Biotech Daily

Wednesday December 5, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ALLIED HEALTH UP 9%, BENITEC DOWN 7%**

*** FDA APPROVES CHEMGENEX, CEPHALON, TEVA SYNRIBO (OMAPRO)**

*** SIRTEX, SINGAPORE DEVELOP CARBON CAGE NANOPARTICLES**

*** ATCOR WINS $334k US TRIAL ORDER**

*** BLUECHIIP MITEGEN CRYOPIN TRACKING DEAL**

*** STEVEN KRITZLER REDUCES TO 7.5% OF NANOSONICS**

*** US GNC TO MARKET PHOSPHAGENICS 'FIRMING' CREAM**

*** CSL REORGANIZES BEHRING PLASMA, BIO DIVISIONS**

MARKET REPORT

The Australian stock market was up 0.37 percent on Wednesday December 5, 2012 with the S&P ASX 200 up 16.8 points to 4,520.4 points. Ten of the Biotech Daily Top 40 stocks were up, 22 fell, three traded unchanged and five were untraded.

Allied Health was the best, up 0.2 cents or 9.1 percent to 2.4 cents with 1.1 million shares traded.

Antisense climbed 8.3 percent; Tissue Therapies was up 7.1 percent; Compumedics was up five percent; Alchemia and QRX were up more than four percent; Pharmaxis was up 3.3 percent; Clinuvel and Universal Biosensors rose more than two percent; Heartware was up 1.4 percent; with Resmed up 0.5 percent.

Benitec led the falls, down 0.1 cents or 7.1 percent to 1.3 cents with 416,000 shares traded.

Cellmid and Starpharma lost more than six percent; Circadian and Genetic Technologies were down more than five percent; Impedimed and Prima both fell 4.35 percent; Avita, Mesoblast, Nanosonics and Phosphagenics were down more than three percent; Optiscan, Patrys, Prana and Sunshine Heart shed more than two percent; Acrux, Anteo, Bionomics, GI Dynamics, Sirtex and Viralytics were down more than one percent; with Cochlear, CSL and Reva down by less than one percent.

CHEMGENEX, CEPHALON, TEVA PHARMACEUTICAL INDUSTRIES

The US Food and Drug Administration has approved the Chemgenex-developed omacetaxine mepesuccinate now known as Synribo for chronic myeloid leukaemia.

The FDA said on October 26, 2012, that it granted accelerated approval to omacetaxine mepesuccinate for subcutaneous injection for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia with resistance and/or intolerance to two or more tyrosine kinase inhibitors.

Omacetaxine mepesuccinate was developed by the Geelong-based Chemgenex with the application for the drug, then known as Omapro, made to the FDA prior to the company's acquisition by Cephalon (BD: Jul 14, 2010; Mar 29, May 3, Jun 1, 8, 21, 2011).

The US-based Cephalon was later acquired by the Israel-based Teva Pharmaceutical Industries.

The FDA said that accelerated approval was based on combined data from two open-label single-arm trials enrolling patients with chronic myeloid leukaemia in chronic phase or in accelerated phase.

The FDA said that the efficacy population included 76 patients with chronic phase and 35 patients with accelerated phase, who had received two or more prior more tyrosine kinase inhibitors, including imatinib.

The FDA said that the major cytogenetic response (MCyR) and major haematologic response (MaHR) were the primary endpoints for chronic and accelerated phase patients, respectively, with MCyR achieved in 18.4 percent of chronic phase patients, with a median response duration of 12.5 months.

The FDA said that MaHR was achieved in 14.3 percent of accelerated phase patients with a median response duration 4.7 months.

An FDA media release said that about 5,430 people would be diagnosed with chronic myeloid leukaemia in 2012.

The regulator said that Synribo blocked certain proteins that promoted the development of cancerous cells and was injected subcutaneously twice daily for 14 consecutive days over a 28-day cycle until white blood cell counts normalized (haematologic response), then administered twice daily for seven consecutive days over a 28-day cycle as long as patients continue to clinically benefit from therapy.

The FDA Office of Hematology and Oncology Products director Dr Richard Pazdur said the approval "provides a new treatment option for patients who are resistant to or cannot tolerate other FDA-approved drugs for chronic or accelerated phases of [chronic myeloid leukaemia]".

