Biotech Daily

Monday June 7, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH FALL: LIVING CELL UP 8%, PHOSPHAGENICS DOWN 10%**

*** BIONOMICS CANCER DRUG 'SAFE BELOW MAXIMUM DOSE'**

*** CHEMGENEX OMAPRO 'SAFE, FAVORABLE TOXICITY PROFILE'**

*** AVITA TAKES LA JOLLA COVE $US6m CONVERTIBLE NOTE**

*** OPAL, MASSACHUSETTS GENERAL HIV COLLABORATION**

*** BEN DILLON REPLACES MARK FORDREE AT FERMISCAN**

*** INNOVATION SERIES MATERIAL SCIENCE LUNCH**

MARKET REPORT

The Australian stock market fell 2.8 percent on Monday June 7, 2010 with the S&P ASX 200 down 123.5 points to 4325.9 points.

Just five of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and eight were untraded.

Living Cell was best, up two cents or eight percent to 27 cents with 130,000 shares traded.

Genetic Technologies climbed 2.5 percent; Chemgenex was up 1.7 percent; with Cellestis, CSL and Heartware up by less than one percent.

Phosphagenics led the falls, down 1.5 cents or 10 percent to 13.5 cents with 1.5 million shares traded, followed by Bionomics down three cents or 9.4 percent to 29 cents with 55,900 shares traded.

Sunshine Heart lost 8.3 percent; Prima fell 7.1 percent; Starpharma and Virax were down more then five percent; Clinuvel fell 4.1 percent; Acrux, Psivida and Sirtex were down more than three percent; Alchemia, Biota, Cathrx, Novogen, Prana and Tissue Therapies shed more than two percent; with Pharmaxis and Universal Biosensors down more than one percent.

BIONOMICS

Bionomics says the pro-drug form of its anti-cancer compound BNC105 is well tolerated without any serious adverse side effects below the maximum dose.

Bionomics said the safety data from its first-in-human trial of the vascular disrupting agent and an inhibitor of cancer cell proliferation BNC105 would be presented overnight at the American Society of Clinical Oncology conference in Chicago.

Bionomics said the phase I, dose-escalation study was conducted in patients with solid tumors, including colorectal carcinomas, head and neck cancers, renal cell cancer and mesothelioma.

The company said the data showed BNC105P (the pro-drug form of BNC105) was well tolerated without any serious adverse side effects below the maximum dose of 18.9mg/m2 and stable disease was observed in four of 16 patients who completed at least two cycles of treatment at doses of 8.4mg/m2 or higher.

Bionomics said a dose of 16.0mg/m2 has been selected for phase II trials, underway for renal cancer and mesothelioma and that one patient with renal cancer and one with mesothelioma experienced disease stabilization in the phase I study.

The company said the plasma concentration of the drug generally increased in proportion to the dose, with an average half-life of less than one hour.

Drug activity was evidenced by vascular shutdown in DCE-MRI images of the tumors post-treatment.

Biomarker analysis in patient blood samples indicated changes consistent with the BNC105 mechanism of action and specifically, tubulin levels were reduced in patients receiving doses of BNCI05P at 12.6mg/m2 and above, indicating that the drug was acting on its intended molecular target.

The presentation entitled 'A first-in-human, phase I pharmacodynamic and pharmacokinetic study of BNCI05P, a novel vascular disrupting agent and inhibitor of cancer cell proliferation' is available at: http://abstract.asco.org/AbstView_74_42278.html.

Bionomics chief executive officer Dr Deborah Rathjen said "the publication of the outcomes of the successful phase I trial strengthens confidence in the ongoing development of BNC105 and underpins the rationale of the phase II trials that are currently in progress".

"We are very excited by the potential of this drug and anticipate initial phase II data being available as early as the end of this year for the renal cancer trial and in the first half of calendar year 2011 for mesothelioma," Dr Rathjen said.

"BNC105 has the potential to treat all solid tumour types, but by selecting renal cell cancer and mesothelioma as the first phase II clinical trial indications for BNC105, Bionomics has selected cancer indications which have a fast path to market," Dr Rathjen said.

"For example renal cancer was the market entry indication for Sutent (Pfizer) and similarly mesothelioma for Alimta (Lilly)," she said.

