Biotech Daily

Monday October 15, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: REVA, USCOM UP 14%; AVITA DOWN 9%**

*** TELIX: STUDY BACKS CANCER IMAGING TRIAL; ANMI, CYCLOTEK DEALS**

*** OPTISCAN STARTS BREAST CANCER MARGIN TRIAL**

*** ADALTA AD-214 'MAJOR MANUFACTURING MILESTONE'**

*** ESENSE-LAB RAISES $3.15m**

*** MEDIBIO RECEIVES $3m FEDERAL R&D TAX INCENTIVE**

*** BIOTRON RECEIVES $1m FEDERAL R&D TAX INCENTIVE**

*** PHARMAUST MONEPANTEL 'PALATABLE TO BEAGLES', ACTIVITY**

*** KAZIA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** W WHITNEY GEORGE TAKES 22% OF RHINOMED**

*** TIGA TAKES 12% OF SIMAVITA**

*** LIVING CELL AGM FOR 3.4m CEO, DIRECTOR OPTIONS**

MARKET REPORT

The Australian Stock Market lost 0.99 percent on Monday October 15, 2018 with the ASX200 down 58.6 points to 5,837.1 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, four traded unchanged and four were untraded.

Reva and Uscom were the best, both up 14.3 percent to 24 cents and 16 cents, respectively, with 16,478 shares and 93,594 shares traded, respectively. Genetic Signatures climbed 6.9 percent; Clinuvel improved 5.8 percent; Opthea was up 4.2 percent; Compumedics, Cynata and Telix were up more than three percent; Airxpanders and Universal Biosensors rose more than two percent; Ellex and Prescient were up more than one percent; with CSL, Cyclopharm and Resmed up by less than one percent.

Avita led the falls, down one cent or 8.7 percent to 10.5 cents, with 3.7 million shares traded. Factor lost 8.2 percent; Actinogen, Dimerix and Osprey were down more than six percent; Bionomics and Medical Developments retreated more than five percent; Impedimed and Imugene fell more than four percent; Neuren, Pharmaxis and Polynovo were down more than three percent; Oncosil, Starpharma and Volpara shed more than two percent; with Mesoblast, Paradigm and Pro Medicus down one percent or more.

TELIX PHARMACEUTICALS

Telix says a bridging study supports its phase III kidney cancer imaging trial and it has extended contracts with Advanced Nuclear Medicine Ingredients and Cyclotek.

Telix said that an interim analysis of the Zir-Dose dosimetry bridging study, as part of phase III readiness for 89-zirconium-desferrioxamine-girentuximab (89-Zr-DFO-girentuximab or 89Zr-TLX250-CDx) imaging in metastatic renal, or kidney, cancer showed that the dosing and dosimetry were appropriate, with improved image quality compared with iodinated girentuximab.

The company said that the 10 patient pharmaco-kinetic, multi-time point imaging study was designed to compare the whole-body dosimetry of TLX250-CDx with historical dosimetry data for 124-iodine-girentuximab (124I-girentuximab).

Telix said it changed the isotope from 124-iodine to 89-zirconium “to lower patient dose, enhance image contrast, lower cost of goods and improve clinical workflow by eliminating the need for thyroid blocking”.

The company said that the Zir-Dose study achieved “both a mass dose comparison between 5mg and 10mg injected dose, as well as full body dosimetry”.

Telix said that the Dresden, Germany-based ABX CRO conducted an interim study on the first five patients, covering both 5mg and 10mg doses, with the 10mg dose confirmed as superior with a 50 percent reduction of liver dose and 25 percent less intestinal dose, compared with 5mg.

The company said that the absorbed dose from 37 megabecquerel (MBq), or 1.0 millicurie (1.0mCi) of 89Zr-girentuximab was 18 millisievert/millicurie (Sv/mCi), about 25 percent less than that of 124I-girentuximab (24mSv/mCi), “validating that the change of isotope results in a meaningfully lower patient radiation dose”.

