Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: LBT UP 9%, BIONICHE DOWN 8%**

*** MESOBLAST REVASCOR PERFUSION ADDS CARDIAC INDICATIONS**

*** WEHI, ASTRAZENECA OLAPARIB PHASE II OVARIAN CANCER EFFICACY**

*** SUNSHINE HEART SHEEP SUCCESS IN WIRELESS HEART PUMP**

*** ANTISENSE RAISES $500k FOR ATL1103 TRIAL**

*** FEDERAL $60m FOR THREE INNOVATION FUNDS; START-UP MISSES**

*** VIRAX APPOINTS PROF ROD SINCLAIR, PROF REINHARD DUMMER**

*** MERCK SERONO EXTENDS BIONOMICS MULTIPLE SCLEROSIS PROGRAM**

*** BLUECHIIP OPENS UNCHANGED, CLOSES DOWN 8%**

MARKET REPORT

The Australian stock market recovered 0.28 percent on Thursday June 9, 2011 with the S&P ASX 200 up 12.8 points to 4549.6 points.

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

LBT was the best, up 0.4 cents or 8.7 percent to five cents with 276,584 shares traded, followed by Mesoblast up 64 cents or 8.05 percent to $8.59 with 1.6 million shares traded.

Nanosonics and Sunshine Heart climbed more than seven percent; Prana was up 5.4 percent; Bionomics and Virax were up more than four percent; Clinuvel and Tissue Therapies were up more than three percent; with Acrux, Anteo, Circadian, Impedimed, Living Cell and Sirtex up more than one percent.

Bioniche led the falls, down nine cents or 8.2 percent to $1.01 with 7,900 shares traded.

Genera and Patrys fell four percent or more; Genetic Technologies, Optiscan and Pharmaxis shed more than two percent; with CSL, Heartware and QRX down more than one percent.

MESOBLAST

Mesoblast says its lead cardiovascular product Revascor improves blood flow in ischemic heart muscle and reduces long term vascular-related complications.

Mesoblast chief executive Prof Silviu Itescu presented further results from the 60-patient phase II trial with partner Cephalon at a Goldman Sachs conference in California.

In January, Mesoblast reported a significant drop in cardiac events, deaths and hospitalizations for the patients treated with Revascor and followed up for six months (BD: Jan 16, 2011).

Today, Mesoblast said it would add chronic angina as a third Revascor indication, in addition to congestive heart failure and acute myocardial infarction.

Mesoblast said that in a subset analysis of the ongoing 60-patient US trial of Revascor for congestive heart failure, 22 patients had reduced myocardial blood flow at baseline by single photo emission computed tomography (SPECT) perfusion scan, indicating the presence of ischemic heart muscle.

Of the 22 patients, 17 were randomized to receive treatment with Revascor while five were controls.

Mesoblast said that six months after treatment with a single injection of Revascor there was significant improvement in blood flow to the ischemic heart muscle, with 51 percent reduction in myocardial ischemia ($p = 0.01$).

In contrast, no change in blood flow to the ischemic heart muscle was seen at six months in the controls, the company said.

Mesoblast said the improvements in blood flow and in myocardial ischemia in patients treated with Revascor were accompanied by a 75 percent reduction in the risk of major adverse cardiac events over a mean follow-up period of 21 months compared with controls with myocardial ischemia and no change in blood flow.

“These positive results open up major new market opportunities for our lead cardiovascular product Revascor,” Prof Itescu said. “By improving blood flow to ischemic heart muscle Revascor may be an effective treatment for a broader range of vascular heart conditions and their life-threatening consequences.”

“We are particularly excited about the prospect that Revascor could be highly effective for patients with chronic refractory angina who do not have other therapeutic options and are so debilitated by pain that their physical activity is either markedly restricted or non-existent,” he said.

“Indeed, in an earlier pilot trial in Australia where we treated such patients with a single injection of an autologous, or patient specific, version of Revascor our proprietary stem cells were highly effective for reduction in angina symptoms and use of anti-angina medications for as long as six months,” Prof Itescu said.