"Both are blockbuster drugs with 2009 sales of $US964 million and $US1.7 billion respectively," Dr Rathjen said.

Bionomics said the poster gave comprehensive details from the study including patient demographics, their disease characteristics, number of doses received, clinical benefit and tolerance of the treatment.

Bionomics fell three cents or 9.4 percent to 29 cents.

CHEMGENEX PHARMACEUTICALS

Chemgenex says its two clinical trials of Omapro for imatinib-resistant chronic myeloid leukemia have shown controllable levels of haematological toxicity.

Chemgenex said the Omapro (omacetaxine mepesuccinate) data was presented during a poster discussion session at the 2010 American Society of Clinical Oncology meeting in Chicago and combined data from cancer centres in the US, Canada, France and Italy.

The company said the data, from 170 patients of which 93 were in chronic phase, 42 were in accelerated phase and 35 were in blast phase, reported on the two phase II/III trials for chronic myeloid leukemia patients who either had failed imatinib (Gleevec) and had the T315I mutation, or had failed imatinib and at least one other tyrosine kinase inhibitor.

The poster's authors concluded: "These results suggest that [omacetaxine mepesuccinate] can be safely administered with a favorable toxicity profile".

Chemgenex said the primary toxicity of omacetaxine was haematologic, with infrequent grade 3/4 non-haematologic events and the grade 3/4 haematologic adverse events were manageable and decreased in frequency and severity with dose adjustments.

Chemgenex said injection site reactions were primarily grade 1/2 events "demonstrating that at-home subcutaneous administration of omacetaxine had an acceptable safety profile" for chronic myeloid leukemia patients who had failed prior therapies.

The cumulative safety data poster is entitled 'Safety of omacetaxine mepesuccinate subcutaneous injection for the treatment of chronic myeloid leukemia patients resistant or intolerant to tyrosine kinase inhibitors: Analysis of two phase II studies' and is available at: http://abstract.asco.org/AbstView_74_54142.html.

Chemgenex chief executive officer Dr Greg Collier said the additional data continued to support Omapro as safe and "reinforces our belief that it is a promising candidate for CML patients who fail to respond adequately to tyrosine kinase inhibitors".

Dr Collier said the company was "in ongoing discussions with the [US Food and Drug Administration] as we respond to the complete response letter to our new drug application for Omapro and in Europe review of the marketing authorization application by the [European Medicines Agency] is proceeding according to schedule".

Chemgenex climbed half a cent or 1.7 percent to 30.5 cents.

AVITA MEDICAL

Avita Medical has signed a convertible note equity draw down facility with La Jolla Cove Investors for a maximum of $US6 million ($A7.4 million).

Avita chief executive officer Dr William Dolphin said the California-based La Jolla Cove agreement secured "valuable funds to support the critical expansion phase as the company's products become established in major global markets".

Avita said that among the key terms of the convertible note comprised of up to four notes each worth $US1.5million with a duration of two years were that $US250,000 could be drawn each month; the notes had interest payable at 4.75 percent and must be repaid upon maturity or converted to ordinary shares within the terms of the notes; the notes could be converted at the election of the holder (or upon default triggers) at 25 Australian cents a share for the first and any other note issued during the first 12 months following the first note issue and for notes issued after 12 months following the first note at the lesser of 40 Australian cents a share or an 18 percent discount to the value weighted average price calculated at conversion, with a floor price of 12 cents per share.

The company said La Jolla Cove was limited to less than 9.9 percent of Avita and would not able to short sell the converted shares.

Avita fell one cent or 8.3 percent to 11 cents.

OPAL THERAPEUTICS, MASSACHUSETTS GENERAL HOSPITAL

Opal Therapeutics says it has a joint development collaboration agreement with Massachusetts General Hospital to develop a novel immunotherapy for HIV.

A media release from Opal said human clinical trials would begin in London this week.

Opal chairman, GBS Ventures Dr Joshua Funder, told Biotech Daily the company licenced the technology from the University of Melbourne and the company was spun-out from the University.

The company said in its media release that it was incorporated in Delaware with operations in Australia, UK and the US and the collaboration leaders for Massachusetts General Hospital were Dr Philip Goulder and Prof Bruce Walker.

Opal's investors include Alloy Ventures, Alta Partners and GBS Ventures.

