Biotech Daily

Wednesday December 19, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: TELIX UP 7%; PARADIGM DOWN 19%**

*** CYCLOPHARM: CANADA GUIDELINES BACK TECHNEGAS FOR IMAGING**

*** TELIX APPLIES FOR JAPAN TLX250-CDX KIDNEY CANCER IMAGING TRIAL**

*** IMMUTEP RAISES $7.2m**

*** SUDA $1.4m MITSUBISHI TANABE ZOLPIMIST INSOMNIA LICENCE**

*** AKAAL, BOSTON PHARMA DEAL FOR AKP-11 FOR PSORIASIS, ARTHRITIS**

*** CLINUVEL: 'SCENESSE GOOD FOR VITILIGO, DARK SKIN REJECTED'**

*** ALCIDION EXTENDS ACT HEALTH CONTRACT**

*** PHOSPHAGENICS, MYLAN, STRIDES SETTLE FOR $176k, NEW DEALS**

*** LIFESPOT'S VAPORIZER FOR CBDS US MARIJUANA TRIALS**

*** BARD1 DR IRMGARD IRMINGER-FINGER INCREASES, DILUTED TO 11%**

*** MGC TRADES ON US OTCQB**

*** THC REQUESTS 'MARIJUANA PERMITS' TRADING HALT**

*** MESOBLAST PROMOTES DR ERIC STRATI TO COMMERCIAL HEAD**

MARKET REPORT

The Australian stock market slipped 0.16 percent on Wednesday December 19, 2018, with the ASX200 down 8.9 points to 5,580.6 points. Twelve of the Biotech Daily Top 40 companies were up, 18 fell, eight traded unchanged and two were untraded.

Telix was the best, up four cents or 6.8 percent to 63 cents with 166,267 shares traded. Cyclopharm and Patrys climbed four percent or more; Pharmaxis, Pro Medicus and Volpara were up more than three percent; Actinogen rose 2.2 percent; Cynata was up 1.9 percent; with Clinuvel, Neuren, Opthea and Polynovo up by less than one percent.

Yesterday's 13.3 percent best, Paradigm, led the falls, down 28.5 cents or 19.1 percent to $1.21 with 1.7 million shares traded. Optiscan lost 10 percent; Impedimed fell 9.1 percent; Proteomics shed 8.75 percent; Genetic Signatures was down 7.1 percent; Kazia and Universal Biosensors fell more than four percent; Airxpanders, Avita, Nanosonics and Orthocell were down more than three percent; Compumedics, Oncosil and Reva shed more than two percent; Cochlear, CSL, Medical Developments, Mesoblast and Prescient were down more than one percent; with Starpharma down 0.4 percent.

CYCLOPHARM

Cyclopharm says new Canadian guidelines have named Technegas as the best ventilation agent for diagnosing pulmonary embolism.

Cyclopharm said the Canadian Association of Nuclear Medicine released guidelines that "strongly recommend clinicians use Technegas above all other ventilation agents in the diagnosis of pulmonary embolism particularly in the presence of other lung conditions, such as chronic obstructive pulmonary disease".

The company said the guidelines included the use of Technegas for chronic obstructive pulmonary disease, cardiac failure and reverse mismatches symptomatic of pneumonia, atelectasis, mucous plug or other causes of bronchi obstruction.

"For ventilation, 99mTc-Technegas is the best radio-aerosol, particularly in patients with COPD," Cyclopharm quoted the guidelines. "Liquid aerosols produced in nebulizers, such as 99mTc-DTPA, are inferior … and should not be used unless Technegas is not available."

"Overall, Technegas remains the best radio-aerosol, particularly in patients with obstructive lung disease," Cyclopharm quoted the guidelines. "Another advantage is that only a few breaths are sufficient to achieve an adequate amount of activity in the lungs, reducing time and personnel exposure to radiation."

For patients with chronic obstructive pulmonary disease and pulmonary embolism "Technegas is considered the agent of choice in this population as there is less central airway deposition, better peripheral penetration, and it does not wash out as quickly as traditional aerosols," Cyclopharm quoted the guidelines.

