Biotech Daily

Wednesday October 19, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: DIMERIX UP 10%; ADMEDUS DOWN 7%**

*** ADMEDUS HSV-2 VACCINE SAFE, CUTS VIRAL SHEDDING, NOT SORES**

*** WEHI IMAGING SHOWS LEUKAEMIA CELLS AVOIDING CHEMO**

*** MEDADVISOR RAISES $8m**

*** FDA EXPANDS AVITA RECELL COMPASSIONATE WOUND TREATMENT**

*** PROF RICHARD SHINE WINS 2016 PRIME MINISTERS SCIENCE PRIZE**

*** IMUGENE REQUESTS CAPITAL RAISING TRADING HALT**

*** PRESCIENT PLEADS SCHULTZ TO ASX 30% QUERY**

*** OPTISCAN PLEADS SCHULTZ TO ASX 27% QUERY**

*** PARADICE INVESTMENTS TAKES 5% OF IMPEDIMED**

*** REGENEUS JUST AVOIDS REMUNERATION 1st STRIKE**

*** PHYLOGICA AGM FOR 30m DIRECTOR OPTIONS**

*** BIO-MELBOURNE BREAKFAST KICKS OFF INNOVATION WEEK**

MARKET REPORT

The Australian stock market climbed 0.45 percent on Wednesday October 19, 2016 with the ASX200 up 24.6 points to 5,435.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and all three Big Caps were up.

Dimerix was the best, up 0.1 cents or 10 percent to 1.1 cents with 4.8 million shares traded. Orthocell climbed 8.5 percent; Avita, Impedimed and Polynovo rose more than four percent; Actinogen, Airxpanders and Reva were up more than two percent; Acrux, Nanosonics, Prana and Psivida improved one percent or more; with Cochlear, CSL, Opthea and Resmed up by less than one percent.

Admedus led the falls for the second day, down three cents or 6.9 percent to 40.5 cents with 8.0 million shares traded. Cellmid lost 5.7 percent; Factor and Viralytics fell more than four percent; Pro Medicus and Uscom shed more than three percent; Cyclopharm and IDT shed more than two percent; Anteo, Atcor, Bionomics, Ellex, Osprey, Pharmaxis and Universal Biosensors were down more than one percent; with Clinuvel, Compumedics, Genetic Signatures, Medical Developments and Sirtex down by less than one percent.

ADMEDUS

Admedus says an interim analysis of 20 patients in its herpes simplex virus-2 phase IIa vaccine trial shows safety, reduced viral shedding but no benefit for new lesions.

Admedus said that 15 patients received the vaccine and five received a placebo, with a lower virus shedding rate for the active group observed post-vaccination when compared with baseline screening and a 58 percent reduction in viral shedding rate for the active group in post-booster when compared with baseline.

Admedus chief operating officer Dr Julian Chick told Biotech Daily that there was no significant viral shedding rate reduction in post vaccination and post booster periods observed in the placebo group.

Dr Chick said that viral shedding was measured by repeated blood tests, but lesion outbreaks or new herpes simplex virus-2 (HSV-2) sores were subjectively reported by the patients.

Dr Chick said that the interim results for viral shedding were superior to competitor products in trials reported by large pharmaceutical companies.

In its media release, Admedus said that lesion outbreaks were compared between baseline, post-vaccination and post-booster with the overall frequency in the vaccine group reduced by 52 percent post-vaccination compared and by 81 percent post-booster compared to baseline.

“However, a similar trend was also observed in the placebo group,” Admedus said.

Admedus said that throughout the treatment the vaccine-treated patients saw a steady decline in viral shedding compared with no change in the patients on placebo.

The company said that an immune response measured by the anti-gD2 antibody and the T-cell responses increased in the vaccine recipients, especially post booster.

Admedus said that the technology was focused on activation of T-cells and the responses post-vaccination were encouraging and not observed in the placebo group.

The company said that there were no safety issues for the first 20 patients or for any of the 44 patients that entered the study to date and all patients had completed vaccinations with full results were expected by July 2017.

Admedus interim executive chair Wayne Paterson said the data from the first 20 patients was “very encouraging when compared to results seen from other similar vaccines in the clinic and continues to support further development of the product”.

“It also provides us with clinical proof-of-concept data around the core technology which has been developed by Prof Ian Frazer,” Mr Paterson said.