“Given these exciting clinical results, we intend to file an investigational new drug application with the United States Food and Drug Administration to commence a phase IIb trial of Revascor in approximately 150 patients with chronic refractory angina by the end of this year,” Prof Itescu said.

Prof Itescu told the conference that Mesoblast had submitted a clinical trial application to European regulatory authorities to begin a phase IIb trial of 225 patients with myocadrdial infarctions and planned to extend this trial to the US and Australia.

The company said the aims of the trial were to see if a single injection of Revascor at the time of a major heart attack could prevent the complication of heart failure, reduce infarct size, and lower the frequency of major adverse cardiac events.

Mesoblast said that expanding the use of Revascor into new vascular indications opened multi-billion dollar annual market opportunities.

Mesoblast was up 64 cents or 8.05 percent to $8.59 with 1.6 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says a 265 patient phase II clinical trial of Astrazeneca's olaparib shows promise for the treatment serous ovarian cancer.

WEHI said the trial of olaparib, an inhibitor of poly-adenosine diphosphate (ADP)-ribose polymerase (or PARP inhibitor), was run at the Royal Melbourne Hospital by its head of the ovarian cancer research laboratory Dr Clare Scott.

WEHI said the London-based Astrazeneca trial of the most common form of ovarian cancer was run concurrently at hospitals in Australia, Europe, Israel and the US.

presentation to the American Society of Clinical Oncology meeting in Chicago on June 7, 2011, entitled 'Olaparib Shows Promise as Maintenance Therapy in Relapsed Serous Ovarian Cancer', lead investigator, Lonodn University College's Dr Jonathan Ledermann, reported that olaparib improved progression-free survival, the primary endpoint, by 3.6 months following the completion of chemotherapy as compared with placebo, translating to a 65 percent reduced risk of progression.

The presentation is at: http://chicago2011.asco.org/ASCODailyNews/Fallopian.aspx

The presentation said that in a pre-planned subgroup analysis, the benefit associated with olaparib was not restricted to patients who were BRCA-mutation positive - a status thought to enhance responsiveness to PARP inhibition.

All subgroups, including those broken out by BRCA-mutation status, age, race or Jewish ethnicity, prior response to the last platinum regimen and time to disease progression on the penultimate platinum regimen, showed a substantial benefit in favor of olaparib.

The time to progression according to either CA-125 concentration or RECIST was also significantly longer with olaparib compared to placebo with a median 8.3 months compared to 3.7 months ($p < 0.00001$).

The most common adverse events associated with olaparib compared with placebo included nausea (68% vs. 35%), fatigue (49% vs. 37%), and vomiting (31% vs. 14%); the majority of these events were mild or moderate in severity.

"Most ovarian cancer patients are treated with surgery to remove as much cancer as possible, followed by chemotherapy to kill the remaining cancer cells," Dr Scott said.

"In four out of five patients, this chemotherapy will initially make the cancer shrink, but for many of these patients the response is brief, the cancer regrows and cannot be effectively treated," Dr Scott said. "The clinical trial tested whether olaparib could serve as a maintenance therapy that would prevent the re-growth of ovarian cancer by extending the remission phase after successful chemotherapy treatment."

"We found that patients who received olaparib stayed in remission for more than eight months on average, which was almost four months longer than for those who received an inactive placebo," Dr Scott said.

WEHI said that olaparib blocked the action of PARP, which helped repair damaged DNA, potentially making the cancer more vulnerable to cell damage and death.

Dr Scott said the study could be an important breakthrough for treating ovarian cancer.

"This is the first time a PARP inhibitor treatment used as a maintenance therapy has shown a substantial benefit in delaying disease progression for patients with the most resistant type of ovarian cancer, high-grade serous ovarian cancer," Dr Scott said.

