Biotech Daily

Tuesday June 30, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 10%; ACTINOGEN, PATRYS DOWN 8%**

*** RACE: INDEPENDENT MOUSE STUDY BACKS BISANTRENE FOR CANCER**

*** ALTERITY, FDA DISCUSS PHASE II ATH434 MSA STUDY ENDPOINTS**

*** AMPLIA: NO TOXICITIES TO PREVENT AMP945 PHASE I TRIAL**

*** REDHILL: UK APPROVES OPAGANIB PHASE II/III COVID-19 TRIAL**

*** INVION RECEIVES 1st GUILIN PAVAY COSMETICS ORDER**

*** ELLEX COMPLETES $97m LUMIBIRD LASER, ULTRASOUND SALE**

*** ORTHOCELL RECRUITS ORTHO-ATI ROTATOR CUFF TRIAL**

*** ELIXINOL 1.36m OLIVER HORN, HELEN WISEMAN RIGHTS AGM**

*** FACTOR POTENTIAL 2nd STRIKE BOARD SPILL AGM**

*** RESAPP: KENYA'S ILARA HEALTH EVALUATES RESAPPDX**

*** AUSTRALIAN ETHICAL TAKES 12% OF ELLEX**

*** PYXIS TAKES 6% OF LIFESPOT**

MARKET REPORT

The Australian stock market was up 1.43 percent on Tuesday June 30, 2020, with the ASX200 up 82.9 points to 5,897.9 points. Nineteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and one was untraded.

Avita was the best, up 83 cents or 10.2 percent to $9.00, with 719,709 shares traded. Osprey climbed 10 percent; LBT was up 9.5 percent; Alterity improved 6.25 percent; Mesoblast was up 5.2 percent; Amplia, Clinuvel, Genetic Signatures and Medical Developments were up more than four percent; Cyclopharm, Immutep and Impedimed were up more than three percent; Telix, Uscom and Volpara rose more than two percent; Nanosonics, Prescient and Resmed were up more than one percent; with Ellex and Paradigm up by less than one percent.

Actinogen and Patrys led the falls, down 8.3 percent to 2.2 cents and 1.1 cents, respectively, with 2.8 million shares and 886,831 shares traded, respectively. Kazia and Oncosil fell four percent or more; Neuren and Resonance were down more than three percent; Antisense, Compumedics and Pro Medicus shed more than two percent; Cynata, Opthea and Starpharma were down more than one percent; with Cochlear, CSL and Polynovo down by less than one percent.

RACE ONCOLOGY

Race says an independent mouse study has found that bisantrene is one of “two potent small molecules that appear to suppress tumor growth in multiple [resistant] cancers”.

Race said it had “become aware of a publication” by researchers at the Los Angeles based City of Hope Beckman Research Institute, relating to research conducted in relation to bisantrene, which Race was currently investigating in phase II trials for acute myeloid leukaemia.

The company said it “was not involved in, or aware of, the research findings of the manuscript” [but would evaluate] the findings … to determine the extent to which they affect the company and its own research activities”.

The article ‘Targeting FTO Suppresses Cancer Stem Cell Maintenance and Immune Evasion’ was published in the journal Cancer Cell and an abstract is available at: https://www.cell.com/cancer-cell/pdfExtended/S1535-6108(20)30216-6.

A media release from the City of Hope said its scientists identified and developed “two potent small molecules that appear to suppress tumor growth in multiple cancers even when other treatments cease to work, possibly due to the development of drug resistance”.

“Called CS1, or bisantrene, and CS2, or brequinar, these cancer inhibitor compounds are part of a protein known as ‘fat mass and obesity-associated protein’ … [or] FTO, the protein plays a critical role in cancer development and progression, primarily because it regulates cancer stem cells and immune evasion”.

The City of Hope media release said that FTO promoted the growth, self-renewal, metastasis and immune escape of cancer cells.

Researcher Dr Jianjun Chen said that “the cancer inhibitors we developed are at least 10 times more effective in killing acute myeloid leukaemia cells than several previously reported FTO inhibitors.

“In the near future, we should use these two compounds alone or in combination with other therapeutic agents such as targeted therapy, standard chemotherapy, immunotherapy or radiotherapy to treat patients with FTO-high cancers,” Dr Chen said.

The City of Hope said that cancers high in the fat mass and obesity-associated protein included acute myeloid leukaemia, glioblastoma, pancreatic cancer and breast cancer.

The media release said that Dr Chen’s team noted that many cancer patients either do not respond to treatments that are currently available such as chemotherapy, targeted therapy or immunotherapy, or that they respond to the therapeutics in the beginning but relapse later due to cancer-regenerating stem cells and the escape of cancer cells from the body's immune surveillance.

The City of Hope said that modifying FTO or using small molecules to inhibit FTO interrupted the supply chain that enabled cancer to develop and progress.

The media release said that studies showed that treatment with a relatively low dose of CS1 or CS2 of 5mg/kg/day 10 times every second day, could, at the very least, double the median survival in mouse models of acute myeloid leukaemia.

