Archimedes' core technology, the Archimedes Model, was a mathematical model of human physiology, diseases, interventions and healthcare systems which has been developed and in collaboration with the American Cancer Society.

The company said the model was detailed, validated and could "run a virtual clinical trial with 1,000,000 people, spanning 30 years of life, in three hours to help understand and resolve vital clinical and administrative healthcare questions".

Genetic Technologies said the study used the Archimedes Model to forecast costs and clinical outcomes resulting from breast cancer risk testing using Brevagen followed by preventative therapy in a population of women who were an intermediate risk of developing breast cancer.

The company said the model compared the results with costs and clinical outcomes resulting from no treatment, to provide output in terms of quality-adjusted life years (Qalys), an arithmetic product of quality and quantity of life equivalent to one full year of life in good health.

Qalys were derived from comparing Brevagen's role in directing preventative tamoxifen therapy with the simulated cost and clinical breast cancer outcomes from mammogram screening, follow-up, diagnosis and treatment in individuals who do not take a Brevagen test.

Genetic Technologies said the study found that adding information about common risk alleles as supplied by the Brevagen test to current decision models for breast cancer chemoprevention improved clinical outcomes and was cost-effective, with an incremental cost effectiveness ratio in the range $US3,800 to $US7,500 depending upon patient age, well below the benchmark number of $30,000 per Qaly saved.

The more people who receive chemoprevention in these populations, the more cost and Qalys that were saved and Brevagen testing resulted in better targeting of chemopreventive therapy.

Genetic Technologies chief executive officer Dr Paul MacLeman said that cost effectiveness and utility was "crucial for the acceptance and reimbursement of novel tests such as Brevagen".

"This independent study clearly demonstrates the value and improvements in health outcomes provided by Brevagen for patients and health care providers," Dr MacLeman said.

Genetic Technologies said the Brevagen test was developed by studying genetic and clinical data from tens of thousands of women and could help define individual breast cancer risk.

The company said that using a blood sample, the Brevagen test could detect the absence or presence of certain common genetic variants associated with increased breast cancer risk.

Genetic Technologies said the test combined an analysis of these variants plus widely used clinical factors to deliver an improved understanding of a woman's overall individual risk.

VICTORIA PREMIER'S PRIZE

Medical researcher Dr Julia Archbold has won this year's $16,000 Premier's award for health and medical research for a breakthrough transplant rejection.

A media release said that Premier John Brumby presented Dr Archbold and three other winners with awards and prize money at a ceremony at Government House yesterday.

Mr Brumby said the health and medical research awards recognized the exceptional achievements of Victoria's young researchers.

"The awards are an initiative of the Victorian Government and the Australian Society for Medical Research and are presented annually to outstanding Victorian postgraduate health or medical research scholars," Mr Brumby said.

"Dr Archbold's research provided groundbreaking insights into organ donation strategies and ways to prevent organ transplant rejection. Her discoveries are potentially beneficial for the 1,700 Australians on waiting lists for life-saving organ transplants," he said.

"This research has received international attention and is a clear demonstration of the strength and ability of Victoria's young scientists to lead the world in medical research," Mr Brumby said. "It also demonstrates why Victoria is on the way to becoming one of the top five centres in the world for biotechnology."

The media release said that Dr Archbold was based at Monash University, she had been published in 11 journals and was "revolutionizing current organ donation thinking".

Mr Brumby also presented Monash University's department of biochemistry and molecular biology with the $30,000 Jack and Robert Smorgon Families Award.

Three other Victorian young scientists received $8,000 commendation awards.

The Brain Research Institute's Dr Radwa Badawy was commended for her research into epilepsy using transcranial magnetic stimulation, proving increased excitability in humans ; the Austin Hospital's Dr Benjamin Howden was commended for his research on resistant staphylococcus aureus; and the Walter and Eliza Hall Institute's Dr Mark McKenzie was commended for discovering how insulin-producing cells were destroyed in diabetes.

The Premier's awards are separate from the Victoria Prize which is expected to be announced in September.

Mr Brumby also announced $800,000 funding for two high performance computers at the Australian Synchrotron at Monash University.

GENESIS RESEARCH AND DEVELOPMENT

Genesis says that Jim McLean has retired from the board after serving as a director since 1994.

Genesis said a new director would be appointed within the next few weeks.

Genesis was untraded at three cents.

IM MEDICAL

IM Medical has requested a suspension to follow on from the trading halt requested on June 4, 2010 for an announcement on negotiations "significant to the company".

IM Medical last traded at 0.2 cents.