The Institute said that Dr Scott was separately studying ovarian cancer samples from patients enrolled in the Australian Ovarian Cancer Study to determine which patients and which ovarian cancers may be most suitable for particular treatments.

"My laboratory is hoping to narrow down the features which will identify ovarian cancer patients who will respond best to future treatments including PARP inhibitors," Dr Scott said. "If we can do this, we would hope to see even better treatment outcomes for patients," Dr Scott said.

SUNSHINE HEART

Sunshine Heart says a study of its next generation transcutaneous powered fully implantable C-Pulse aorta cuff heart assist system in sheep has been successful.

Sunshine Heart said the study, conducted at the Texas Heart Institute in Houston, showed that a combined driver and C-Pulse cuff implanted around the heart's aorta could be successfully powered from a wireless, external battery unit eliminating the need for wires to breach the skin, thereby improving patient comfort and reducing the risk of infection.

The Texas Heart Institute's director of minimally invasive surgery Dr William Cohn said that "hundreds of thousands of people with early heart failure … could benefit from a fully implantable, un-tethered device that is safe and easy to implant and that doesn't compromise patient mobility."

"The promising outcomes of this study could eventually lead to an important therapy that has the potential to change the early management of heart failure, which remains our biggest unmet health care challenge in the United States today," Dr Cohn said.

Sunshine Heart said that the C-Pulse power unit and driver unit were located outside the body and connected to the cuff through tubing that exited through the patient's abdomen.

The company said the prototype fully-implantable C-Pulse system had the power source outside the body.

Sunshine Heart said that the driver, which controlled the C-Pulse cuff, was miniaturized and implanted inside the sheep and the internal driver was powered through the skin using transcutaneous energy transfer, an established technology that used a high-frequency electromagnetic field to transfer electricity across the skin without wires.

Sunshine Heart said the system successfully augmented the sheep's heart function, confirming the viability of a fully implantable unit.

Sunshine Heart chief executive officer Dave Rosa said the study was important and was "completed more than one year ahead of schedule" and demonstrated the feasibility of a C-Pulse system powered using transcutaneous energy transfer technology.

"While the company's primary focus is to initiate a pivotal trial using a new single unit system planned for release later in the year, our [research and development] team will continue to study and refine the specifications of the C-Pulse system," Mr Rosa said.

"Our goal is to ultimately develop a fully-implantable device that will connect directly to, and potentially receive its [electrocardiogram] signals from a patient's pacemaker, in the event they have already received pacemaker therapy," Mr Rosa said.

Sunshine Heart was up 0.4 cents or 7.7 percent to 5.6 cents with 3.2 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has raised $500,000 through the issue of 62,500,000 shares at 0.8 cents a share to Tempo Capital.

Antisense said the shares came with 31,250,000 attaching options exercisable at 1.5 cents each within 18 months of issue.

Antisense said it would use the funds to complete additional key studies in association with the first human trial of ATL1103, which it said was designed to block growth hormone receptor (GHr) expression.

The company said ATL1103 was being developed for diseases where reducing growth hormone and insulin growth factor 1 (IGF-I) effects could lead to treatment in diseases including growth and sight disorders as well as some forms of cancer.

Antisense said it expected to commence dosing by October 2011.

Antisense was unchanged at one cent with eight million shares traded.

FEDERAL GOVERNMENT

The Federal Government has provided $60 million through the Innovation Investment Fund to three fund managers.

A media release from the Department of Innovation said Carnegie Venture Capital, the Medical Research Commercialisation Fund and Southern Cross Venture Partners would each receive $20 million matching grants.

A Department of Innovation spokesman told Biotech Daily the Government originally intended to provide $80 million to four funds, dependent on the funds finding private matching funds, but Start-up Australia was unable to secure that funding following private investors withdrawing from the process (BD: Nov 5, 2010).

Innovation Minister Senator Kim Carr said innovation fund managers played “a key role in helping smart start-up companies get their products and services into national and international markets”.

“These fund managers will invest in new companies that are commercializing Australian research and development,” Senator Carr said.

