Biotech Daily

Thursday November 14, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMPEDIMED UP 13%, LIVING CELL DOWN 6%**

*** MESOBLAST: 'PROCHYMAL BENEFIT FOR PAEDIATRIC ACUTE GVHD'**

*** REGENEUS DEVELOPING CANINE CANCER VACCINE, HUMAN POTENTIAL**

*** RESONANCE, ALLIANCE TO PROVIDE EUROPEAN IMAGING**

*** NOVOGEN, GENEA COLLABORATE ON DEGENERATE DISEASES**

*** CORRECTION: REVA**

*** AVEXA PLAN TO RAISE UP TO $3m, SMALL PARCEL FACILITY**

*** ECO QUEST COMPLETES 1-for-20 CONSOLIDATION**

*** TALU TAKES CM CAPITAL'S 10% OF UNIVERSAL BIOSENSORS**

*** HOCKINGS TAKE 19.99% OF PHYLOGICA**

*** CAPITAL CONCERNS, LOGUE FAMILY BELOW 5% OF IMMURON, AGAIN**

*** GENETIC TECHNOLOGIES DIRECTOR TOMMASO BONVINO TO RETIRE**

MARKET REPORT

The Australian stock market climbed 0.68 percent on Thursday November 14, 2013 with the S&P ASX 200 up 36.2 points to 5,355.4 points. Nineteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and one was untraded. All Big Caps rose.

Impedimed was best for the second day in a row, up 13.3 percent to 25.5 cents. Anteo and Phylogica climbed more then 11 percent; Allied Health and Reva rose more than nine percent; Tissue Therapies was up seven percent; Clinuvel climbed 5.9 percent; Avita, Neuren, QRX and Phosphagenics rose more than four percent; Genetic Technologies was up 3.3 percent; Mesoblast, Universal Biosensors and Viralytics rose more than two percent; with Acrux, Bionomics, Cochlear and Prana were up more than one percent.

Living Cell led the falls, down 0.6 cents or 6.4 percent to 8.8 cents with 594,896 shares traded, followed by Patrys down 6.35 percent to 5.9 cents with 41.0 million shares traded. Antisense fell 5.9 percent; both Circadian and Pharmaxis fell four percent; Compumedics, Ellex and Psivida were down more than three percent; Prima shed 2.8 percent; with Optiscan down 1.6 percent.

MESOBLAST

Mesoblast says the recently acquired Osiris mesenchymal stem cell product Prochymal has shown significant benefit for severe paediatric acute graft versus host disease.

Mesoblast said that independent research published in the journal 'Biology of Blood and Marrow Transplantation' showed that use of Prochymal in 75 children, with a median age of eight years, with acute graft versus host disease (GVHD) gave an overall survival to 100 days of 47.9 percent compared to an average of 30 percent for grade C and D.

Mesoblast chief executive Prof Silviu Itescu told Biotech Daily that 60.0 percent of the children in the study were in the worst category, grade D, which normally had a survival rate of five percent.

"That's the whole point [of the study]," Prof Itescu said. "Under a special access scheme we are getting all the patients who ordinarily have very low survival rates."

Prof Itescu said that Mesoblast would make the treatment available to all children who needed it.

"We will make it available without consideration of cost," Prof Itescu said.

Prof Itescu said the company would have discussions with the European Medicines Agency and US Food and Drug Administration over the next three month.

He said that FDA Breakthrough designation was one of several pathways the company could take for regulatory approval.

Prof Itescu said that study was a fully independent trial.

The study, entitled 'Allogeneic Human Mesenchymal Stem Cell Therapy (remestemcel-L, Prochymal) as a Rescue Agent for Severe Refractory Acute GvHD in Pediatric Patients', was led by the Durham, North Carolina-based Duke University Medical Center's chief of the division of pediatric blood and marrow transplantation Prof Joanne Kurtzberg and co-authored by Osiris chief executive officer Dr Charles Randall Mills.

An abstract is at: http://www.bbmt.org/article/S1083-8791%2813%2900506-5/abstract.

The abstract concluded that collectively overall response at day 28 for patients treated for severe refractory acute graft versus host disease "was 61.3 percent and this response correlated with statistically significant improved survival 100 days post infusion of [human mesenchymal sten cells]".

"Patients who responded to therapy by day 28 had a higher … estimated probability of 100-day survival than patients who did not respond (78.1% vs 31.0%, $p < 0.001$) [and] prochymal infusions were generally well tolerated without any evidence of ectopic tissue formation," the abstract concluded .

Mesoblast said that acute graft versus host disease occurred in about 50 percent of all donor-derived, or allogeneic, haematopoietic stem cell transplants, from donor bone marrow, cord blood, or peripheral blood for the treatment of diseases including hematological malignancies, certain forms of anemia, and immunological deficiencies, when immune cells in the donated cell population attack recipient organs, such as skin, gastrointestinal tract and liver, because the recipient cells are seen as foreign.

Mesoblast said that of the 75 children, 88 percent had severe grade C or D disease with inadequate responses to standard of care treatment.