The research articles lead author Dr Rui Su said the mouse study “suggests that combining FTO inhibitor treatment with other therapies will improve patient outcomes because this method will eradicate cancer stem cells and mechanisms that suppress the immune system”.

The City of Hope said that because bisantrene and brequinar had been tested in multiple clinical trials Dr Chen and colleagues believe the basic research had “access to a freeway entrance that will fast track it into clinical trials”.

Race was up 11 cents or 18.6 percent to 70 cents with 1.3 million shares traded.

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Alterity says the US Food and Drug Administration has agreed part of its phase II trial design for ATH434 for multiple system atrophy and they would work on the endpoints.
Last month, Alterity said a phase I trial of ATH434 (previously PBT434) for multiple system atrophy (MSA), a form of atypical Parkinsonism, showed that it crossed the blood brain barrier in humans at levels indicating efficacy (BD: May 21, 2020).
Today, the company said the meeting with the FDA followed the phase I trial last year and further data analysis.
Alterity said the FDA had agreed to the proposed patient population, safety monitoring plan and strategy for evaluating drug exposure, but non-clinical investigations would be required to support the phase II study.
The company said it would work with the FDA to develop an endpoint best suited for patients with multiple system atrophy and it was encouraged to use data from a natural history study planned with the Nashville, Tennessee-based Vanderbilt University Medical Centre.
Alterity said the natural history study would enrol early stage multiple system atrophy patients and assess changes in clinical parameters and biomarkers for up to one year.
The company said it was also pursuing a regulatory pathway in Europe and Australia and given the uncertainty of study conduct and recruitment due to the Covid-19 pandemic, it would target sites that were minimally impacted.
Alterity said planning was underway to meet with European authorities.
Alterity chief medical officer Dr David Stamler said “the FDA clearly recognizes the seriousness of MSA and the need for new treatments to address this devastating orphan disease”.
“Our pre-[investigational new drug application] meeting was very collegial, and I look forward to again collaborating with the Division of Neurology to determine the best development path for ATH434 in the US,” Dr Stamler said.
“With the information obtained from this meeting, we have a clear path forward for conducting our phase II study in MSA,” Dr Stamler said.
Alterity was up 0.1 cents or 6.25 percent to 1.7 cents with 6.1 million shares traded.

AMPLIA THERAPEUTICS

Amplia says preliminary toxicology studies of AMP945 did not identify “any toxicities that are likely to prevent a phase I trial … later this year”.
Amplia said the studies included repeat-dose administration of its focal adhesion kinase (FAK) inhibitor AMP945 in a rodent and non-rodent species and identified ‘no observed adverse effect level’, which could be used to determine the starting phase I dose.
The company said it expected a consolidated report of the studies in late July and subject to ethics committee approval and funding, it planned a six to nine-month phase I trial to be completed by mid-2021.
Amplia said the trial would assess safety, tolerability, pharmacokinetics and pharmacodynamics of AMP945 in both single and multiple doses, with data used to support progression to a phase II trial, expected to begin in late 2021, for patients with solid cancers and/or fibrotic diseases, including idiopathic lung fibrosis.
Amplia chief executive officer Dr John Lambert said the company was “very pleased to receive the final piece of key data from the pre-clinical studies conducted to date”.
“Achieving this milestone marks an important transition for Amplia as we transform the company into a clinical-stage drug development company,” Dr Lambert said.
Amplia was up half a cent or 4.2 percent to 12.5 cents.

REDHILL BIOPHARMA

Redhill says the UK has approved a 270-patient, phase II/III study of opaganib for severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) infection.
Redhill said the UK Medicines & Healthcare Products Regulatory Agency approved the multi-centre, randomized, double-blind, parallel-arm, placebo-controlled study for hospitalized patients with Sars-Cov-2, the cause of Covid-19, and pneumonia.
The company said the study would be conducted at up to 40 clinical sites in the UK, Italy, Russia and other additional countries, with clinical trial authorization applications submitted in Russia and Italy.
Redhill said it would conduct a parallel 40-patient, randomized, double-blind, placebo-controlled phase IIa study of opaganib in the US, but the study was not powered for statistical significance.
The company said patients would be administered either opaganib, an orally administered sphingosine kinase-2 (SK2) selective inhibitor that showed anti-cancer, anti-inflammatory and anti-viral activities, or a placebo alongside standard-of-care therapy.
Redhill said the primary endpoint would be to evaluate the proportion of patients that required intubation and mechanical ventilation by day-14.
The company said an independent data safety monitoring board would conduct an unblinded, futility-only interim analysis when 100 subjects had been evaluated.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
On the Nasdaq, Redhill fell 34 US cents or 4.62 percent to $US7.02 ($A10.20) with 437,809 shares traded

INVION

Invion says it has received its first order for Australian-made photo-active ingredients from the Shanghai-based Guilin Pavay Biotechnology for its cosmetic products.
In February, Invion said it would be paid $250,000 to manufacture and supply active dermatological ingredients to Guilin Pavay Biotechnology through its subsidiary Epitech Dermal Science (BD: Feb 3, 2020).
Today, the company said it had a three-year manufacturing and supply agreement with Pavay to supply photo-active ingredients for use in a range of dermatology products, which would be “test-marketed to Chinese consumers”.
Invion said the agreement could be extended by a further three years.
Invion chief executive officer Craig Newton said the company was “pleased to advance our working relationship with Pavay Biotech, which is in line with our strategy of leveraging the [research and development] expertise of the Invion group”.
“While the initial order is modest in size, we hope that Pavay is successful in its consumer awareness and sales campaigns and that orders increase over time,” Mr Newton said.
Invion was unchanged at 0.8 cents with 5.3 million shares traded.