Telix said that the dosimetry observed for TLX250-CDx was “well within legislated radiation safety limits in any regulatory jurisdiction”.

Telix chief executive officer Dr Christian Behrenbruch said the interim data “enables us to proceed with first patients in our global multi-centre phase III trial for TLX250-CDx with the confidence that we have the dosing and dosimetry right, with much improved image quality compared with iodinated girentuximab”.

“Although this is a small study in terms of number of subjects, radiation dosimetry studies are especially demanding on patients and we are grateful to those who have volunteered to participate in the clinical trial, as well as our excellent clinical collaborators at Radboud University Medical Centre in the Netherlands,” Dr Behrenbruch said.

In separate announcements, Telix said it had expanded its partnership with the Liege, Belgium-based Advanced Nuclear Medicine Ingredients SA (ANMI) for the 68 Gallium-labeled prostate-specific membrane antigen 11 (68Ga-PSMA) cold kit for detecting prostate cancer and with Cyclotek (Aust) Pty Ltd to include 89Zr-girentuximab (TLX250-CDx) for imaging patients with clear cell renal cell cancer using positron emission tomography.

The company said that the 68Ga-PSMA kit was developed by ANMI and commercialized by Telix for the US where it was marketed as Illumet.

Telix said that “in response to considerable clinical interest” it had begun scale-up manufacturing in the US, following the recent filing of a drug master file and the launch of several major clinical trials using the product (BD: Jul 25, Aug 13, 2018).

The company said that large-scale Illumet manufacturing was “a significant milestone” for a new drug application for 68Ga-PSMA in the US.

Telix said it had extended its master service agreement with Cyclotek to support trials and pave the way for the provision of TLX250-CDx to the regional market.

Telix was up 2.5 cents or 3.5 percent to 74 cents.

OPTISCAN IMAGING

Optiscan says it has approval for a trial of its confocal microscope technology to assess the surgical margin in patients undergoing breast cancer conservation surgery.

The company did not specify the number of patients in the trial or expected timelines.

Optiscan said the lumpectomy trial would be conducted at the Perth, Western Australia-based Hollywood Private Hospital, with company director and cardiologist Dr Philip Currie as one of the principal investigators, with Dr Peter Willsher and Dr Jespal Gill.

The company said that the goal of the four-stage clinical trial was “to assist both breast surgeons and pathologists to provide real-time determination of the required surgical margin reducing the risk of residual tumor, the need for repeat surgery and the associated emotional distress suffered by the patients”.

Optiscan said that if the goals were achieved they would have a “significant positive impact for patient welfare as well as substantially reducing the number of repeat operations and reducing associated costs for the patients, hospitals, insurers and the taxpayer”.

The company said that the first stage of the trial would examine ex-vivo excised breast tissue specimens by both confocal laser endomicroscopy and standard histopathology to trial multiple imaging techniques to determine patterns of normal, non-malignant and malignant tissue without impacting the ability to undertake standard histopathology of the same specimens.

Optiscan said breast cancer was the second most frequently diagnosed new cancer and had the second highest mortality rate in women with 252,710 new cases of invasive breast cancer diagnosed in the US in 2017 and 17,730 new cases diagnosed in Australia.

The company said that lumpectomies accounted for about 60 percent of surgeries for early stage breast cancer, with a goal to completely excise the tumor with a rim of healthy breast tissue called a negative margin with acceptable cosmesis, balancing the volume of tissue removed to obtain the negative surgical margins to improve survival, quality of life and body image.

Optiscan said the current determination of sufficient tumor margin was comprehensive histopathological analysis performed a few days after surgery.

If successful, the use of confocal laser endomicroscopy (CLE) would enable the analysis to be performed in the operating theatre at the time of the initial operation with the histopathological analysis then later confirming complete primary excision with a negative margin.

Dr Willsher said there was “an important clinical problem with lumpectomies, with residual cancer at the surgical margin [positive margin] found in 20 percent to 30 percent of cases with these cases requiring early re-operation after the histopathological analysis has been undertaken”.