The company said that at day 28, 61 percent responded to Prochymal with improvement in at least one grade of organ involvement and responses were seen across all disease grades and involved organs, with day 28 response a significant predictor of improved survival at day 100.

Prof Itescu said the "for these children, no other effective therapy exists" and given the "very encouraging results" the company would analyze the data set and engage with regulatory authorities "as early as possible to discuss product approval options"

Mesoblast was up 15 cents or 2.5 percent to $6.15.

REGENEUS

Regeneus says the US Department of Agriculture's Center for Veterinary Biologics has approved the commercialization of its canine cancer vaccine.

Regeneus is developing its Hiqcell fat-stem cell based product for osteoarthritis, which was originally trialled in dogs (BD: Nov 29, 2011; Oct 8, 2013).

Today, Regeneus said that the canine cancer vaccine used the dog's own tumor proteins as the source of the biological therapy and the company hoped to expand its use to human cancer vaccine.

Regeneus head of veterinary health Dr Duncan Thomson said the approval provided "an accelerated pathway to make our autologous vaccine available to treat dogs with life threatening cancerous tumors in the US".

The company said that cancer accounted for almost half of the deaths of pets over 10 years of age, which was roughly the same rate as humans.

Regeneus said it plan a US marketing study to generate data to support the commercialization of the cancer vaccine, expected to begin "in early 2014".

The company said that the vaccine involved removal of a tumor or biopsy from the dog in order to produce a personalized vaccine to stimulates the dog's immune system to see the cancer cells as foreign and prevent further tumor growth as well as development of new tumors.

Regeneus said the technology was developed at Sydney's Royal North Shore Hospital by the Kolling Institute of Medical Research's Prof Ross Davey and Dr Chris Weir.

Regeneus said it had an exclusive worldwide licence for commercialization of the technology for veterinary applications and an option over all human applications.

The company said the vaccine had been through extensive pre-clinical testing which demonstrated it could induce remission or significantly slow tumor growth in an aggressive glioma animal model.

Regeneus said Dr Weir had prepared personalized vaccines to treat 40 dogs with a range of life threatening tumors including melanoma, bone cancer and liver cancer.

Dr Weir said the study demonstrated that there were no adverse side effects from the vaccine and more than 80 percent of dogs treated had increased survival times as compared to published survival data for these types of cancer.

Regeneus chief executive officer Prof Graham Vesey said the "success of the vaccine to date in a variety of hard to treat cancers in dogs bodes well for a clinical study of the vaccine for human cancer in the near future".

Regeneus was up nine cents or 32.1 percent to 37 cents with 2.6 million shares traded.

RESONANCE HEALTH

Resonance says it has executed a contract with Alliance Medical to provide Ferriscan services in the UK and potentially across their broader European network.

Resonance said that the London-based Alliance was "Europe's largest independent provider of imaging services" with 39 magnetic resonance imaging facilities in the UK.

The company said Alliance had provided imaging services for more than 20 years and had won multi-year contracts with the UK National Health Service and had magnetic resonance imaging facilities in Germany, Ireland, Italy, the Netherlands and Spain.

Resonance said the collaboration with Alliance to provide Ferriscan would be launched at the UK Forum on Haemoglobin Disorders on November 21, 2013, with more than 100 specialists expected to attend.

Previously, the company has said that Ferriscan was used to evaluate iron overload.

Resonance was up 0.2 cents 15.4 percent to 1.5 cents.

NOVOGEN

Novogen says it is collaboration with the Sydney-based Genea Biocells in a pilot program to develop drugs for genetic and non-genetic degenerative diseases.

Novogen said the indications included muscular dystrophy, motor-neurone disease, Huntington's disease, cystic fibrosis and Alzheimer's disease.

The company said that a pilot drug had been shown to be highly cytotoxic against the initial screen of stem cells from a neuromuscular dystrophy disease.

Novogen said that Genea Biocells pioneered the isolation and in-vitro differentiation of stem cells from embryos with genetic disorders and held "the world's largest bank of pluripotent human embryonic stem cells" with more thna 100 lines covering some 30 different diseases.

The company said that the program was based on the discovery that one of the Novogen drug families induced apoptosis, or programmed cell death, in cancer stem cells in a highly potent manner, with the company to date focusing that biological property on the development of anti-cancer drugs.

Novogen chief executive officer Dr Graham Kelly said that the success of the cancer program led Novogen scientists to speculate that the same compounds might be equally effective against abnormally-behaving stem cells associated with common degenerative diseases.

"The more we work with cancer stem cells, the more we have come to suspect that the action of our drugs is not so much the fact that the stem cells are cancerous, but that they are behaving abnormally," Dr Kelly said.

"It was this suspicion that led us to this pilot study looking at their effect on abnormal stem cells responsible for causing degenerative diseases," Dr Kelly said. "This early data completely supports our hypothesis."

"As a result of this discovery, we now are committing the necessary resources to take this program to its next phase, which is to design and screen drugs against a wide range of stem cells associated with diseases such as cystic fibrosis, muscular dystrophy, Fragile X, Huntington's disease and Alzheimer's disease," Dr Kelly said.