The FDA said Synribo was approved under an "accelerated approval program", which allowed the agency to approve a drug to treat a serious disease based on clinical data showing that the drug has an effect on a surrogate endpoint that was reasonably likely to predict a clinical benefit to patients.

The FDA said the program provided earlier patient access to promising new drugs while the company conducted additional clinical studies to confirm the drug's clinical benefit and safe use.

The regulator said that Synribo also received orphan-product designation because it was intended to treat a rare disease or condition.

SIRTEX MEDICAL

Sirtex says it has an agreement with Singapore Health Services to explore the potential of injectible carbon cage nanoparticles.

Sirtex said the technology was developed by the Australian National University and carbon cage nanoparticles could safely deliver radioactive substances to specific cancer sites deep within the body and could potentially avoid detection by patients' immune systems, improving their ability to target specific cancers.

Sirtex said that carbon cage nanoparticles were sub-micron size particles of graphitic carbon that encapsulated a metallic core and the technology was well-proven, having its genesis in Technegas which was originally invented by Dr Bill Burch at the Royal Canberra Hospital and the Australian National University in 1984.

The company said that Technegas was widely used in nuclear medicine as an inhalable aerosol of carbon cage nanoparticles containing a radiologically detectable radioisotope for the diagnosis of blood clots in the lungs.

Cyclopharm owns the intellectual property to Technegas and manufactures the product.

Sirtex said it had been working closely with the Australian National University for the past six years to develop an injectable form of the carbon cage nanoparticles that could carry therapeutic radioisotopes for the treatment of cancer and had in-licenced the technology from the Australian National University.

Sirtex said that it would work with researchers from Singapore General Hospital and the National Cancer Centre Singapore on several research projects.

The company said that the first project would evaluate the technology's use in the treatment of advanced ovarian cancer that had spread within the abdominal and pelvic cavities.

Sirtex said that ovarian cancer was a common cancer in women and had few or no symptoms in its early stages and as a result, most women were diagnosed late, when the disease had spread and prognosis was poor.

Sirtex said that besides ovarian cancer, gastro-intestinal, hepatobiliary and other female genito-urinary cancers could also benefit from the treatment.

Singapore Health (Sing Health) deputy chief executive officer and National Cancer Centre Singapore director Professor Soo Khee Chee said the partnership with Sirtex was "clear testimony of our capability to provide high quality pre-clinical and translational research that can be used to develop new products".

"Collaborations with industry partners such as Sirtex provide new, cutting-edge technologies that allow us to offer our patients better treatment options, faster," Prof Chee said.

Sirtex chief executive officer Gilman Wong said the company was directing its injectible carbon cage nanotechnology to address specific unmet clinical needs in the treatment of cancers.

Mr Wong said that Sing Health had the expertise "to effectively conduct pre-clinical development and quickly translate these findings into clinical use".

Singapore Economic Development Board director of biomedical sciences Kevin Lai said that the Sirtex-Sing Health collaboration "showcases the strengths of Singapore's translational clinical research ecosystem".

"Singapore's clinician scientists have the ability to help companies develop novel applications for innovative, cutting-edge, technologies," Mr Lai said.

"This validates Singapore's position as a node for the innovation and commercialization of biomedical research," Mr Lai said.

Sirtex fell 15 cents or 1.3 percent to $11.58.

ATCOR MEDICAL

Atcor says it has secured a $US350,000 ($A334,092)order to supply its Sphygmocor systems for a publicly-funded US multi-centre diabetes study.

Atcor said it could not name the hospital conducting the trial and acquiring its non-invasive Sphygmacor measure of central aortic blood pressures and arterial stiffness.

Atcor chief executive officer Duncan Ross said that “at least 65 percent of people with diabetes die from some form of heart disease or stroke”.

“The co-occurrence of one or more diseases in an individual is not uncommon and arterial stiffness and elevated central blood pressures are often linked with diabetes,” Mr Ross said.

“Sphygmocor will play an important role contributing to authoritative trial results,” Mr Ross said.

Atcor was untraded at 7.5 cents.

BLUECHIIP

Bluechiip says that Ithaca New York-based manufacturer Mitegen has signed a licence agreement for the tracking of cryopins.