ELLEX MEDICAL LASERS

Ellex says it has completed the $97.4 million sale of its laser and ultrasound business to Lumibird, will change its name to Nova Eye Medical and its ASX code to EYE.
Ellex chairman Victor Previn said the sale was “a major milestone … and allows us … to focus on the high growth glaucoma consumable device market”.
Ellex fell half a cent or 0.7 percent to 68 cents.

ORTHOCELL

Orthocell says it has completed recruitment of a 30-patient trial of its autologous tenocyte injection Ortho-ATI for rotator cuff tendinopathy and tear.

Orthocell said the study, in collaboration with Johnson & Johnson's Depuy Synthes Products, would assess the effectiveness of Ortho-ATI to treat rotator cuff tendinopathy and tear compared to cortico-steroid injections.

The company said it did not recruit patients who had received previous treatment injections in the past three months, had previous shoulder surgery, had significant pathology of affected shoulder or had bilateral shoulder pathology.

Orthocell said rotator cuff tendinopathy and tear affected more than 50 percent of adults over 50 years of age and could lead to considerable disability, reduced quality of life and missing work.

Last year, Orthocell said it expected the trial to be recruited by July 2019 but today said that the "detailed exclusion criteria caused delays to the anticipated recruitment timeframes … [which was] not reflective of the significant patient population that is normally suitable for treatment with Ortho-ATI (BD: Mar 6, 2019)

Orthocell was unchanged at 31.5 cents with 1.1 million shares traded.

ELIXINOL GLOBAL

Elixinol says it will vote to issue chief executive officer Oliver Horn 1,299,222 performance rights and director Helen Wiseman 62,271 performance rights.

Elixinol said the annual general meeting would vote to issue Mr Horn 937,500 rights, vesting in two equal tranches at six and 18 months from July 30, 2020 and a further 361,722 performance rights as a long-term incentive, vesting on February 28, 2023.

Elixinol said the performance rights to Ms Wiseman related to remuneration as a non-executive director and would vest on February 28, 2024.

The company said it would also vote to elect Mr Horn and Ms Wiseman as directors, to re-elect chair Paul Benhaim, adopt the remuneration report, approve the 10 percent placement capacity, appoint BDO Audit as its auditor and approve leaving entitlements for former directors Andrew Duff and Greg Ellery.

The meeting will be held virtually on July 30, 2020 at 10.30am (AEST).

Elixinol fell half a cent or 3.1 percent to 15.5 cents with 4.7 million shares traded.

FACTOR THERAPEUTICS

Factor says its annual general meeting will vote on its remuneration report and face a potential second-strike board spill.

Last year, Factor said its remuneration report resolution was opposed by 310,288,800 votes (42.7%), providing the first trigger for a potential board spill at this year's annual general meeting (BD: Mar 27, 2019).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election at a subsequent meeting.

Today, Factor said it would vote on a special resolution for a 10 percent placement capacity and to elect Dr David Brookes and re-elect John Michailidis as directors.

The meeting will be held virtually on July 30, 2020 at 10am (AEST).

Factor was unchanged at 0.3 cents with 2.1 million shares traded.

RESAPP HEALTH

Resapp says Kenya's Ilara Health will conduct a three-month evaluation of its Resappdx smartphone application for acute respiratory disease diagnosis.
Resapp said the evaluation would be held at five Kenyan medical facilities and was expected to begin by October 2020.
Resapp was unchanged at 17.5 cents with 1.6 million shares traded.

ELLEX MEDICAL LASERS

Australian Ethical Investment says it has increased its substantial shareholding in Ellex from 15,878,458 shares (11.06%) to 17,532,327 shares (12.21%).
The Sydney-based Australian Ethical said that between June 12 and 25, 2020 it bought 1,653,869 shares for $994,154 or 60.1 cents a share.
Ellex was up half a cent or 0.7 percent to 68 cents.

LIFESPOT HEALTH

Pyxis Holdings says it has become a substantial shareholder in Lifespot with 6,038,192 shares or 6.24 percent.
The Claremont, Western Australia-based Pyxis said that between April 14 and June 29, 2020 it acquired 3,188,192 shares for $107,539 or 3.4 cents a share.
Lifespot was up 0.3 cents or 8.6 percent to 3.8 cents with 1.1 million shares traded.