The company said that the independent expert review of this data recommendation “relative to results seen in other HSV-2 vaccine studies currently in the clinic, is to continue to progress the development of the vaccine”.

Admedus said that the double-blind, placebo-controlled trial randomized 44 patients, of whom eight patients subsequently withdrew with none relating to issues from the vaccine, to receive the COR-1 HSV-2 vaccine or placebo in a three-to-one ratio.

The company said that patients were divided into two treatment groups one receiving a double inoculation split across both arms and the second receiving the double inoculation into one arm, following baseline assessments each patient received three doses of vaccine or placebo, with two vaccinations per dose, four weeks apart and a booster at six months following the first vaccination, with a final follow-up and assessment conducted after an additional six months.

The company said that the data reviewed and announced today related to the first 20 patients and that individual patient data would be received in 2017.

Admedus fell three cents or 6.9 percent to 40.5 cents with eight million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says visualizing leukaemia in mice shows that the migration of cancer cells should be targeted, rather than specific bone marrow tissue, WEHI said its researchers working with London's Imperial College investigated how the blood cancer leukaemia survived chemotherapy leading to high rates of relapse after initial chemotherapy and resistance to subsequent treatments.

The research, entitled 'T-cell acute leukaemia exhibits dynamic interactions with bone marrow microenvironments' was published in Nature and an abstract is available at: http://www.nature.com/nature/journal/vaop/ncurrent/full/nature19801.html.

The abstract said that the researchers used a mouse model of human T-cell acute lymphoblastic leukaemia (T-ALL) and intra-vital microscopy to monitor the progression of disease within the bone marrow at both the tissue-wide and single-cell level over time, from bone marrow seeding to development/selection of chemo-resistance.

"We observed highly dynamic cellular interactions and promiscuous distribution of leukaemia cells that migrated across the bone marrow, without showing any preferential association with bone marrow sub-compartments," the researchers said.

"Unexpectedly, this behaviour was maintained throughout disease development, from the earliest bone marrow seeding to response and resistance to chemotherapy," the abstract said. "Our results reveal that T-ALL cells do not depend on specific bone marrow microenvironments for propagation of disease, nor for the selection of chemo-resistant clones, suggesting that a stochastic mechanism underlies these processes."

"Although T-ALL infiltration and progression are independent of the stroma, accumulated disease burden leads to rapid, selective remodelling of the endosteal space, resulting in a complete loss of mature osteoblastic cells while perivascular cells are maintained," the researchers said.

"This outcome leads to a shift in the balance of endogenous bone marrow stroma, towards a composition associated with less efficient haematopoietic stem cell function," they said

"This novel, dynamic analysis of T-ALL interactions with the bone marrow microenvironment in vivo, supported by evidence from human T-ALL samples, highlights that future therapeutic interventions should target the migration and promiscuous interactions of cancer cells with the surrounding microenvironment, rather than specific bone marrow stroma, to combat the invasion by and survival of chemo-resistant T-ALL cells," the abstract concluded.

WEHI said that the research "overturned popular theory that acute lymphoblastic leukaemia cells resist cancer treatment by hibernating in bone marrow".

Dr Hawkins said that the findings showed that while chemotherapy was able to eliminate the majority of cancerous cells, the remaining treatment-resistant cells were not 'hiding' to survive but were "playing hide-and-seek with the chemotherapy … sprinting off in all directions, dividing, jumping in and out of blood vessels and using such highways in the body to migrate and recolonize".

Dr Hawkins said previous techniques involved analysis of static images but "our new technique allows us to watch action unfolding for days, with the ability to zoom in and out on the same patch of tissue from 3.5mm by 2.5mm, right down to a single micron".

Imperial College's Dr Cristina Lo Celso said "we now know that it is ineffective to design treatments to target the surrounding stromal cells or hiding places, because the cancer cells are not hiding".

"To beat leukaemia, we must instead develop a treatment that targets the ability of the cells themselves to run around the body … [and] stop these cells in their tracks," Dr Lo Celso said.

MEDADVISOR

Medadvisor says it has raised $8 million in a “significantly over subscribed” placement at four cents a share.

Medadvisor said that in conjunction with the placement, 57,894,737 shares would be issued to Healthnotes as part of the $5.5 million acquisition of which 60 percent would be paid in cash and 40 percent in scrip.

