Biotech Daily

Thursday November 26, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: GENETIC TECH UP 23%; TISSUE THERA DOWN 12.5%**

*** JAPAN TO PAY UP TO $234k PER MESOBLAST TEMCELL GVHD COURSE**

*** AVEXA AGM VOTES TO ACQUIRE TALI HEALTH**

*** PHARMAUST HIRES GENSCRIPT FOR PRE-PHASE II PPL-1 OPTIMIZATION**

*** REGENEUS 45-DOG KVAX VACCINE TRIAL FOR CANINE LYMPHOMA**

*** PROGEN RECEIVES $1m FEDERAL R&D TAX REFUND**

*** PRIMA RECEIVES $420k FEDERAL R&D TAX REFUND**

*** SUN AGM CHANGES NAME TO DIMERIX**

*** ONCOSIL WITHDRAWS 10% PLACEMENT RESOLUTION, OTHERS PASSED**

*** NOVOSKIN, NOVOWOUND ACQUISITIONS DELAY POLYNOVO AGM**

*** CELL CARE REDUCES TO 20% OF CRYOSITE**

*** GREENLIGHT REDUCES TO 5.6% OF GI DYNAMICS**

*** PRESCIENT APPOINTS PROF FARHAD RAVANDI LEUKAEMIA ADVISOR**

MARKET REPORT

The Australian stock market was up 0.33 percent on Thursday November 26, 2015 with the ASX200 up 17.0 points to 5,210.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell, and six traded unchanged. All three Big Caps were up.

Genetic Technologies was the best, up 0.6 cents or 23.1 percent to 3.2 cents with 19.85 million shares traded. Orthocell and Polynovo climbed more than six percent; Compumedics was up five percent; Actinogen improved four percent; Cellmid, Clinuvel, Mesoblast and Psivida were up more than three percent; Oncosil was up 2.9 percent; Avita, CSL, Medical Developments and Sirtex were up more than one percent; with Admedus, Cochlear and Resmed up by less than one percent.

Tissue Therapies led the falls, down 0.6 cents or 12.5 percent to 4.2 cents with 10,655 shares traded. Prima lost 7.1 percent; Antisense, Circadian and IDT were down more than six percent; Anteo and Uscom fell five percent or more; Acrux and Biotron lost four percent or more; Ellex and Living Cell were down more than three percent; Benitec, Optiscan and Viralytics shed more than two percent; Nanosonics, Pro Medicus, Starpharma and Universal Biosensors were down more than one percent; with Neuren and Impedimed down by less than one percent.

MESOBLAST

Mesoblast says that Japan will reimburse up to $234,000 per course of Temcell mesenchymal stem cells, acquired from Osiris, for acute graft versus host disease.
Mesoblast said the Japan National Health Insurance told licencee JCR Pharmaceuticals that the approved and reimbursed dosing regimen in Japan for Temcell was for all patients, eight doses of 2,000,000 cells/kilogram, delivered as an intravenous infusion.
Mesoblast said that for patients with persistent symptoms beyond four weeks, a further weekly dose of 2,000,000 cells/kilogram could be given for four additional weeks.
The company said that reimbursement was authorized at YEN868,680 ($A9,767) per bag of 72,000,000 cells and the average adult patient in Japan was expected to receive 16 or up to 24 bags of 72,000,000 cells.
Mesoblast said that it expected a Temcell treatment course in an adult Japanese patient to be reimbursed at YEN13,898,880 ($A156,000) or up to YEN20,848,320 ($A234,000).
Mesoblast said that the launch of Temcell for acute graft versus host disease after an allogeneic bone marrow transplant was expected in February 2016.
The company said that it was entitled to royalties and other payments at predefined thresholds of cumulative net sales.
Mesoblast said it was “well-positioned to have the first industrially manufactured allogeneic cell-based product approved in the [US], with its product candidate for the treatment of steroid refractory [acute graft versus host disease] in children”.
The company said that it expected to complete recruitment of its open label, 60-patient phase III trial in children with steroid-refractory acute graft versus host disease by the end of 2016 and to announce top-line interim results of the trial by October 2016.
Mesoblast said that the interim analysis might support a biologics licence application regulatory filing by the end of 2016.
The company said that in the US, pricing reimbursement methodology was expected to consider the burden of illness associated with steroid-refractory acute graft versus host disease as well as health utilization costs and might result in a higher price than in Japan.
Mesoblast said that the life-threatening illness was designated as an orphan indication.
The company said that there were about 30,000 allogeneic bone marrow transplants each year and in the US there were expected to be 8,900 allogeneic bone marrow transplants in 2015, of which 25 percent were in children, with 50 percent expected to develop acute graft versus host disease.
Mesoblast said that liver or gastrointestinal involvement occurred in up to 40 percent of all patients with acute graft versus host disease and were associated with the greatest risk of death, with mortality rates of up to 85 percent.
The company said that there were no currently approved treatments for steroid-refractory acute graft versus host disease in the US.
Mesoblast recovered 5.5 cents or 3.7 percent to $1.55 with 4.3 million shares traded.

