Biotech Daily

Tuesday November 13, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: USCOM UP 4%; AIRXPANDERS DOWN 9%**

*** QBIOTICS 1st EBC-46 SOLID TUMOR TRIAL: '2 COMPLETE RESPONSES'**

*** COCHLEAR $20m FOR NYXOAH OSA HYPOGLOSSAL NERVE STIMULATION**

*** IMUGENE: 'HER-VAXX SAFE, ANTIBODIES FOR GASTRIC CANCER'**

*** SIENNA RECEIVES $443k FEDERAL R&D TAX INCENTIVE**

*** IDT BUYS-BACK, CANCELS 659K SHARES**

*** FACTOR REQUESTS 'TRIAL RESULTS' TRADING HALT**

*** PHARMAUST: CATALENT GMP MONEPANTEL FOR DOG CANCER TRIALS**

*** IMUGENE 18% OPPOSE 25m CHAIR PAUL HOPPER OPTIONS**

*** AUSCANN HIRES PCI PHARMA FOR MARIJUANA CAPSULES FOR PAIN**

*** MGC SELLS DERMA TO CANNAGLOBAL CANADA**

MARKET REPORT

The Australian stock market lost 1.8 percent on Tuesday November 13, 2018 with the ASX200 down 107.1 points to 5,834.2 points. Four of the Biotech Daily Top 40 stocks were up, 29 fell, two traded unchanged and five were untraded. All three Big Caps fell.

Uscom was the best, up half a cent or 3.7 percent to 14 cents, with 58,000 shares traded. LBT and Orthocell climbed more than two percent; with Dimerix up one percent.

Airxpanders led the falls, down 0.3 cents or 8.6 percent to 3.2 cents, with 2.15 million shares traded.

Benitec, Immutep and Mesoblast lost more than six percent; Starpharma fell 5.7 percent; Cochlear, Polynovo, Prescient, Volpara and Universal Biosensors fell four percent or more; Avita, Compumedics, Osprey, Medical Developments and Resmed were down more than three percent; Actinogen, Clinuvel, CSL, Ellex, Neuren, Oncosil, Paradigm, Prana, Reva and Telix shed more than two percent; Impedimed, Nanosonics, Optiscan and Pro Medicus were down one percent or more; with Cynata, Genetic Signatures and Opthea down by less than one percent.

QBIOTICS

Qbiotics says its 22-patient, first-in-human phase I/IIa trial of tigilanol tiglate, or EBC-46, for solid tumors achieved a complete response in two patients.

Qbiotics told Biotech Daily that the open-labelled trial of its tropical rainforest-derived compound enrolled 22 patients with 29 tumors.

The company said the study was designed to establish the safety and tolerability, maximum tolerated dose, preliminary efficacy, and pharmacokinetics of intra-tumoral tigilanol tiglate in patients with cutaneous, subcutaneous, head and neck or nodal tumors.

Qbiotics said that tigilanol tiglate was administered as a bolus injection on day-1 with escalating doses beginning at 0.06mg/m2 (milligram per metre squared of body surface) in patients with tumors estimated to be at least twice the volume of injection.

In its media release the company said the trial was conducted at four Australian hospitals and showed “promising results in patients with a variety of solid tumor types, supporting a broad potential application of the pharmaceutical”.

Qbiotics said the study concluded when an efficacious dose was achieved without a maximum tolerated dose being reached, providing an early indication that tigilanol tiglate was well-tolerated in humans.

The company said the results supported its intent to proceed to a phase IIa efficacy trial.

Qbiotics said the study indicated that tigilanol tiglate injected into tumors was well tolerated, as a maximum tolerated dose was not reached.

The company said that the study results showed signs of clinical efficacy identified in nine different tumor types including a complete response, or full tumor destruction, achieved in two patients.

Qbiotics chief executive officer Dr Victoria Gordon said that results from the trial “indicate the potential of our drug as a well-tolerated anti-cancer treatment with application across a range of solid tumor indications.”

“These results are an encouraging step forward in the treatment of solid tumors in humans and support our advancement with a clinical phase IIa efficacy trial,” Dr Gordon said.

Qbiotics said that in pre-clinical studies tigilanol tiglate had been shown to have “multiple inter-related effects that are responsible for its anti-cancer efficacy”.

The company said that “within the first few hours of treatment there is an oncolytic effect on tumor cells resulting in mitochondrial swelling and tumor cell membrane destruction.”