The company said that “strong interest was received from existing and new investors, with a number of new and leading Australian institutions joining the shareholder register”.

“Key pharmacy groups also participated in the placement, providing industry recognition and positive validation,” Medadvisor said.

The company said that the placement was led by joint managers Peloton Capital and Veritas Securities.

Medadvisor said that $4 million would be used for the acquisition of Healthnotes and $4 million would be for growth initiatives.

Medadvisor was up 0.1 cents or 2.3 percent to 4.5 cents with 1.15 million shares traded.

AVITA MEDICAL

Avita says the US Food and Drug Administration has approved an increase in the number of patients who can be treated with its Recell spray-on skin device.

Avita said the FDA had given a third expansion of its compassionate use investigational device exemption program for Recell, allowing the company to treat up to 48 patients who have insufficient healthy skin available for standard skin grafting of their injury.

The company said that the FDA had increased to 15 the number of hospitals that could deploy the protocol and several hospitals had been introduced to its autologous skin cell harvesting approach through its current trial.

Avita chief executive officer Adam Kelliher said the company welcomed the compassionate use expansion, which allowed surgeons “to further deploy our devices in the US for patients who suffer extensive injuries and are in a life-threatening condition”.

Avita said that under the compassionate use protocol, Recell use could be granted when the patient’s treating physician believed there was no suitable alternative treatment.

The company said that the FDA first approved the initial investigational device exemption for up to 12 subjects in life-threatening circumstances in April 2014 and in October 2015, the FDA doubled the number of patients permitted to 24 patients and in July this year, the number was again increased to 36 patients, with 34 compassionate use cases using Recell conducted to date.

Avita head of clinical development Andrew Quick said the company was “grateful to the FDA for the opportunity to serve this highly vulnerable population”.

“It also provides further opportunities to collaborate with leading US surgeons to develop our understanding around what we anticipate will become best practice for treatment of skin injuries and defects in patients who have insufficient donor skin for conventional treatment,” Mr Quick said.

The company said that the expansion of the investigational device exemption followed the FDA’s separate October 5, 2016 approval of continued access, which allowed surgeons participating in the trial to access the Recell device for up to 60 patients.

Avita said it was seeking FDA pre-market approval for Recell and the fully-enrolled clinical trial at seven US burns centres was “on track … to submit its clinical data package in early 2017, with an anticipated market approval later in the year”.

Avita was up half a cent or 4.35 percent to 12 cents with 1.1 million shares traded.

FEDERAL GOVERNMENT

The Prime Minister Malcolm Turnbull has awarded the $250,000 Prime Minister's prize for science to the University of Sydney's Prof Richard Shine.
A media release from the Prime Minister's office said that Prof Shine won the award for his work in protecting snakes and lizards from cane toads.
"Professor Shine has created traps for cane toads, taught quolls and goannas to avoid toads, and now plans to release small cane toads ahead of their potential arrival in new areas so predators survive their first meal of cane toad but have an aversion to eating them again," Mr Turnbull said.
The media release said that the $250,000 Prime Minister's prize for innovation was awarded to the Capital Markets Co-operative Research Centre and Macquarie University's Prof Michael Aitken for making stock markets fair and efficient.
The Prime Minister's Office said that the $50,000 Frank Fenner prize for life scientist of the year was awarded to University of Queensland and ARC Centre of Excellence for Environmental Decisions' Prof Kerrie Wilson for conservation that works for government, ecosystems and people.
The inaugural $50,000 prize for new innovators went to the University of South Australia's Dr Colin Hall for creating new manufacturing jobs by replacing glass and metal with plastic and the $50,000 Malcolm McIntosh prize for physical scientist was awarded to the University of Sydney's Prof Richard Payne for re-engineering nature to fight for global health.
The media release said that Suzy Urbaniak would share the $50,000 Prime Minister's prize for excellence in science teaching in secondary schools with Perth's Kent Street Senior High School.
The Prime Minister's Office said that Gary Tilley would share the $50,000 Prime Minister's prize for excellence in science teaching in primary schools with his school Sydney's Seaforth Public School.