“There are also multiple important negative consequences of a positive margin, which include the emotional trauma to patient, post-operative infections, poor cosmesis, prolonged hospital stay, delayed adjuvant therapy and higher costs,” Dr Willsher said.

Optiscan said that Dr Gill had begun comparing the confocal laser endomicroscopy imaging obtained with the Optiscan Five-2 Viewnvivo system with the traditional histopathology imaging of the identical pathological tissue specimens.

“I am very impressed with the real-time, high quality, high resolution imaging at cellular level that this technology provides,” Dr Gill said.

“The application of CLE in this clinical problem has a major opportunity to significantly reduce the need for reoperation in these vulnerable patients, something we all wish to avoid if we can,” Dr Gill said.

Optiscan was untraded at six cents.

ADALTA

Adalta says that its cell line manufacturing process for lead fibrosis candidate AD-214 has produced “just over 1.0 gram per litre of protein in cell culture”.

Adalta chief executive officer Sam Cobb told Biotech Daily that the “first read-out from the manufacturing process is what we expected at one gram per litre, which can be difficult to achieve”.

“We have seen several companies fall over at the manufacturing stage so this is a major milestone for Adalta,” Ms Cobb said.

In June, Adalta said it had begun development of the AD-214 cell line with Selexis SA and KBI Biopharma Inc, both of which were subsidiaries of the Tokyo-based JSR Life Sciences (BD: Jun 5, 2018).

Today, the company said the contract manufacturers were responsible for process development, analytical development, formulation development and clinical manufacturing services.

Adalta chief operating officer Dallas Hartman said “the first step in generating AD-214 product is developing a stable cell line and we are comfortable with the current cell line yields as provided by Selexis”.

“The process for expression and purification will now be optimized at KBI and based on this initial readout, we believe that the yields are sufficient to meet our requirements moving forward,” Ms Hartman said.

The company said that AD-214 was a new version of its lead therapeutic program for idiopathic pulmonary disease and was expected “to deliver significantly improved half-life … enhanced activity and be applicable across a broader range of fibrotic disease areas, making it more attractive to patients and pharmaceutical partners”.

“Based on our current timelines, we expect to complete the four-week, non-human primate toxicology study in the second half of 2019, which will then lead us into the clinic in early 2020,” Ms Cobb said.

Adalta was up two cents or 6.7 percent to 32 cents.

ESENSE-LAB

Esense says it has raised $3.15 million through an “oversubscribed” placement of 105,000,000 Chess depository instruments (CDIs) at three cents per CDI.

Esense said that the funds raised would be used “predominantly to fund the company’s commercialization and research and development activities”.

The company said that the placement to sophisticated and professional investors was a 14 percent discount to the 15-day volume-weighted average price.

Esense said that applicants would receive one free attaching option for every three shares subscribed exercisable at six cents each within four years of issue.

The company said that the Sydney-based Everblu Capital was the lead manager to the placement.

Esense was up 0.2 cents or 5.7 percent to 3.7 cents.

MEDIBIO

Medibio says it has received $3,146,835 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Medibio said that the funds related to expenditure for the year to June 30, 2018.

Medibio was up 0.1 cents or 1.9 percent to 5.3 cents.

BIOTRON

Biotron says it has received $1,072,831 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Biotron said that the incentive refund resulted from expenditure on its anti-viral drug development program for the year to June 30, 2018.
Biotron was up nine cents or 52.9 percent to 26 cents with 122.0 million shares traded.

