Biotech Daily

Tuesday May 28, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRO MEDICUS UP 6%; PROTEOMICS DOWN 9%**

*** INVION IVX-P02 HITS CANCER, NO CELL TOXICITY IN MICE**

*** TELIX, FDA PROSTATE CANCER IMAGING MEETING; DISTRIBUTORS**

*** PARADIGM: 'OSTEO-ARTHRITIS KNEE PAIN DOWN 51%'**

*** FEDERAL COURT EXTENDS MICRO-X CLEANSING NOTICE**

*** ORTHOCELL REQUESTS CAPITAL RAISING TRADING HALT**

*** MEDLAB APPOINTS MEGA LIFESCIENCES NANABIS DISTRIBUTOR**

*** SIGMA TAKES 5% OF BTC**

*** WALKER GROUP INCREASES, DILUTED TO 8.5% OF BTC**

*** CELLMID APPOINTS BART WUURMAN LYRAMID MIDKINE CEO**

*** TBG LOSES DIRECTOR, COO EUGENE CHENG**

MARKET REPORT

The Australian stock market was up 0.51 percent on Tuesday May 28, 2019, with the ASX200 up 32.9 points to 6,484.8 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and three were untraded. All three Big Caps were up.

Pro Medicus was the best, up $1.24 or 5.55 percent to $23.60 with 234,121 shares traded. Clinuvel and Cynata climbed more than four percent; Kazia, Mesoblast and Uscom were up more than three percent; LBT, Optiscan, Polynovo, Telix and Universal Biosensors rose more than two percent; Cyclopharm and Pharmaxis were up more than one percent; with Cochlear, CSL, Ellex, Nanosonics and Resmed up by less than one percent.

Proteomics led the falls, down three cents or 9.2 percent to 29.5 cents, with 75,770 shares traded. Impedimed lost 8.1 percent; Genetic Signatures and Oncosil fell more than four percent; Patrys was down 3.85 percent; Antisense, Medical Developments, Neuren, Paradigm and Volpara shed two percent or more; with Opthea and Starpharma down by more than one percent.

INVION

Invion says its photo-sensitizer, IVX-P02, is taken up by cancer cells and shows no toxicity at any dose tested in mice and will progress to human trials by October 2019.

Invion said that its research partner, Melbourne's Hudson Institute of Medical Research, performed two experiments to examine the "uptake, localization and clearance from tumor tissue" and the resulting mouse data showed that injected IVX-P02 "cleared rapidly from circulation" with about 90 percent gone within 30 minutes and largely undetectable after two hours.

Invion said that increasing doses up to 10mg/kg had no influence on the clearance rate.

The company said that IVX-P02 accumulated in tumor tissue within 30 minutes of injection and was retained within tumor tissue for at least 48 hours after administration.

Invion said that "there was no toxicity noted for any dose of IVX-P02 tested … [and] no identification of any evidence of retention in any other organs, including the liver, kidney, spleen, ovaries, fallopian tube, lung, heart, brain or intestine.

The company said that experiments demonstrating the use of IVX-P02 to treat ovarian cancer were underway and focussed on the direct destruction of established ovarian cancers in mice, accumulation of IVX-P02 in circulating tumor cells and the immune consequences of photo-dynamic therapy using IVX-P02.

Hudson Institute ovarian cancer head Dr Andrew Stephens said the study showed the uptake of IVX-P02 in circulating tumor cells, or cells from primary tumors circulating in the blood, which suggested application as a metastatic cancer treatment.

"This is the first time that photo-sensitizer accumulation in [circulating tumor cells] has been demonstrated in-vivo," Dr Stephens said.

"The data suggests the potential application of IVX-P02 for haematological cancers in addition to solid tumors, as well as in therapies designed to prevent recurrence," Dr Stephens said.

Invion said that haematological cancers occurred in blood-forming tissue, such as the bone marrow, or in the cells of the immune system, such as leukaemia, lymphoma, and multiple myeloma, and blood cancers were treated with "quite severe therapies that have immuno-suppressive and other side effects".

"This new development is in its early stages, but it could lead to the development of a less harsh treatment for patients with metastatic cancer," Dr Stephens said.

"The important thing is that IVX-P02 is taken up selectively by cancer cells and is not retained in any of the other organs, and in the blood, it is taken up selectively by circulating cancer cells and not by red blood cells," Dr Stephens said.

Invion was up 0.4 cents or 28.6 percent to 1.8 cents with 94.3 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has requested a pre-new drug application meeting with the US Food and Drug Administration for its prostate cancer imaging agent TLX591-CDx, or Illumet.

Telix said it had prepared a pre-NDA package and expected to meet with the FDA in July to determine the status of a marketing authorization submission.

The company said that application process built on the drug master file submitted last July and since then, "multiple investigational new drug applications have referenced Telix's [file], including the Endocyte, now Novartis, Vision phase III trial and several important academic studies" (BD: Mar 26, Apr 10, Jul 25, Aug 10, 13, 2018).

Telix said it had contracted the Suwanee, Georgia-based United Pharmacy Partners Inc and the Boca Raton, Florida-based Pharmalogic as distributors.