The media release said that previous innovation fund managers supported companies such as Seek.com.au, G2 Therapies and Dynamic Hearing as well as the Sydney-based BTF, a Biomérieux subsidiary, which developed the Bioball “the world's most precise quantitative reference standards for microbiological testing”.

Senator Carr said the Innovation Investment Fund provided high growth companies with capital and access to commercialization skills and international networks.

“The Innovation Investment Fund complements other Australian Government support programs like Commercialisation Australia and the proposed research and development tax credit,” Senator Carr said.

“The range of programs available ensures Australian companies are supported at all stages, from start-up stage to market,” Senator Carr said.

Carnegie Venture Capital said it invested in internet and media technology as well as medical device companies and included Starpharma chief executive officer Dr Jacinth (Jackie) Fairley in its key personnel.

The Medical Research Commercialisation Fund is a collaboration of 29 medical research institutes with assistance from the State Governments of Victoria, New South Wales, Queensland and Western Australia and is managed by Brandon Capital in Melbourne.

Southern Cross Venture Partners focus on information technology, telecommunications, clean technologies and materials.

VIRAX

Virax says it has appointed Prof Rod Sinclair and Prof Reinhard Dummer to its clinical advisory board to advise on the development of its TG1042 skin cancer immunotherapy.

Virax said it planned to begin phase I/IIa trials of TG1042 for basal cell carcinoma later this year.

The company said the clinical advisory board would initially comprise chief executive officer Dr Larry Ward and dermatologists Prof Rod Sinclair from the University of Melbourne and Prof Reinhard Dummer from the University Hospital in Zurich.

Virax said TG1042 was a clinical stage immunotherapy treatment product that had shown clinical efficacy in the orphan skin cancer, cutaneous lymphoma.

The company said it completed a successful pre-submission meeting with the Australian Therapeutic Goods Administration in April and was continuing discussions with the TGA on the design of the clinical trial and the associated patient population.

Virax was up 0.1 cents or 4.55 percent to 2.3 cents.

BIONOMICS

Bionomics says Merck Serono has extended the Kv1.3 multiple sclerosis drug research collaboration for “at least another year”.

Bionomics said Merck Serono was a division of Germany’s Merck KGaA and the companies agreed that further extensions to the 2008 agreement could occur beyond June 13, 2012.

Bionomics said Merck Serono was actively developing potential new treatments for multiple sclerosis and other autoimmune conditions based on compounds from the Bionomics Kv1.3 program, using Bionomics' expertise in Kv1.3 biology and Merck Serono's expertise in multiple sclerosis pharmacology, clinical development and commercialization.

Bionomics chief executive officer Dr Deborah Rathjen said the extension was “a clear signal of progress towards a potential new treatment for multiple sclerosis”.

The company said it received an upfront payment of $US2 million and committed research funding that had been extended and Merck Serono would fund all development, including clinical development of drug candidates.

Bionomics said that for each compound successfully developed and commercialized as a result of the partnership, it could receive milestone payments up to $US47 million and would be eligible to receive undisclosed royalties on the net sales of licenced products.

The company said the compounds licenced by Merck Serono targeted the potassium ion channel Kv1.3, a modulator of the immune system and a target found on human immune cells which are associated with nerve cell damage in patients with multiple sclerosis.

Bionomics said that inhibitors of Kv1.3 had been shown to inhibit the proliferation of these immune cells, suggesting they had application in the treatment of multiple sclerosis and potentially other autoimmune conditions, including arthritis.

Bionomics was up three cents or 4.8 percent to 66 cents.

BLUECHIIP

Bluechiip opened unchanged on the ASX today with just four buyers for 148,000 shares with the highest bid 13 cents and nine sellers for 255,000 units.

About 30 minutes into trading a parcel of 50,000 shares went through at the initial public offer price of 25 cents.

Bluechiip closed down two cents or eight percent at 23 cents with 96,100 shares traded.