PHARMAUST

Pharmaust says it has completed testing of different monepantel tablet prototypes in healthy Beagle dogs showing “good palatability and absorption”.
Pharmaust said that the studies were a collaboration with the Vancouver, British-Columbia based BRI Biopharmaceutical Research Inc and the data was “better than expected” (BD: Jul 11, 2016; Jun 27, 2017; May 28, 2018).
The company said that good palatability and absorption was vital as it would be the product for its phase II efficacy study to start by April, 2019.
Pharmaust said the levels tested were those nominated for the first stage of the dose escalation programs for both human and dog anti-cancer clinical trials.
The company said that the levels of monepantel in the blood using one tablet “exceeded the levels predicted to achieve anti-cancer activity”.
Pharmaust said it had sufficient data to take the best biologically performing and most financially economical tablet to manufacture through a scale up process and the tablets would be used in formal dose escalation studies in healthy Beagle dogs to determine the maximum dose that can be given and with what safety margin.
The company said that from previous dog and sheep studies, it appeared that blood levels for anti-cancer activity fell within “a very acceptable safety margin”, yet this must be formally proven to regulatory authorities before continuing to market.
Pharmaust chief scientific officer Dr Richard Mollard said the tablet reformulation data was “very encouraging”.
“We can now continue on to the next step of formally confirming anti-cancer activity in target species in clinical trials using a very convenient delivery method and with a tremendous amount of knowledge of how the drug performs in the body,” Dr Mollard said.
Pharmaust was up 0.4 cents or 11.4 percent to 3.9 cents with 1.2 million shares traded.

KAZIA THERAPEUTICS

Kazia has requested a trading halt “pending the release of an announcement with regard to a proposed capital raising”.
Trading will resume on October 17, 2018 or on an earlier announcement.
Kazia last traded at 43 cents.

RHINOMED

W Whitney George says he has increased his holding in Rhinomed from 24,241,401 shares (20.60%) to 25,667,050 shares (21.81%).
The Carlsbad, California-based Mr George said that between April 24 and October 11, 2018 he bought 1,425,649 shares for $US284,855 ($A400,668) or 28.1 cents a share.
Rhinomed was up 3.5 cents or 13.5 percent to 29.5 cents.

SIMAVITA

The Melbourne-based Tiga Trading says it has become a substantial shareholder in Simavita with 48,212,657 shares (11.63%).
The Tiga notice, signed by secretary Avee Waislitz, said the holders were Thorney Holdings Pty Ltd, Thorney Investment Group Australia and Jamahjo Pty Ltd, with 36,000,000 shares acquired at three cents a share on October 9, 2018, the same price as the Simavita placement which raised $1,975,000 (BD: Oct 4, 2018).
Simavita was unchanged at 3.1 cents.

LIVING CELL TECHNOLOGIES

Living Cell will vote to grant chief executive officer Dr Ken Taylor 1,000,000 options with four directors to be issued 600,000 options each.
Living Cell said the options would all be exercisable at the 10-day volume-weighted average price to November 29, 2018, with Dr Taylor's options vesting one year after issue and exercisable within three years, while the director options would vest immediately with a four-year life-span.
The company said the director options would be granted to interim chairman Prof Bernard Tuch, Prof Robert Elliott, Laurie Hunter and Robert Willcocks.
Last year, Living Cell withdrew six annual general meeting resolutions to increase directors' fees by 33 percent and issue 600,000 options to each of five directors, following non-significant results for its 18-patient trial of its NTCell treatment for Parkinson's disease (BD: Nov 10, 15, 2017).
In 2015, Living Cell had a remuneration report first strike with the meeting voting 39.55 percent against the report, and the company withdrew resolutions to issue each of chairman Roy Austin and directors Prof Elliott, Mr Hunter, Prof Bernard Tuch and Mr Willcocks 300,000 options exercisable at 7.5 cents and 300,000 options exercisable at 10 cents, as part of their directors remuneration (BD: Oct 13, Nov 13, 2015).
Today, the company said that if approved the options would "comprise a component of the directors' remuneration".
"Remunerating directors in this manner reduces the cash cost to the company and aligns the reward to directors with those to shareholders," Living Cell said.
The company's notice of meeting said shareholders would vote to adopt the remuneration report, approve the 10 percent placement capacity and the election of directors Prof Elliott and Dr Taylor.
The meeting will be held at the Regatta Room, Pullman Auckland, Cnr Princes Street and Waterloo Quadrant, Auckland, New Zealand on November 15, 2018 at 2pm (NZDT).
Living Cell was unchanged at three cents.