Biotech Daily

Thursday March 24, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: OSPREY UP 12%, ATCOR DOWN 11%**

*** LIVING CELL BEGINS 18-PATIENT PHASE IIB NTCELL PARKINSON'S TRIAL**

*** US GRANTS MESOBLAST 'KEY' RHEUMATIC PATENT**

*** CLINUVEL 'CONFIDENT' AFTER NICE WORKSHOP FOR UK BENEFITS**

*** EUROGOLD $3m PROSPECTUS FOR BARD1 AG CANCER BLOOD TEST**

*** TISSUE THERAPIES 'FACTOR THERAPEUTICS' NAME CHANGE EGM**

*** MGC SIGNS $477k CZECH CANNABIS COSMETICS DISTRIBUTION**

*** CALDERA: ROBERT MITCHELL CEO FOR PROSTATE CANCER TESTS**

*** RACI DINES ON OPTHEA'S DR MEGAN BALDWIN**

MARKET REPORT

The Australian stock market fell 1.13 percent on Thursday March 24, 2016 with the ASX200 down 58.1 points to 5,084.2 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, six traded unchanged and five were untraded. All three Big Caps were up.

Osprey was the best, up three cents or 11.5 percent to 29 cents with 31,500 shares traded.

Antisense and Universal Biosensors climbed more than seven percent; Compumedics was up 5.9 percent; both Benitec and Living Cell improved four percent; Mesoblast and Oncosil were up more than three percent; Nanosonics, Opthea, Pharmaxis and Sirtex rose more than two percent; Anteo, Biotron, Cochlear, CSL, Impedimed, Orthocell and Resmed were up more than one percent; with Medical Developments and Pro Medicus up by less than one percent.

Atcor led the falls, down two cents or 11.1 percent to 16 cents with 217,992 shares traded.

Genetic Technologies lost five percent; Neuren, Prima and Starpharma fell more than four percent; Bionomics was down 3.4 percent; Acrux and Tissue Therapies shed more than two percent; Actinogen was down 1.4 percent; with Clinuvel and Viralytics down by less than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says that following Auckland Hospital research committee approval, patient recruitment has begun in its phase IIb trial of NTCell for Parkinson's disease.
Living Cell said that the New Zealand Minister of Health authorized the 18-patient trial of the implanted NTCell encapsulated porcine choroid cells last year, with ethics approval in February (BD: Nov 12, 2015; Feb 3, 2016).
The company said the phase IIb trial followed the four-patient phase I/IIa trial, which met the primary endpoint of safety and showed clinically and statistically significant efficacy data one year after NTCell treatment (BD: Jun 15, Oct 27, 2015).
Living Cell said that the phase IIb trial aimed to confirm the most effective dose of NTCell, define any placebo component of the response and further identify the initial target Parkinson's disease patient sub group.
The company said that if the trial was successful it would apply for provisional consent to treat paying patients in New Zealand and launch NTCell as the first disease modifying treatment for Parkinson's disease in 2017.
Living Cell was up 0.2 cents or four percent to 5.2 cents.