Cyclopharm managing-director James McBrayer told Biotech Daily that "this level of endorsement is unprecedented".

"Rarely does a product get a recommendation like this in a guideline," Mr McBrayer said.

The company said it had 96-patients in a US Food and Drug Administration directed trial and intended to submit a literature review protocol to the FDA on December 27, 2018, and if successful with a 505(b)2 new drug application it would end trial recruitment.

Cyclopharm said it was "on-track to achieve its target commencement of Technegas sales into the US in late 2019".

Cyclopharm was up five cents or 4.35 percent to $1.20.

TELIX PHARMACEUTICALS

Telix says Japan has granted permission for the company apply for a phase I/II study of 89-zirconium-girentuximab, or TLX250-CDx, for kidney cancer imaging.

Telix said it had until January 11, 2019 to make the application for the TLX250-CDx trial to validate the US and European experience of imaging kidney cancer in Japanese patients.

The company said the trial was expected to begin by July 2019, subject to regulatory approval, using product manufactured by Japan partner JFE Engineering.

Telix said the trial would bridge to the 250-patient, Zircon phase III study of TLX250 for renal cell carcinoma imaging (BD: Oct 23, 2018).

In a separate announcement, the company said it had enrolled the last of 10 patients in a trial of TLX250-CDx at the Netherlands' Radboud University Medical Centre "to compare the whole-body dosimetry of 89-zirconium-girentuximab, TLX250-CDx for the imaging of kidney cancer, with historical dosimetry data for 124-iodine-girentuximab".

Telix said it changed the isotope from 124-iodine to 89-zirconium "to reduce patient dose, enhance image contrast, lower cost of goods and improve clinical workflow by eliminating the need for thyroid blocking" and it expected final result by April 2019.

Telix was up four cents or 6.8 percent to 63 cents.

IMMUTEP

Immutep says it has raised $US5.2 million ($A7.2 million) through the issue 2,600,000 American depository shares (ADSs) at $US2.00 a share or 2.8 cents per Australian share.
Immutep said the shares were equivalent to 260,000,000 Australian shares.
The company said that "in a concurrent private placement … [it] agreed to issue warrants to purchase up to 208,000,000 ordinary shares represented by 2,080,000 ADSs" exercisable at $US2.50 per ADS within three years.
Immutep said the placement was led by Altium Capital and the proceeds would support its LAG-3 related programs, including the clinical development of eftilagimod alpha, or IMP321, in four clinical trials, the pre-clinical development of IMP761 and working capital.
Immutep was unchanged at 3.2 cents with 3.7 million shares traded.

SUDA PHARMACEUTICALS

Suda says it will licence its Zolpimist oral spray for insomnia to Mitsubishi Tanabe Pharma Singapore for up to $US980,000 ($A1,361,857).
Suda said it would receive an upfront payment of $US100,000, milestone and option payments up to $US880,000, a double-digit royalty and a handling fee for product.
The company said the licence covered Singapore, Malaysia and the Philippines, with a 12-month option on Thailand, Indonesia, Vietnam, Myanmar, Cambodia, Laos and Brunei.
Suda said if Mitsubishi Tanabe exercised the option of supplying Zolpimist to the other countries, Mitsibishi Tunabe would pay it $US35,000 followed by milestone payments of $US25,000 for each country.
Suda executive chairman Stephen Carter said "we have been in discussion with Mitsubishi Tanabe for several months and are very excited with the prospect of this partnership which will expand Zolpimist coverage across Asia".
"Completing another agreement with a major pharmaceutical company, reinforces the work and developments of the company," Mr Carter said.
Suda was up 0.05 cents or 9.1 percent to 0.6 cents with 34.6 million shares traded.

