Biotech Daily

Tuesday June 6, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LIVING CELL UP 9%, PRIMA DOWN 8%**

*** MRCF, UNISEED $21m FOR QUE FOR HOT FLUSHES, DR ROB CROMBIE CEO**

*** CHINA EXTENDS ELLEX ITRACK GLAUCOMA TREATMENT**

*** STARPHARMA DEP-IRINOTECAN BEATS IRINOTECAN IN MICE**

*** GI DYNAMICS: 'ENDOBARRIER RE-USE SAFETY, EFFICACY'**

*** JAPAN PATENT FOR PHARMAUST MONEPANTEL**

*** LIVING CELL: 'PARKINSON'S PATIENTS IMPROVING AT 130 WEEKS'**

*** ANATARA RECEIVES $840k FEDERAL R&D TAX INCENTIVE**

*** MEDIBIO TRADES ON US OTC MARKET**

MARKET REPORT

The Australian stock market lost 1.52 percent on Tuesday June 6, 2017 with the ASX200 down 87.4 points to 5,667.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and one was untraded. All three Big Caps fell.

Living Cell was the best, up one cent or 9.1 percent to 12 cents with 976,587 shares traded.

Bionomics and Starpharma climbed more than eight percent; Orthocell was up 7.25 percent; Ellex and LBT improved four percent or more; Cellmid and Opthea were up more than three percent; Universal Biosensors and Viralytics rose more than two percent; Actinogen and Neuren were up more than one percent; with Airxpanders and Psivida up by less than one percent.

Yesterday's 16.1 percent best, Prima, led the falls, down 0.3 cents or 8.3 percent to 3.3 cents with 10.2 million shares traded.

Admedus and Atcor lost five percent or more; Medical Developments fell 4.3 percent; Avita, Benitec, Impedimed, ITL and Nanosonics were down more than three percent; Cochlear, Cyclopharm and Sirtex shed more than two percent; CSL, Factor Therapeutics, Osprey, Pro Medicus and Reva were down more than one percent; with Clinuvel, Mesoblast and Resmed down by less than one percent.

QUE ONCOLOGY, MEDICAL RESEARCH COMMERCIALISATION FUND, UNISEED

The MRCF and Uniseed have invested $US16 million ($A21.4 million) in Que for hot flushes in women treated for cancer and hired Dr Rob Crombie as chief executive officer.

The Medical Research Commercialisation Fund (MRCF) and Uniseed said that Que was jointly established by the Atlanta, Georgia-based Emory University and the University of Queensland commercialization company Uniquest and the series A funding would assist Que develop "novel cancer supportive care and anti-cancer therapies".

In a media release the two funding bodies said that Que would use the funds to advance development of Q-122, which was a new non-hormonal therapy for the treatment of hot flushes in women undergoing endocrine therapy for breast cancer.

The media release said that the product had the potential to expand its use in related conditions, including hot flushes associated with menopause.

The MRCF and Uniseed said breast cancer survivors were often prescribed drugs which reduced or blocked oestrogen, a hormone that could stimulate the growth of breast cancers, but reducing oestrogen in women increased the likelihood and intensity of hot flushes, which could have a serious and adverse effect on patients impacting on their cancer treatment compliance and Que was hoping Q-122 would treat the unmet need.

MRCF chief executive officer Dr Chris Nave said the symptoms of hot flushes "can be so extreme for some women undergoing long-term preventative breast cancer treatment that it keeps them out of work and even routine daily activities can become difficult to complete".

"Evidence shows that up to 75 percent of women undergoing treatment suffer hot flushes in some form," Dr Nave said. "In the most extreme cases, women can have over 20 events in a single day … [and] some cancer patients have reported that they'd rather discontinue taking their cancer drugs than suffer continued hot flushes."

Uniquest chief executive officer Dr Dean Moss said the investment was an endorsement of the prospects of the company and its programs.

"This investment will support the company as it continues to navigate the clinical trial and regulatory processes required to bring this life-changing treatment to the market, where it could make a real difference to many women around the world, as well as seeking to progress its preclinical pipeline," Dr Moss said.

The media release said that Que was planning a randomized, placebo-controlled phase IIa trial by July 2018.

The companies said that the trial would build on promising results seen in a prior 16-patient phase Ib trial, in which 14 of the woman, or 87.5 percent, had a reduction in severe hot flushes.

The funding bodies said that Dr Rob Crombie had been appointed as Que chief executive officer.

The media release said that Dr Crombie was previously Prescient's managing director, Arana's head of Melbourne operations and Evogenix's chief operating officer.