Dr Kelly said that destroying the aberrant stem cells was an important first step toward eventually being able to successfully treat these kinds of conditions.

Genea Biocells general manager Dr Uli Schmidt said his company's stem cell technologies were intended to be used "as a resource to screen drugs in the hope of developing therapies for genetic disorders".

"Being able to selectively modulate disease-affected stem and progenitor cells is a highly interesting observation that will help us better understand and potentially design treatments for such disorders," Dr Schmidt said.

Genea Biocells is a subsidiary of Genea, formerly Sydney IVF, a public unlisted company.

Novogen was up 7.5 cents or 34.1 percent to 29.5 cents with 13.2 million shares traded.

REVA MEDICAL

Last night's edition reported that Reva intended to file its Conformité Européenne (CE) mark application by the end of this year, with approval expected by April 2015.

Reva has told Biotech Daily that the application would be filed by the end of 2014, with approval expected by April 2015.

The mistake was made by the former sub-editor and Biotech Daily apologizes unreservedly.

Reva was up five cents or 9.3 percent to 59 cents.

AVEXA

Avexa says it hopes to raise up to $3,305,986 through a share plan at 1.3 cents a share and conduct a small parcels share sale facility.
Avexa said that funds raised through the share plan would go to working capital.
The company said the plan was structured “primarily to encourage our loyal, smaller shareholders to apply to increase their shareholding”.
Shareholders can buy up to $15,000 in shares in parcels of $1,000, $5,000 or $15,000.
Avexa said the record date would be November 13, the plan would open on November 21 and close on December 17, 2013.
The company said the unmarketable parcels facility would be available to holders at November 8, 2013.
In 2010, 24-week data from Avexa’s phase III of apricitabine HIV trial showed a non-significant positive clinical benefit for the drug (BD: Feb 4, 5 and 15, 2010).
At that time, Avexa had about $23 million in cash (BD: Sep 2, 2010).
Avexa continued to attempt to licence apricitabine, but in 2012 said it would invest $10 million for a share of a coal mine in Alabama with hoped-for profits to fund its drug development programs (BD: Nov 5, 2012).
In December 2012, Avexa’s Alabama coal mine proposal was passed with 206,642,405 votes (53.47%) in favor and 179,828,346 votes (46.53%) against with the no votes amounting to 21.2 percent of the company (BD: Dec 14, 2012).
In its Appendix 4C quarterly report to September 30, 2013, Avexa said it held cash reserves of $10.1 million investments of $580,000 and had invested $US1.3 million in Coal Holdings USA.
Avexa was unchanged at 1.4 cents with 1.6 million shares traded.

ECO QUEST

Eco Quest, to be renamed Cynata Therapeutics, says its one-for-20 consolidation has been completed.
Eco Quest said that following the consolidation it had 32,406,701 shares, 11,164,701 listed 2014 options exercisable at 20 cents, 25,000 unlisted 2013 options exercisable at $3.98, 500,000 unlisted 2016 options exercisable at 40 cents and 5,000,000 unlisted 2018 options exercisable at 40 cents.
Eco Quest was in a suspension at a consolidated 50 cents.

UNIVERSAL BIOSENSORS

The Brisbane-based Talu Ventures says it has acquired CM Capital’s 17,794,384 Universal Biosensors Chess depositary interests or 10.2 percent of the company.
Talu said it had taken over as the manager and trustee from CM Capital of CM Capital Venture Trust No 3 and CM Capital 3A.
Universal Biosensors was up 1.5 cents or 2.9 percent to 54 cents.

PHYLOGICA

Perth cardiologist Dr Bernard and Dianne Hockings have increased their substantial shareholding in Phylogica from 26,999,999 (5.78%) to 116,140,000 shares (19.99%).
The substantial shareholder notice said that BEF and DC Hockings increasd through the conversion of notes into 89,140,001 shares at a conversion price of 1.14 cents a share.
Phylogica was up 0.2 cents or 11.8 percent to 1.9 cents.

IMMURON

Capital Concerns Pty Ltd as the Logue Family Super Fund has again ceased its substantial in Immuron with the sale of 5,250,000 shares.
In May, Capital Concerns and the Logue family resumed their substantial shareholding in Immuron with 54,627,723 shares or 5.38 percent, acquiring 30,000,000 shares for $90,000 or 0.3 cents a share (BD: May 8, 2013).
Today, Capital Concerns and the Logue family said they sold 5,250,000 shares for $72,986 or an average price of 1.37 cents a share.
Immuron was unchanged at 1.2 cents with 22.1 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says that director Tommaso Bonvino will stand down effective from the annual general meeting on November 29, 2013.
Genetic Technologies said that Mr Bonvino was going to seek re-election at the meeting but withdrew “for personal reasons”.
Genetic Technologies said it acknowledged the contribution made by Mr Bonvino during his years as a director.
Genetic Technologies was up 0.2 cents or 3.2 percent to 6.3 cents.