IMUGENE

Imugene has requested a trading halt "pending an announcement in relation to a proposed capital raising".
Trading will resume on October 21, 2016 or on an earlier announcement.
Imugene last traded at 0.8 cents.

PRESCIENT

Prescient has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 30.4 percent from 11.5 cents to 15.0 cents on October 18, 2016 and noted a significant increase in trading volume.
Prescient fell one cent or 7.7 percent to 12 cents.

OPTISCAN

Optiscan has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 26.8 percent from 4.1 cents to 5.2 cents on October 18, 2016 and noted a significant increase in trading volume.
Optiscan was unchanged at five cents.

IMPEDIMED

Paradice Investment Management has become a substantial shareholder in Impedimed with the acquisition of 18,853,802 shares or 5.038 percent.
The initial substantial shareholder notice said that the Sydney-based Paradice bought and sold shares between August 5 and October 13, 2016 with the single largest acquisition 5,049,203 shares for $6,734,759 or $1.33 a share.
The notice said that the shares were held by National Nominees, JP Morgan Nominees, HSBC Nominees and Citicorp Nominees.
Impedimed was up 6.5 cents or 4.1 percent to $1.65 with 904,731 shares traded.

REGENEUS

Regeneus shareholders cast 7,308,671 votes (24.2%) against the company's remuneration report with 22,909,276 votes (75.8%) in favor.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.
The annual general meeting results notice said that more than 7,517,431 votes (24.9%) were cast against the share option plan with 22,687,824 votes (75.1%) in favor, while the re-election of director Dr Roger Aston was also opposed by 7.2 million votes, but was supported by 46.6 million votes.
Regeneus said that the approval of the placement capacity was passed easily.
The company's most recent Appendix 3B new issue announcement said that Regeneus had 208,885,143 shares on issue, meaning that the votes against the share option plan amounted to 3.6 percent of the company, not sufficient to requisition extraordinary general meetings.
Regeneus fell half a cent or 3.6 percent to 13.5 cents.

PHYLOGICA

Phylogica will vote to grant chair Stephanie Unwin 10,000,000 options and chief scientific adviser and director Prof Paul Watt 20,000,000 options.
Phylogica said that Ms Unwin's options would vest in three equal tranches on issue, on November 30, 2017 and November 30, 2018 and have a nil exercise price expiring on November 30, 2019.
Phylogica said that Prof Watt's options would vest in two equal tranches when the company's 5-day volume-weighted average price reached three cents a share and when the 5-day volume-weighted average price reached five cents a share, and would have a nil exercise price and expire on November 30, 2018.
The company's notice of meeting said that shareholders would also vote on the remuneration report, approval of the 10 percent placement capacity and the re-election of directors Ms Unwin and Dr Bernard Hockings.
The meeting will be held at the Seminar Room, Telethon Kids Institute, 100 Roberts Road, Subiaco, Western Australia on November 25, 2016 at 2pm (AWST).
Phylogica fell 0.1 cents or 5.9 percent to 1.6 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it is supporting Innovation Week from November 7 until November 11, 2016.

The Network said that Innovation Week was “an Australia-wide annual celebration of innovation in science, technology, engineering, mathematics and medicine in Australia led by the Australian Science and Innovation Forum in partnership with the Australian Academy of Technological Sciences and Engineering”.

The Bio-Melbourne Network said the Royal Society of Victoria would host a Bio-Breakfast entitled ‘Genomics and personalised medicine: Have we arrived at our destination?’

The Network said that the Bio-Breakfast would be the launch event of Innovation Week, which would include a video message from the Minister for Industry, Innovation and Science Greg Hunt.

Bio-Melbourne chief executive officer Dr Krystal Evans said that “the personalization of healthcare is one of the biggest global drivers of innovation in medical technology and pharmaceuticals today and advances in genomics have created opportunities to deliver patient specific information to tailor treatments to the individual in a way never before possible.”

The Network said that Murdoch Children’s Research Institute director Prof Kathryn North and CNSDose chief executive officer Prof Ajeet Singh would be speakers at the Bio-Breakfast.

The Bio-Breakfast will be held at the Royal Society of Victoria, 8 LaTrobe Street, Melbourne on November 7, 2016 with a breakfast from 7.30am until 8am and presentations until 9am.

The Network said that all proceeds would go to funding Innovation Week.

For bookings go to: http://bit.do/innovationweek.