Que founder and director and Emory professor Prof Dennis Liotta said he was "grateful for the strong support of our new investors who share our excitement for the potential of Q-122 to safely and effectively treat the hundreds of thousands of breast cancer survivors who suffer from hot flushes".

"This funding will enable the company to further advance this promising product candidate in its lead indication of women undergoing endocrine therapy for breast cancer," Prof Liotta said.

The MRCF said it led the investment, with participation by Uniseed, Uniquest, Emory University and Centrosome Ventures.

Que is a private company.

ELLEX MEDICAL LASERS

Ellex says that China has approved its Itrack laser-based minimally invasive glaucoma surgery device.
Ellex said that the Itrack was the only minimally invasive glaucoma surgery device approved for sale in China and its approval had been extended until May 23, 2022.
The company said that China was "a key market" for the Itrack and it was working with its distributor to train doctors in the surgery technique and to build sales.
Ellex was up four cents or four percent to $1.04.

STARPHARMA

Starpharma says its dendrimer enhanced-irinotecan shows "significantly better anti-tumor activity and increased survival compared with irinotecan" in mice.
Starpharma said the dendrimer enhanced product (DEP) version of the cancer drug irinotecan was one of several internal DEP candidates under development along with DEP-docetaxel and DEP-cabazitaxel.
The company presented pre-clinical data graphs at the American Society of Clinical Oncology meeting in Chicago showing little or no difference between irinotecan and the vehicle control for efficacy measured by anti-tumor effect and mean tumor volume, or on survival rate curves, but with a marked difference for DEP-irinotecan.
Starpharma said efficacy and survival rates for mice treated with DEP-irinotecan compared to irinotecan were "highly statistically significant" with $p < 0.0001$ for both.
The company said that irinotecan was primarily used to treat colorectal cancer, which, although one of the most common cancer types, was an area of significant unmet need with few treatment options.
Starpharma said that irinotecan was originally commercialized as Camptosar and had peak sales of $US1.1 billion prior to losing patent exclusivity.
The company said that irinotecan had a US Food and Drug Administration black-box warning for severe diarrhoea and myelo-suppression, including neutropenia.
Starpharma said that in its studies, a single treatment cycle of DEP-irinotecan administered on days 1, 8 and 15 significantly improved anti-tumor activity and enhanced survival compared to irinotecan in all cancer models tested and in one colon cancer model, DEP-irinotecan resulted in complete tumor regression and 100 percent survival.
The company said that following these results it would be "expediting its development and scaling up the drug for further pre-clinical studies prior to clinical trials".
Starpharma chief executive officer Dr Jackie Fairley said that the "impressive results for DEP-irinotecan are promising in their own right and more so when coupled with the mounting data from both our internal and partnered DEP programs, which consistently demonstrate reproducible benefits in efficacy and tolerability from our DEP platform using a range of anti-cancer drugs".
"We are focused on rapidly building value across the DEP portfolio and our recently commissioned internal scale-up facilities will allow us to manufacture DEP-irinotecan, as well other internal and partnered DEP candidates, to accelerate their development," Dr Fairley said.
Starpharma said that irinotecan was a pro-drug, which needs to be converted in the liver to the active anti-cancer agent, SN-38, whereas its DEP-irinotecan incorporated the active irinotecan derivative SN-38, avoiding the need for hepatic conversion.
The company said that DEP-irinotecan was expected to accumulate preferentially in tumor tissue to exert its superior anti-tumor effect, as was seen with other DEP conjugates
Starpharma climbed six cents or 8.8 percent to 74 cents.

GI DYNAMICS

GI Dynamics says a German five-patient study shows its Endobarrier duodenal liner can be safely re-implanted and further reduces weight and blood-sugar levels.

GI Dynamics said an investigator-initiated study, entitled 'Is Re-Implantation of the Duodenal-Jejunal Bypass Liner Viable?' was presented at the German Diabetes Congress in Hamburg, Germany.

The company said the study examined the safety and efficacy of Endobarrier re-implantation and explored whether it is technically feasible to re-implant Endobarrier in patients who previously had the device implanted and explanted, as well as whether the re-implantation would achieve similar weight and metabolic effects as on patients who had received prior Endobarrier implantation.

GI Dynamics said that each patient completed an initial 12-month course of Endobarrier treatment after which the device was explanted and the patients were monitored for four months.

The company said that a second Endobarrier was implanted for a further 12 month course and subsequently removed.