MESOBLAST

Mesoblast says it has been granted "a key patent covering its mesenchymal precursor cells for the treatment or prevention of a broad range of rheumatic conditions".
Mesoblast said the US Patent and Trademark Office granted the patent, entitled 'Method of treatment or preventing rheumatic disease', providing coverage to July 4 2032.
The company said that further patent term extension could occur along with regulatory exclusivity extensions.
Mesoblast said that the granted claims covered the use of cell populations enriched for mesenchymal precursor cells, defined as Stro-1 positive multi-potential cells isolated from any tissue source and which might have been culture-expanded, for the treatment of various rheumatic diseases, including rheumatoid arthritis, osteoarthritis, psoriatic arthritis, ankylosing spondylitis, sacroiliitis, enteric arthritis and Reiter's syndrome.
The company said that the granted claims covered the use of the cell populations to reduce levels of inflammatory cytokines tumor necrosis factor-alpha (TNF-alpha), interleukin-6 and interleukin-17, all established mediators of inflammatory arthritis in rheumatic diseases.
Mesoblast said the mesenchymal precursor cells secreted "potent immune-modulatory and anti-inflammatory factors and [were] thought to mediate their effects on inflammatory joint conditions by inhibiting multiple cytokine pathways implicated in joint inflammation of rheumatic diseases".
The company said the patent underpinned the value of its strategy for developing a cell-based therapy for rheumatoid arthritis and other inflammatory joint conditions.
Mesoblast said that top-line results from the first cohort of its phase II trial in rheumatoid arthritis patients who previously failed one or more biologic agents, showed that a single infusion of the lower dose of its mesenchymal precursor cell drug candidate MPC- 300-IV safe and resulting in early and sustained clinical responses (BD: Feb 16, 2016).
Mesoblast said that the second cohort evaluating a higher dose of MPC-300-IV was fully-enrolled, with results from both cohorts expected to be reported by October 2016.
Mesoblast said it had more than 661 patents or patent applications across more than 72 patent families providing substantial competitive advantages for the commercial development of cell-based therapeutic products using mesenchymal lineage cells.
Mesoblast was up eight cents or 3.2 percent to $2.56 with 978,479 shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says that a UK National Institute for Health and Care Excellence workshop is one of the last steps to approval of Scenesse for erythropoietic protoporphyria.
Clinuvel says the National Institute for Health and Care Excellence public workshop discussed the benefits and costs of Scenesse (afamelanotide 16mg) in the treatment of adult patients with erythropoietic protoporphyria (EPP).
The company said the meeting included a review of the specific burden of erythropoietic protoporphyria on patients' lives, the number of treatment centres in the UK, patients eligibility for treatment and the lack of a standard of care.
The company said the Institute was responsible for evaluating reimbursement for the UK National Health Service, providing a brief and recommendation to the Governement.
Clinuvel said that the objective of the meeting was to agree on the remit and characterization of the relatively high cost and low volume treatment as an innovative and specialized technology to be introduced in England.
The company said that under the UK reimbursement system, Government Ministers needed to refer selected health topics and new treatments back to the Institute for evaluation under the highly specialized technology program.
Clinuvel chief executive officer Dr Philippe Wolgen said that the Institute involved "all relevant stakeholders in the reimbursement discussion".
"We left the meeting with a feeling of confidence that the technology advisors and executive management of [the Institute] had done ample diligence on disease burden and therapeutic effectiveness, which are essential considerations for decisions on reimbursement," Dr Wolgen said.
Clinuvel did not disclose when it expected the Institute to make a decision, nor the cost of treatment.
Clinuvel fell one cent or 0.2 percent to $4.15.

EUROGOLD

Eurogold has filed its prospectus to raise $3 million at two cents a share for the acquisition of Bard1 AG to develop a blood test for cancer.
In December 2015 and February 2016 the Western Australian gold mining company said it hoped to acquire the Swiss public company, founded in 2011 by the University Hospital of Geneva's the head of the molecular gynaecology and obstetrics laboratory Dr Irmgard Irminger-Finger (BD: Feb 24, 2016).
The company said at that time that Bard1 AG had developed "a simple blood test for screening and diagnosing lung cancer at early stages of disease progression".
Eurogold was due to hold an extraordinary general meeting today for investors to vote on resolutions relating to the capital raising, a significant change in the nature and scale of activities and a name change to Bard1 Life Sciences, the appointment of Dr Irminger-Finger as a director, along with the University of Western Australia's director of the centre for cell therapy and regenerative medicine Prof Geoffrey Laurent, who was also a member of Bard1's scientific advisory board.
The extraordinary general meeting began at the time of publication and results will be announced in the first post-Easter edition on March 29, 2016.
Eurogold said that the lead manager for the offer was the Perth, Western Australia-based State One Equities.
The prospectus is available through the ASX platform under the company's EUG code.
Eurogold was suspended at three cents.