AKAAL PHARMA PTY LTD

Melbourne's Akaal Pharma says it has licencing agreement with Boston Pharmaceuticals for its AKP-11 for inflammatory, immune and vascular diseases.
Akaal said that AKP-11 was a first-in-class, topical spingosine-1-phosphate-1 (s1p1) modulator which had shown "clinical activity … in multiple phase I clinical studies".
Akaal co-founder and head of research and development Dr Gurmit Gill told Biotech Daily that the first indications were for psoriasis, atopic dermatitis and arthritis.
The company said that Boston Pharmaceuticals would be responsible for the further clinical development and commercialization of AKP-11 for the Americas and Europe.
Akaal said the specific financial terms were not disclosed and it retained the rights for the rest of the world.
Akaal chairman Bagicha Singh Sandhu said the company prioritized and expanded its dermatology and pain programs "to serve the wider global community suffering from these diseases and where there is need of safe and effective treatment".
"We are keen to bring innovative drugs to patients as quickly as possible, and we believe this agreement with an innovative US partner will rapidly advance the development of this novel compound and potentially its availability to patients," Mr Sandhu said.
Akaal is a private company based at Melbourne's La Trobe University.

CLINUVEL PHARMACEUTICALS

Clinuvel says Scenesse with ultraviolet light achieves re-pigmentation in vitiligo, but skin darkening is culturally and socially unacceptable among Asian patients.

Clinuvel said the 21-patient, Singapore, phase II study of six doses, once every 28 days of Scenesse with narrowband ultraviolet B light (NB-UVB) twice a week was effective and safe, with a statistically significant increase in pigmentation on areas of vitiligo for total body, areas of head and neck ($p = 0.05$) and re-pigmentation remained stable for the three months following completion of the treatment.

The company said the therapy was tolerable and acceptable to all patients remaining in the trial, with no serious adverse events reported in the study.

Clinuvel said there was no statistically significant difference in the change of quality of life over time as measured by a quality of life questionnaire.

The company said that of the 21 patients enrolled in the trial, three patients withdrew consent and discontinued treatment “due to concerns with experiencing much darker constitutional skin following drug administration compared to baseline, despite this having been explained during the patient consent process”.

Clinuvel said that the patients expressed concerns at the overall temporary epidermal darkening activated by Scenesse in combination with NB-UVB as skin darkening is culturally and socially unacceptable in certain Asian populations”.

Singapore National Skin Centre lead investigator Prof Steven Thng said he had treated “the entire spectrum of dermatology patients, [but] this is the first time we have observed how strong cultural aspects dominate patients’ perception of skin color and re-pigmentation, even though they suffer from vitiligo”.

“Since there had been no effective systemic re-pigmentation therapy, patients’ anxiety for overall darkening of the skin had never been communicated and was a real surprise to us,” Prof Thng said.

This company said the new finding indicated that dark skin versus whiter skin in vitiligo patients in Singapore was regarded quite differently than in other parts of the world.

“The treatment with Scenesse was remarkably effective in achieving re-pigmentation in those patients who chose to overcome their anxiety of darkening and significantly improved their appearance,” Prof Thng said.

“I can see a great application of this new therapy in the future, but it will need to be restricted specifically to those patients of Asian descent who do not suffer the psychological distress of overall temporary darkening caused by the hormonal treatment,” Prof Thng said.

Clinuvel was up 12 cents or 0.7 percent to $18.00.

ALCIDION GROUP

Alcidion says subsidiary MKM Health has renewed its hospital software support contract with Australian Capital Territory Health for two years.

Alcidion said the contract extension was valued at $1.27 million and would run from January 1, 2019 to December 31, 2020.

The company said that the two-year extension would provide continuing support for a range of third-party products, MKM Health products, custom built products, expert advisory services, technical services and integration support.

Alcidion chief executive officer Kate Quirke said that “MKM Health has had a long-standing relationship providing technical support and integration services to ACT Health for well over a decade”.

Alcidion fell 0.1 cents or 2.2 percent to 4.5 cents.