A table provided by GI Dynamics showed that average HbA1c levels fell from 9.1 percent at baseline to 6.7 percent at 12 months of Endobarrier use, rising to 7.8 percent after four months of non-use and falling to 7.1 percent following a further 12 months.

The table showed a better result for body weight with the average weight dropping from 115.8kg at baseline to 95.0kg at 12 months of Endobarrier use, rising to 97.3kg after four months of non-use and falling to 91.1kg following a further 12 months.

Insulin use dropped from 60 international units baseline to 19iU at 12 months of Endobarrier us, rising to 33iU after four months of non-use and falling to 20iU following a further 12 months of Endobarrier use.

Principal investigator Dr Jurgen Stein said that "although small, this study provided important information regarding serial usage of Endobarrier".

"Re-implantation and re-explantation of the Endobarrier device were performed on all five study subjects without any complications and the early clinical data is promising," Dr Stein said."In addition, there was a significant reduction in insulin."

GI Dynamics chief executive officer Scott Schorer said the study showed "early indication of efficacy to support multiple treatments utilizing Endobarrier".

"Especially encouraging is the reduction of blood sugar and weight combined with concurrent reduction in insulin," Mr Schorer said.

GI Dynamics fell 0.1 cents or 1.75 percent to 5.6 cents.

PHARMAUST

Pharmaust says that Japan has granted a core patent relating to its monepantel or PPL-1 in trials for cancer in dogs and humans.

Pharmaust said that the patent, entitled 'Kinase Inhibitors for the Treatment of Cancer' claimed the use of amino-acetonitrile derivatives as potent kinase inhibitors for the treatment of cancer and provided protection until 2033.

The company said that amino-acetonitrile derivatives included the Novartis Animal Health and Elanco compound monepantel, which it had patented for cancer applications.

Pharmaust chief executive officer Dr Richard Hopkins said the method of use patent extended the core intellectual property in another key market.

"We have now secured granted patents for this family in Australia, China, the US and Japan, providing us strong strategic protection for this class of molecule," Dr Hopkins said.

Pharmaust fell 0.2 cents or 2.5 percent to 7.9 cents

LIVING CELL TECHNOLOGIES

Living Cell says that 130 weeks after treatment all four patients in its phase I/IIa study of NTCell for Parkinson's were well, with no safety concerns and continued improvement.
Living Cell said that safety was the primary endpoint of the open study of 40 NTCell pig choroid brain cell capsules into the putamen on one side of the brain (BD: Feb 28, 2012).
The company said that treatment in all patients continued "to show improvement over baseline, as measured by the Unified Parkinson's Disease Rating Scale [with] efficacy … most evident in the measurement of motor function.
Living Cell said that during follow-up patients had the right to request implantation on the other side of the brain, continue as is, or have deep brain stimulation, with one patient electing for deep brain stimulation and the other three patients' choices not cited.
Living Cell principal investigator at the Auckland City Hospital Dr Barry Snow said the sustained improvement was "interesting and encouraging".
"The results to date certainly validate the phase IIb dose ranging study in progress, in which higher doses of NTCell are implanted into the putamen on both sides of the brain and which includes a sham surgical-controlled placebo group," Dr Snow said.
Living Cell chief executive officer Dr Ken Taylor said the company was "looking forward to the results of the larger phase IIb study … designed to measure efficacy".
"This study will 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," Dr Taylor said.
Living Cell was up one cent or 9.1 percent to 12 cents.

ANATARA LIFESCIENCES

Analytica says it has received $839,686 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Anatara said the cash incentive related to research and development expenditure for the year to June 30, 2016 "and reflects a year of increased spending while the company was preparing its application to the Australian Pesticides and Veterinary Medicines Authority for the marketing approval of Detach in Australia".
Anatara was up 7.5 cents or 9.1 percent to 90 cents.

MEDIBIO

Medibio says its US stock has begun trading on the over-the-counter OTC Market Group's OTCQB Venture Market under the code MDBIF effective form June 5, 2017.
Medibio said that the OTCQB was designed for early-stage and developing companies that were current in their reporting and underwent an annual verification and management certification process.
The Investopedia website said that OTCQB was the middle tier of three over-the-counter markets and replaced the OTC Bulletin Board, or OTCBB, with no minimum financial standards and included shell companies, penny stocks and small foreign issuers.
Investopedia said the over-the-counter quality exchange OTCQX was the highest level of the three markets, with the OTC Pink the lowest level.
Medibio was up one cent or three percent to 34 cents with 1.1 million shares traded.