“At the same time, tigilanol tiglate activates specific isozymes of protein kinase C, PKC, resulting in increased permeability of the tumor vasculature leading to tumor vascular destruction,” the company said.

Qbiotics said that a localized inflammatory response was also induced, thereby recruiting and activating innate immune cells, principally neutrophils and macrophages, which then targeted the tumor mass and released “reactive oxygen species, proteases and cytokines that function in an anti-microbial role”.

“This acute inflammatory response generally resolves within two to three days,” the company said.

“Full tumor destruction usually occurs within four to seven days of treatment,” Qbiotics said.

The company said that healthy granulation tissue then filled the newly-created wound bed with full wound closure occurring typically within four to five weeks.

Last week, Qbiotics said it hoped to raise up to $26 million at 60 cents a share for its Australian tropical rainforest-derived anti-cancer and wound healing compounds and was considering a potential ASX listing in 2020 or 2021 (BD: Nov 6, 2018).

Qbiotics is a public unlisted company.

COCHLEAR

Cochlear says it has invested EUR13 million ($A20.3 million) in Nyxoah SA for its hypoglossal nerve stimulation for obstructive sleep apnoea.
Cochelar said that the Mont-Saint-Guibert, Belgium-based Nyxoah was developed and commercialized the “best-in-class hypoglossal nerve stimulation therapy”.
The company did not say what percentage of Nyxoah it would hold, but Nyxoah’s website said that it previously raised EUR18 million ($A28.2 million) in 2016.
Cochlear said that it “actively monitors the market for novel technologies and implantable devices that over the long term may leverage or enhance its core technology”.
The company said the investment formed part of its innovation fund.
Cochlear fell $7.43 or 4.2 percent to $168.02 with 249,574 shares traded.

IMUGENE

Imugene says its 18-patient, dose-escalation, phase Ib HER-Vaxx with chemotherapy trial showed no safety issues and an increase of antibody levels at all dose levels.
Imugene said the “topline phase Ib results” were expected in December 2018.
In 2016, the company said it had begun its phase Ib/II trial of HER-Vaxx for gastric cancer at eight sites in Asia, including Hong Kong, Thailand and Taiwan, testing three doses of HER-Vaxx in combination with standard of care chemotherapy drug cisplatin and either fluorouracil or capecitabine (BD: Nov 7, 2016; Aug 31, 2017; Sep 11, 2018).
Today, the company said the study cohort review committee had selected the recommended dose for the proposed phase II trial of the HER-Vaxx cancer vaccine for gastric cancer patients expected to begin “in early 2019”.
Imugene chief executive officer Leslie Chong said the company was “encouraged by the fact that all vaccinated patients developed increased antibody levels to the HER-2 target protein”.
“Completion of the phase Ib dose escalating trial and start of the phase II study are important milestones for Imugene and the many medical professionals seeking treatments for patients with advanced gastric cancer who often have very few medical options,” Ms Chong said.
Imugene said the 68-patient, phase II study would test the efficacy, safety and immune response in gastric cancer patients with metastatic gastric cancer overexpressing the HER-2 protein.
The company said that the phase II trial would be randomized into two arms of either HER-Vaxx plus standard-of-care or standard-of-care alone, with a primary endpoint of overall survival and a secondary endpoint of progression-free survival.
Imugene said the trial would be conducted at sites across Asia, Eastern Europe and India where there was a high prevalence of gastric cancer, but clinicians and patients had difficulty accessing treatments such as Herceptint and Perjeta.
Imugene was unchanged at 2.1 cents with 28.9 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says it has received $443,605 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Sienna said the rebate related to research and development expenditure for the 2018 financial year.
Sienna was untraded at 8.5 cents.

IDT AUSTRALIA

IDT says it has completed its unmarketable parcel buy back of 659,381 shares held by 598 shareholders at 15.5 cents a share.
In September, the company said it would buy-back up to 10 percent of its shares and provided an unmarketable parcel facility for investors with shareholdings worth less than $500 (BD: Sep 26, 2018).
IDT said the buyback shares had been cancelled.
IDT was up half a cent or 2.9 percent to 18 cents.