TISSUE THERAPIES

Tissue Therapies shareholders will vote to change the company's name to Factor Therapeutics and ratify its recent $9.65 million placement (BD: Mar 17, 18, 2016).
Last week, the company raised $9.65 million at 3.5 cents a share and said that it had a fully underwritten $5.3 million rights issue.
Today the company said that the name change was "on the basis of re-branding the company as part of the transformation strategy … and to articulate product potency and positioning beyond chronic wound care" (BD: Nov 23, 2015).
The meeting will be held at McCullough Robertson, Level 11, Central Plaza Two, 66 Eagle Street, Brisbane, Queensland, on April 28, 2016 at 4pm (AEST).
Tissue Therapies fell 0.1 cents or 2.4 percent to four cents with one million shares traded.

MGC PHARMACEUTICALS

MGC says cosmetics subsidiary MGC Derma has signed a European distribution agreement for its cannabinoid-based cosmetic product range.
MGC said the agreement with the Prague-based Czech Medical Herbs was its first European distribution agreement and would see the distribution of its Ananda cosmetics products in the Czech Republic, with similar distribution agreements under discussion for Poland, Hungary and the US.
The company said that under the agreement, it had received its first order for its Ananda line cosmetics range of 15 cannabinoid-based cosmetics including Moisturizing Day Cream SPF 50, Active Firming Anti-Aging Mask, Active Whitening Facial Cream, Anti Puffiness and Dark Circles Eye Serum, which was expected to generate more than EUR320,000 ($A476,914) in gross sales revenue, with a retail value of more than EUR1,000,000.
MGC said it was developing about 50 cannabinoid-based cosmetic products which should be available for sale by the end of 2016.
MGC managing-director Nativ Segev said that the sales of the first range of cosmetics "marks a major milestone for MGC Pharmaceuticals".
"With the imminent launch of our new consumer online shop and more products to come in the range, we expect a material uplift in revenue to follow this first sales order," Mr Segev said.
MGC

CALDERA HEALTH

The Auckland, New Zealand-based Caldera Health says it has appointed Robert Mitchell as its chief executive officer to commercialize of its prostate cancer tests.
Caldera said it was developing a gene-based multi-biomarker test designed for routine use in the diagnosis of prostate cancer.
The company said that Mr Mitchell was an experienced senior executive with more than 30 years in pharmaceutical businesses.
Caldera said that Mr Mitchell previously was the head of product strategy for Roche and the Medicines Co.
Caldera is a public unlisted company.

ROYAL AUSTRALIAN CHEMICAL INSTITUTE

The Royal Australian Chemical Institute says Opthea's Dr Megan Baldwin will discuss drugs targeting the vascular endothelial growth factor pathway at its April dinner.

RACI said that its Bioactive Discovery and Development Group would host the dinner with Opthea (formerly Circadian) chief executive officer Dr Baldwin.

The Institute said that Dr Baldwin's presentation "The journey so far" would cover aspects of her career and insights into discoveries within the vascular endothelial growth factor (VEGF) family, joining Genentech and working with VEGF pioneer Napoleone Ferrara, as well as the growth of Genentech as the largest US biotechnology company and US Food and Drug Administration approval of Avastin, Lucentis and Tarceva, and the return to Australia and commercializing VEGF intellectual property with Circadian and Opthea and corporate drug development approaches in oncology and ophthalmology.

RACI noted that Dr Baldwin was a "serious candidate" for Biotech Daily's 2015 CEO of the Year Award.

The Institute said that their dinners were "excellent opportunities to meet with chemists from the private and public sectors, to engage with the carefully selected pre-dinner speaker, and enjoy some fine food in relaxed surroundings"

The RACI diner will be held at The Pumphouse Hotel, 128 Nicholson Street, Fitzroy on April 19, 2016 from 7pm.

RACI said that registration for this event could be made online until April 15, 2016 at: http://www.ivvy.com/event/VBG562/.