Telix was up 2.5 cents or 2.75 percent to 93.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says knee pain in 205 osteoarthritis patients with bone bruising treated with injectable pentosane polysulfate sodium was reduced by an average 51.3 percent.
Paradigm said the results from a further 22 patients treated under the Australian Therapeutic Goods Administration special access scheme were in line with previous results as patient numbers increased (BD: Aug 15, Sep 25, Nov 7, Dec 7, 2018).
In December, the company said its 112-patient, phase IIb trial showed that injected pentosan polysulfate sodium (PPS) significantly reduced knee osteoarthritis pain compared to placebo ($p = 0.031$) (BD: Dec 18, 2018).
Today, Paradigm said that 89.7 percent of patients treated had a reduction in joint pain and 91.2 percent had an improvement in knee function.
The company said that function was improved by 58.4 percent and pain scores were reduced by over 51.3 percent on average from baseline pain scores.
Paradigm said the pain reduction with in its pentosan polysulfate sodium showed "superiority over the 15 percent pain reduction scores reported for opioid treatments for chronic pain in [osteo-arthritis] of the knee and hip".
Paradigm's chief executive officer Paul Rennie said the company was "very pleased to see that since October 2017 and after the report of the eighth group of [special access scheme] patients there is a consistent average knee pain reduction of greater than 50 percent across 205 patients".
"The number of patients seeking treatment via the TGA [special access scheme] is a strong feedback that the patients are receiving a clinically meaningful benefit from the … treatment," Mr Rennie said.
"Our strategy of obtaining real world evidence as we prepare our [US Food and Drug Administration investigational new drug] submission for our phase III [osteoarthritis] trial will provide valuable data on our newly manufactured phase III trial product and will assist in fine tuning our phase III trial design," Mr Rennie said.
Paradigm fell 3.5 cents or 2.4 percent to $1.445 with 803,394 shares traded.

MICRO-X

Federal Court Justice John Middleton has extended the time for a Micro-X cleansing notice to the second business day after the orders were granted on May 27, 2019.
Last week, Micro-X requested a trading halt followed by a suspension yesterday to apply to the Court for orders allowing the extension of the cleansing notice following "an inadvertent administrative oversight" (BD: May 23, 27, 2019).
Today, the Court orders cited affidavits from director Richard Hannebery and company lawyer Catherine Macrae in relation to the cleansing notice for shares issued between January 3 and May 7, 2019.
The Federal Court said the period of five business days usually allowed to lodge a cleansing notice would be "extended to the second business day after the day on which these orders are entered" for 6,914,809 shares issued on January 3, 122,122 shares issued on January 11 and the 370,370 shares issued on May 7, 2019.
A Micro-X executive told Biotech Daily the Court orders included a typographical error and the 122,222 shares were issued on January 11, with amended orders being sought.
The Court ordered that "any person who claims to have suffered substantial injustice or is likely to suffer substantial injustice by the making of any or all of the orders has liberty to apply to vary or to discharge them within 28 days of the entry of orders" and "there be no order as to costs".
Micro-X was up half a cent or 1.75 percent to 29 cents.

ORTHOCELL

Orthocell has requested a trading halt pending “an announcement regarding a capital raising”.
Trading will resume on May 30, 2019 or on an earlier announcement.
Orthocell last traded at 46.5 cents.

MEDLAB CLINICAL

Medlab has appointed Mega Lifesciences Public Company to distribute its marijuana-based Nanabis in South America.
Medlab said the Bangkok, Thailand-based Mega Lifesciences was involved in manufacturing, marketing, selling and distributing quality pharmaceutical, food additives and fast-moving consumer goods in 33 countries.
The company said that Nanabis is a highly purified cannabidiol and tetrahydrocannabinol blend which used its Nanocelle delivery platform.
Medlab did not provide details of the distribution agreement terms.
Medlab was unchanged at 40 cents.

BTC HEALTH

The Melbourne-based Sigma Company says it has become a substantial shareholder in BTC with 8,143,533 shares or 5.02% of the company.
Sigma said it bought the shares on May 22, 2019 for $651,483 or 8.0 cents a share as part of BTC’s recent placement which raised $8 million to buy the Admedus’ hospital infusion business (BD: May 15, 2019).
BTC fell half a cent 4.55 percent to 10.5 cents.

BTC HEALTH

Walker Group Holdings says it has increased but been diluted in BTC from 12,860,583 shares (11.84%) to 13,783,910 shares (8.50%).
The Walker Group failed to state the cost of the shares as required by the Corporations Act.

CELLMID

Cellmid had appointed Bart Wuurman as chief executive officer of its midkine asset subsidiary Lyramid.
Cellmid said its midkine assets were being developed as therapies and diagnostic tests for fibrotic diseases, cancer and ischemic heart diseases.
The company said Mr Wuurman had more than 30 years of experience in drug development, financing, business development and licencing.
Cellmid said previously Mr Wuurman was the Breukelen, Netherlands-based DDF Ventures managing-director and prior to that worked for the London-based Antisoma and the Groningen, Netherlands-based Lanthio Pharma.
The company said Mr Wuurman would receive 2,000,000 options in two tranches on condition of the successful licencing, partnering or funding of the clinical development program for midkine, a diagnostic biomarker for cancer management.
Cellmid was up two cents or 11.1 percent to 20 cents.

TBG DIAGNOSTICS

TBG says that Eugene Cheng has retired as a director at the May 28, annual general meeting and did not seek re-election.

TBG said it thanked Mr Cheng “for his significant contribution to the company as group chief operating officer and subsequently as a non-executive director”.

TBG was untraded at five cents.