Opal said cellular immunity had an important role in the progression of both HIV and hepatitis C, but treatments had generally failed to induce strong cellular immune responses.

Opal said it had developed a unique approach to generate high levels of targeted cellular immune responses for the treatment of chronic infection.

"The studies under this collaboration will test and validate this novel approach as a therapeutic vaccine to treat HIV," Prof Walker said.

Opal said it retained rights to commercialize the vaccine globally and would "not only develop a product for developed markets such as the US, Europe and Japan, but will also work together with other parties to ensure access to the vaccine to the least developed countries at minimum cost and without royalties".

Opal said it would contribute funds, technology, intellectual property, and commercialization expertise, while Massachusetts General would contribute funds, intellectual property, technical expertise and clinical development capability.

Under the agreement, not-for-profit company Medicines Development would undertake initial clinical studies.

Opal said its technology "demonstrated strong reduction of the AIDS virus in non-human primate studies".

The company said the London trial would assess the safety and immunogenicity of the therapy for the first time in humans.

Opal said immunotherapy used short peptides from the target virus to generate a strong immune response so patients could improve control of the infection.

Opal said the peptides were mixed outside the body with blood to bind to immune cells and were then distributed through the body to stimulate an immune response.

Opal is a private company.

FERMISCAN

Fermiscan says Benjamin Robert Dillon had replaced Mark Andrew Fordree as a director on June 2, 2010.

The notice to the ASX was signed by former Medicines Australia chief executive officer Ian Chalmers who was appointed a director of Fermiscan with former EG Capital principal Mark Fordree last year (BD: Sep 17, 2009).

Mr Dillon is believed to be the same Ben Dillon who was chief executive officer of Polartechnics.

Last year, Polartechnics attempted to merge with Fermiscan but the deal failed (BD: Apr 17, 20; Jun 29; Jul 16, 2009).

Polartechnics was liquidated earlier this year (BD: Feb 11, 2010).

Fermiscan remains in a suspension and last traded at three cents.

INNOVATION SERIES

The June 23, 2010 Innovations Series lunch in Sydney will discuss material science opportunities for Australian industry.

A media release from Zernike Australia said the Innovation Series was its initiative, in partnership with the Australian Institute for Commercialisation and the Brisbane Technology Park.

Zernike partner and deputy chief executive officer of with the Australian Institute for Commercialisation Dr John Kapeleris will be the event's master of ceremonies and told Biotech Daily that new materials ranged from components for Cochlear implants and Resmed sleep apnoea devices to Starpharma's dendrimer technology, Tissue Therapies, would healing materials and Polynovo's bio-degradable Novosorb.

Dr Kapeleris said materials engineering ranged from the macro to the micro and nano scale, with applications in biotechnology and medical technology.

The media release said Australia's manufacturing future "lay in developing niche products in the health, defence, mining and energy sectors".

The Commonwealth Scientific and Industrial Research Organisation's Materials Science and Engineering chief Dr Calum Drummond said finite resources and space and a rapidly increasing global population was fuelling the 'more from less' imperative and product lifecycles had expanded from 'cradle to grave' to include the need for recycling and waste minimization.

"We are trying to extract as much value as possible from inputs and then re-use them," Dr Drummond said. "It's all about sustainability and the need to accommodate an increasingly urbanized world".

The media release said Polymarketing Pty Ltd director Michael Turner would outline practical strategies to improve business performance and innovation.

He said defence and indigenous communities presented surprising opportunities for Australian business.

"In the US, the Federal Government has decreed that three percent of all its contracts must go to a veteran-owned business," Mr Turner said. "This presents huge opportunities for Australian businesses to work through US veteran-owned companies".

The head of the Institute of Materials Engineering at the Australian Nuclear Science and Technology Organisation Prof Lyndon Edwards will discuss how material science has transformed work, health and leisure and the challenges and opportunities for the next generation of materials scientists.

Professor Edwards said most modern materials were designed in detail at the atomic level and, while Australia had done well to date, to remain competitive it was critical we continued to invest in top quality research facilities.

The lunch will be held at the Sydney Westin Hotel on June 23, 2010 from 12pm to 2.30pm and cost $160 per person.

To attend: call 1300 368 379 or email: info@innovationseries.com.au.