Bluechiip said the agreement allowed Mitegen to integrate its tracking technology into the cryopins it manufactures and sells to organizations like the Australian Synchrotron and other synchrotrons around the world.

The company did not disclose the value of the agreement, which allowed Mitegen to develop and sell the enhanced product, adding a further product to Bluechiip’s product range and another revenue stream.

Bluechiip said that Mitegen designed, manufactured and distributed products for crystallization, crystallography and x-ray diffraction of proteins, viruses and small molecule/inorganic compounds and supplied crystallography goniometer bases, commonly referred to as cryopins, for crystal mounts used in synchrotrons.

Mitegen’s customers include academic, medical, pharmaceutical, government and industrial laboratories in more than 40 countries.

Bluechiip managing director Brett Schwarz said the agreement with Mitegen followed several agreements with other companies “that operate in significant markets”.

“These agreements help validate the Bluechiip technology and underline how important our technology is when it comes to the accurate tracking of information on important assets,” Mr Schwarz said.

Mitegen chief executive officer Robert Newman said the Bluechiip technology “offers numerous advantages over traditional bar-coding of bases and is extremely well-suited for cryogenic conditions, as well as room temperature studies”.

Bluechiip was up one cent or 4.8 percent to 22 cents.

NANOSONICS

Steven Kritzler has reduced his substantial holding in Nanosonics from 22,364,333 shares (11.44%) to 19,684,773 shares (7.54%).

The Sydney-based Mr Kritzler said he sold 2,600,000 shares for $1,274,000 or 49 cents a share

Nanosonics was down 1.5 cents or three percent to 48 cents.

PHOSPHAGENICS

Phosphagenics says it has an agreement with the Pittsburgh, Pennsylvania-based General Nutrition Co to supply a 'firming cream'.

Phosphagenics chief executive officer Dr Esra Ogru told Biotech Daily that her company's formulated cream included its tocopheryl phosphate mixture or TPM technology to "remove cellulite and improve elasticity of the skin giving firmer looking skin".

Dr Ogru said the cream did not include AOP9604 which had been claimed to reduce fat.

In its media release, Phosphagenics said it would manufacture the cosmetic product for the General Nutrition Co (GNC), which would market and sell it under its own brand "through its lucrative category of diet products".

"We see this arrangement as a forerunner to other similar agreements for our personal care range," Dr Ogru said.

"The TPM technology used in our formulations is being continually validated by global companies looking to market a point of difference for their products," Dr Ogru said.

"We have established a strong scientific basis for these products, which has allowed us to make claims of more effective delivery of key ingredients in cosmetic formulations," DR Ogru said.

Phosphagenics said that GNC expected to launch the cream by April 2013.

Phosphagenics fell half a cent or 3.45 percent to 14 cents.

CSL

CSL says Australian plasma operations will become part of its global plasma business CSL Behring, with vaccines, pharmaceuticals and diagnostics becoming Bio-CSL.

The company said that the internal changes follow a reorganization of CSL Biotherapies and would take effect from January 1, 2013.

CSL said the integration of the Australian operations with CSL Behring would create a single, integrated supply chain for the company's plasma and recombinant products.

CSL said that the establishment of a stand-alone business within the CSL group to focus on vaccines, pharmaceuticals and diagnostics, including third party logistics, would provide a dedicated management structure for the products and services.

CSL chief executive officer Dr Brian McNamee said that "while the structure and name of our Australian operations are changing, both CSL Behring and Bio-CSL will remain fully committed to the reliable supply of high quality, life-saving medicines for Australians."

CSL said that CSL Behring in Australia would be led by Dr Simon Green, who joined CSL in 1998 and was most recently the head of research and development product development, focussed on building recombinant protein manufacturing capabilities.

The company said that Dr Green had spent several years as general manager at CSL Behring's manufacturing site in Germany.

CSL said that Bio-CSL would be led by former CSL Biotherapies vice president commercial operations Dr John Anderson, who had more than 25 years in the pharmaceutical industry and since joining CSL in 2002 "his achievements have included the successful commercialization of … Gardasil".

CSL fell 45 cents or 0.8 percent to $52.95 with 1.8 million shares traded.