AVEXA

Avexa has passed all its annual general meeting resolutions including those relating to the acquisition of the Monash University-based Tali Health diagnostics company.
Avexa said that all resolutions were approved with more than 217.9 million votes in favor and up to 28.3 million votes against.
In October, Avexa said it would acquire Tali in exchange for scrip for its technology for diagnosing and treating developmental disabilities, including autism, conditional on completing a $4 million placement, Tali shareholder approval and said it would ask shareholders to approve a 20-to-one consolidation (BD: Oct 12, 2015).
Avexa was up 0.1 cents or 20 percent to 0.6 cents.

PHARMAUST

Pharmaust says it has appointed the New Jersey-based Genscript to investigate the use of PPL-1, or monepantel, with the current standard-of-care for a phase II trial.
Pharmaust chairman Dr Roger Aston told Biotech Daily that the company had decided to reveal that its lead drug PPL-1 was monepantel, marketed by Novartis as Zolvix as a treatment for roundworm infestation in sheep.
Pharmaust said that it had demonstrated that combinations of chemotherapy and monepantel "result in synergy with respect to anticancer activity" and it would investigate and validate combinations in different cancers in Genscript's in-vitro and in-vivo pharmacology capability to optimize its treatment regiments for a phase II trial.
The company said the work with Genscript would be a prelude to initiating a phase II trial.
Pharmaust said that Genscript had developed a range of validated tumor models based on xenograft models and established a tumor tissue bank with various patient-derived human primary tumor models.
Pharmaust was unchanged at nine cents.

REGENEUS

Regeneus says it has begun a 45-dog trial of its Kvax cancer vaccine technology in combination with chemotherapy as a treatment for canine lymphoma.
Regeneus said that the trial would be conducted at Sydney's Small Animal Specialist Hospital and seek to extend remission times for dogs diagnosed for B-cell lymphoma and treated with chemotherapy.
The company said that once the dogs were in remission they would be treated with Kvax.
Regeneus said that reviewers would measure lymph nodes, time of remission and survival time.
The company said that remission lasted an average eight to 10 months with chemotherapy, with a median survival time of about one year.
Regeneus said that the Kvax process removed a small amount of tumor or biopsy as source material to produce a personalised cancer vaccine to stimulate the dog's immune system to see the cancer cells as foreign and prevent growth of the tumor as well as development of new tumors.
The company said that lymphoma was responsible for seven to 14 percent of all canine cancers with an estimated annual incidence rate of about 90 per 100,000 dogs and was compared to and used as a model for non-Hodgkins lymphoma in humans.
Regeneus said that a Kvax trial for osteosarcoma, or bone cancer, was being conducted in the US which was fully recruited and ongoing.
The company said that to date there had been no safety concerns with Kvax and phase I trials of the human equivalent technology RGSH4K were progressing.
Regeneus was unchanged at 10 cents.

PROGEN PHARMACEUTICALS

Progen says it has received $1,112,472 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Progen said the rebate related to research and development expenditure for the year to June 30, 2015
Progen was unchanged at 22 cents.