FACTOR THERAPEUTICS (FORMERLY TISSUE THERAPIES)

Factor Therapeutics has requested a trading halt “pending an announcement regarding clinical trial results”.
In April 2017, the company began recruitment for its 168-patient, randomized, double-blinded, placebo-controlled, US Food and Drug Administration-directed, phase II trial of VF001 for venous leg ulcers (BD: Apr 7, 2017).
In June the company said it expected to recruit up to 155 patients (BD: Jun 26, 2018).
In 2008, the company, formerly known as Tissue Therapies, began European approval-directed trials in Perth and Toronto of the original wound treatment, then called Vitrogro (BD: Jul 9, 2008).
In 2011, the company said that Vitrogro had demonstrated wound healing in 22 of 24 venous leg ulcers, but in 2013 European regulators changed Vitrogro’s classification from device to medicine (BD: Jul 14, 2011; Mar 18, 2013).
From 2015, the then Tissue Therapies appointed Dr Christian Behrenbruch as an executive director, changed its name to Factor Therapeutics, appointed Dr Rosalind Wilson as its chief executive officer and began the current FDA-directed trial of VF-001 for venous leg ulcers (BD: Oct 12, 2015; Mar 24, Apr 29, 2016; May 22, 2017).
Trading will resume on November 15, 2018 or on an earlier announcement.
Factor Therapeutics last traded at 7.3 cents.

PHARMAUST

Pharmaust says that Catalent Pharma Solutions will provide scaled-up manufacture of good manufacturing practice-grade monepantel tablets for its dog cancer trials.
Pharmaust said the Somerset, New Jersey-based Catalent would manufacture the tablets at its San Diego, California facility for the Australian dose-escalation phase I study in healthy beagles.
The company said the study would determine the numbers of tablets and the optimal frequency of administration to ensure safety and provide information on the optimum dosing levels for the efficacy studies.
Pharmaust said that later phase II studies would “aim to confirm the anti-cancer activity of monepantel capsules in dogs with B-cell lymphoma”.
Pharmaust chief scientific officer Dr Richard Mollard said that “scale manufacture of [good manufacturing practice] grade monepantel tablets is a tremendous milestone”.
“Pharmaust has demonstrated that the tablet prototypes can deliver a significant level of drug within the blood of healthy dogs … [and] is now looking forward to studying the safety and anticancer activity of monepantel at these higher blood levels,” Dr Mollard said.
Pharmaust fell 0.1 cents or 2.4 percent to four cents.

IMUGENE

Imugene's annual general meeting passed all resolutions, but with up to 18.2 percent opposition to the issue of 25,000,000 options to chairman Paul Hopper.
Imugene said that the issue of options to Mr Hopper was supported by 535,704,116 votes with 122,950,981 votes (18.2%) opposed and 17,389,706 votes at the porxy's discretion which were voted for the resolution.
The company said that the issue of 50,000,000 options to chief executive officer Leslie Chong was passed by 647,692,266 votes (95.8%), including proxy discretion, with 28,257,537 votes (4.2%) against.
Imugene said the remuneration report was passed with 547,847,393 votes (84.3%) in favor, including proxy discretion and 102,352,733 votes (15.7%) against.
The company said that the 10 percent placement capacity was opposed by 11.8 percent of the meeting and director Dr Axel Hoos was re-elected unopposed and with 719,285,359 votes in favor.
The company's most recent Appendix 3B said that Imugene had 3,609,845,520 shares on issue meaning that the opposition to Mr Hopper's options amounted to 3.4 percent of the company, not sufficient to requisition extraordinary general meetings.

AUSCANN GROUP

Auscann says it has appointed Philadelphia, Pennsylvania-based PCI Pharma to manufacture its medical marijuana solid, hard-shell capsules for chronic pain.
Auscann said the capsules were expected to be available by July 2019.
The company said that the target market was "the estimated 1.9 million Australians who suffer chronic neuropathic pain" and would be supplied through the Australian Therapeutic Goods Administration special access scheme.
Auscann said that strain improvement cultivation was expected to begin at the Western Australia site it expects to establish in early 2019 with genetics provided by the Smiths Falls, Ontario-based Canopy Growth.
Auscann fell 1.5 cents or 1.8 percent to 80 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has completed the sale of MGC Derma to private marijuana investment company Cannaglobal Canada (BD: Aug 27, Oct 19, 2018).
MGC said that it would receive a 10 percent holding in Cannaglobal and a five year supply agreement.
The company said that Cannaglobal had transferred $C500,000 ($A526,416) for the first order of cannabidiol and cosmetic materials required to manufacture the MGC Derma range.
MGC said that all material conditions for the transaction had been satisfied and it expected the deal to be completed about November 30, 2018.
MGC fell half a cent or 9.8 percent to 4.6 cents with 7.9 million shares traded.