PHOSPHAGENICS

Phosphagenics says it has settled costs with Mylan Laboratories and will pay Strides Pharma GBP100,000 ($A176,167), concluding the legal dispute between the companies.
Last month, Phosphagenics said the Singapore International Arbitration Centre found "that Phosphagenics was unsuccessful in all of its claims" (BD: Nov 12, 2018).
Last year, Phosphagenics said it had a $US300 million damages claim over Mylan's licence of its tocopheryl phosphate mixture (TPM) daptomycin for skin infections and staphylococcus aureus bloodstream infections originally licenced to Strides Arcolab subsidiary, the India-based Agila Specialties, acquired by Mylan in 2013 (BD: Oct 30, 2012; Mar 3, May 29, 2017; Oct 23, 2018).
Today, the company said the original agreement had been terminated and the new agreement included the rights for Mylan to licence, market and/or sell tocopheryl phosphate mixture-daptomycin as it saw fit.
Phosphagenics said if Mylan decided to licence, market and/or sell the tocopheryl phosphate mixture, Phosphagenics would be entitled to a royalty of five percent and Mylan would source the tocopheryl phosphate mixture exclusively from Phosphagenics.
The company said that Strides had been granted first right of refusal to all Phosphagenics human tocopheryl phosphate mixture assets.
Phosphagenics chief executive officer Dr Ross Murdoch said "we have worked feverishly since [the arbitration] to negotiate an outcome that eliminates the potential for a substantial adverse costs order".
"We are very pleased to have a negotiated outcome supported by all parties that avoids substantial cash payments, retains and potentially increases the future value available to Phosphagenics from TPM-daptomycin and also provides a clear incentive and opportunity for further deals," Dr Murdoch said.
Phosphagenics chairman Dr Greg Collier told Biotech Daily that the negotiations led to Mylan agreeing to forgo all costs from the legal dispute.
Dr Collier said the company could have been liable for Mylan's legal costs and Phosphagenics' costs were more than $5 million, the company was debt free and had a one-year runway enabling it to continue developing and licencing its TPM products.
Phosphagenics was up 0.55 cents or 220 percent to 0.8 cents with 177.5 million shares traded.

LIFESPOT HEALTH

Lifespot says it has a sales and distribution agreement with CBDS Health to use its Seng Vital smart vaporizer system in marijuana clinical trials in North America.
Lifespot said CBDS (Clinical Blockchain Data Sciences) Health was focused on research in clinical trials using information technologies and big data analytics.
Lifespot was untraded at 6.7 cents.

BARD1 LIFE SCIENCES

Bard1 executive director Dr Irmgard Irminger-Finger says that she has increased and been diluted from 108,252,420 shares (19.61%) to 112,152,737 shares (11.28%).
Dr Irminger-Finger said that between November 27 and 29, 2018, she sold 8,599,683 shares for $204,982 or 2.38 cents a share.
Dr Irminger-Finger said she bought 12,500,000 shares for $250,000 in Bard1's recent rights issue that raised $3.314 million at two cents a share (BD: Dec 18, 2018).
Bard1 was up 0.2 cents or 9.1 percent to 2.4 cents with 53.0 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it will trade on the US over-the-counter quality exchange B (OTCQB) under the code MGCLF from December 18, 2018.
MGC said that the OTC Markets Group operated the OTCQX quality exchange, the OTCQB venture market and the Pink open market for 10,000 US and non-US securities.
The company said the OTCQB venture market was for early-stage and developing companies.
MGC said that trading on the OTCQB was “a milestone” as it provided better access to institutional investors and a broader shareholder base.
MGC fell 0.1 cents or 2.6 percent to 3.7 cents with 1.8 million shares traded.

THC GLOBAL GROUP (FORMERLY THE HYDROPONICS COMPANY

Hydroponics has requested a trading halt “pending an announcement … regarding the issue of permits … by the Department of Health, Office of Drug Control”.
Trading will resume on December 21, 2018 or on an earlier announcement.
THC last traded at 43 cents.

MESOBLAST

Mesoblast says it has appointed Dr Eric Strati as its head of commercial activities to drive the launch of remestemcel-L in the US and Europe for graft versus host disease.
Mesoblast said that Dr Strati joined the company in 2015 and previously Novartis executive director of managed markets and a member of the launch teams for Entresto for chronic heart failure and Cosentyx for moderate to severe psoriasis.
Mesoblast fell 1.5 cents or 1.4 percent to $1.07 with 1.3 million shares traded.