PRIMA BIOMED

Prima says it has received $419,482, from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Prima said the rebate related to research and development expenditure for the year to June 30, 2015.
Prima fell 0.4 cents or 7.1 percent to 5.2 cents with 2.6 million shares traded.

SUN BIOMEDICAL, DIMERIX BIOSCIENCES

The Sun annual general meeting has overwhelmingly voted to change the company's name to Dimerix Limited and its ASX code to DXB.
Sun was up 0.1 cents or 20 percent to 0.6 cents with 1.5 million shares traded.

ONCOSIL MEDICAL

Oncosil says it withdrew a resolution to increase its placement capacity, with all other resolutions passed overwhelmingly.
Oncosil chief financial officer Tom Milicevic told Biotech Daily that the board felt there was no need to increase the placement capacity by a further 10 percent above the existing 15 percent capacity.
The company said that the remuneration report, change of auditor, the increase in executive directors remuneration pool and the re-election of chairman Dr Roger Aston were passed with more than 58.9 million votes in favour and up to 762,588 votes opposed.
Dr Aston's re-election was passed with no opposition.
Oncosil was up 0.5 cents or 2.9 percent to 17.5 cents with 1.5 million shares traded.

POLYNOVO

Polynovo says that the Australian Securities and Investments Commission has approved the postponement of its annual general meeting to December 17, 2015.
Polynovo said that the meeting was originally planned for November 30 the deferral was "necessary to enable shareholders to vote on the increased share placement capacity resolution fully informed".
The company said that the increase was required to enable shares to be issued as part consideration for the purchase of the 20 percent minority interests in Novoskin and Novowound, pending due diligence and shareholder approval (BD: Nov 25, 2015).
Polynovo was up one cent or 6.25 percent to 17 cents.

CRYOSITE

Cell Care Australia and related parties have reduced their substantial shareholding in Cryosite from 10,709,334 shares (22.96%) to 9,229,995 shares (19.79%).
Cryosite and Cell Care are both involved at cord blood storage.
The Moorabbin, Victoria-based Cell Care said that the shares were also held by the Middle Park, Victoria-based James Craig, Bellwether Finance and Bellwether International, and the Balwyn Victoria-based Alastair Lucas, Matsarol Pty Ltd and Odsam Pty Ltd.
Cell Care said that the 1,479,339 shares were sold between November 18, 2013 and November 25, 2015 for prices ranging from 58 cents to 27.5 cents.
Cryosite fell half a cent or 1.8 percent to 27.5 cents.

GI DYNAMICS

Greenlight Capital says it has reduced its GI Dynamics holding from 28,301,887 Chess depository instruments (CDIs) (5.98%) to 26,613,065 shares (5.6%).
The New York-based Greenlight said that on November 24, 2015, it sold 1,688,822 CDIs at 2.7 cents each.
GI Dynamics was up 0.2 cents or 7.4 percent to 2.9 cents with 4.9 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says it has appointed leukaemia expert Prof Farhad Ravandi to its scientific advisory board.
Prescient said that Prof Ravandi was head of leukaemia developmental therapeutics at the Houston-based University of Texas MD Anderson and Moffitt Cancer Center.
The company said that the appointment was “significant” ahead of its phase Ib/II trial of PTX-200 for acute myeloid leukaemia, planned for the MD Anderson and Moffitt Cancer in early 2016 (BD: Nov 24, 25, 2015).
Prescient said that Prof Ravandi was involved in clinical and translational research for the treatment of patients with various haematological malignancies, with a particular focus on leukaemias and had published extensively on clinical research results.
The company said that Prof Ravandi was an investigator on its 32-patient phase I acute myeloid leukaemia trial at the MD Anderson and Moffitt Cancer Centre, which showed that 17 of 32 patients with advanced malignancies had stable disease after one cycle of treatment and three patients had more than 50 percent bone marrow blast reduction .
Prescient was up half a cent or 8.3 percent to 6.5 cents.