Biotech Daily

Wednesday December 14, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA, COMPUMEDICS UP 4%**
- GENETIC SIGNATURES DOWN 9%

*** SIRTEX SIR-SPHERES US CANCER NETWORK CONFIDENCE UPGRADE**

*** GI DYNAMICS RAISES $1.5m, PLAN FOR $988k MORE**

*** PRESCIENT DOSES 1st PTX-200 AML PATIENT**

*** TAKEDA USES DIMERIX RECEPTOR-HIT FOR ORPHAN RECEPTORS**

*** UP TO 17% OF BENITEC AGM OPPOSE DIRECTOR DR JOHN CHIPLIN**

*** BIO-MELBOURNE, DR THOMAS LÖNNGREN WORKSHOP BREXIT, TRUMP**

MARKET REPORT

The Australian stock market climbed 0.71 percent on Wednesday December 14, 2016 with the ASX200 up 39.6 points to 5,584.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and three were untraded. All three Big Caps were up.

Avita and Compumedics were equal best, up four percent to 13 cents and 78 cents, respectively, with 209,515 shares and 56,369 shares traded, respectively.

Living Cell and Pro Medicus climbed more than three percent; Orthocell and Starpharma rose more than two percent; Airxpanders, Benitec, CSL, Medical Developments, Mesoblast, Nanosonics, Pharmaxis, Sirtex and Viralytics were up one percent or more; with Cochlear, Opthea and Resmed up by less than one percent.

Genetic Signatures led the falls, down four cents or 9.1 percent to 40 cents with 62,250 shares traded, followed by Psivida down 9.05 percent to $2.11 with 6,375 shares traded.

Bionomics, Factor Therapeutics and Neuren fell more than four percent; Cellmid and Universal Biosensors were down three percent or more; Atcor, Ellex, Oncosil and Prima shed more than two percent; with Acrux and Clinuvel down by less than one percent.

SIRTEX MEDICAL

Sirtex says the use of SIR-Spheres for metastatic colorectal cancer has been upgraded by the US National Comprehensive Cancer Network.

In a media release to the US, where the company is not listed, and a Twitter notice, but not an announcement to the ASX, Sirtex said the latest National Comprehensive Cancer Network clinical practice guidelines in oncology for colon cancer and rectal cancer included yttrium-90 resin microspheres as a category 2a recommended treatment.

Sirtex chief medical officer Dr David Cade told Biotech Daily that although it did not change recommendations for use above last-line salvage use, it provided greater confidence to physicians for the use of the SIR-Spheres.

Dr Cade said that SIR-Spheres were recommended "for metastatic colorectal cancer patients who have failed standard therapy with colorectal cancer confined to the liver or mostly confined to the liver".

Dr Cade said that the NCCN panel had four levels of categories of evidence and confidence from category 1 based on high-level evidence and consensus that the intervention is appropriate through category 2a and 2b to category 3 based on any level of evidence with major disagreement that the intervention was appropriate.

Dr Cade said that category 2a was based on a lower level of evidence but there was uniform consensus that the intervention was appropriate.

The Sirtex US media release said the recommendation "places SIR-Spheres Y-90 resin microspheres at the same designation as the recommended [metastatic colorectal cancer] systemic chemotherapeutic regimens".

Sirtex America chief executive officer Kevin Richardson said that the NCCN guidelines "aim to assist medical teams, patients and their families in making informed treatment-related decisions with the goal of optimal cancer care".

"The 2A designation represents a very important milestone … and provides further validation for the role of our medical device as an important treatment option for unresectable, liver dominant metastatic colorectal cancer," Mr Richardson said.

Sirtex said SIR-Spheres were "the first and only microspheres with FDA premarket approval for colorectal cancer that has metastasized to the liver".

The website of BTG International, formerly the privatized British Technology Group, said it had developed the competitor Therasphere yttrium-90 microspheres, which had FDA authorization as a humanitarian device in radiation treatment or as a neo-adjuvant to surgery or transplantation in patients with unresectable hepatocellular, or liver, cancer, but said "the effectiveness of this device for this use has not been demonstrated".

BTG said that Therasphere was currently the subject of three phase III trials, two of which were being conducted under an FDA investigational device exemption approval.

Sirtex was up 21 cents or 1.3 percent to $16.82 with 938,357 shares traded.

GI DYNAMICS

GI Dynamics says it has commitments to raise $1,537,030 in a private placement at 2.2 cents per Chess depositary interests and hopes to raise $987,910 in a share plan.

GI Dynamics said that the funds "should allow [it] to continue operating … through the 2017 calendar year and allow it time to further solidify its on-going European commercial and United States development options".

The company said that record date for the capped share plan was December 13, 2016, but did not provide the opening and closing dates

GI Dynamics said Bell Potter Securities was the sole lead manager to the placement.

GI Dynamics was up 0.3 cents or 12.0 percent to 2.8 cents.

PRESCIENT THERAPEUTICS

Prescient says the Tampa, Florida-based H Lee Moffitt Cancer Centre has dosed the first of up to 18 patients in its phase Ib/II trial of PTX-200 for acute myeloid leukaemia.
Prescient said the phase Ib study would enrol 15 to 18 patients and was an open-label, dose-escalation study of PTX-200 to determine the dose to be used in combination with cytarabine in the phase II part of the study.
The company said that up to four dose levels would be evaluated, with the initial dose level of 25mg/m2 PTX-200 and each dose level increased by 10mg/m2.
Prescient said doses would be administered for up to four 21-day cycles with safety and clinical activity evaluated at the end of each cycle, as well as the effect of PTX- 200 on Akt signalling, inhibition of proliferation and induction of apoptosis, or cell death.
Prescient was up 0.4 cents or 4.7 percent to 8.9 cents with 7.9 million shares traded.

DIMERIX

Dimerix says that the Tokyo, Japan-based Takeda has used its Receptor-HIT technology to discover new molecules active on an orphan receptor complex.
Dimerix said that Takeda senior scientist Dr Louise Dickson presented the work using its receptor heteromer investigation technology (Receptor-HIT) to help define new G-protein-coupled receptor (GPCR) functions, which could lead to novel therapies, at the British Pharmacological Society meeting in London, December 13 to 15. 2016.
The company said the work for Takeda resulted in the identification of an interaction between S1P1 receptor and an orphan receptor, a GPCR for which no endogenous ligand had been discovered and Takeda's use of the Receptor-HIT technology in a high throughput screening format confirmed the potential to identify new therapeutic agents and tool compounds active against orphan GPCR targets.
The company said that there were about 150 orphan receptors and "considerable potential for Receptor-HIT to open up entire new avenues of drug discovery".
Dimerix chairman Dr James Williams said the program "highlights the broad utility of the Receptor-HIT technology for drug discovery and development … [and was] one example whereby our proprietary discovery technology has been used by the broader pharmaceutical industry in their quest to discover new therapies."
Dimerix was unchanged at 0.8 cents.

BENITEC

Benitec's annual general meeting passed all resolutions, but with up to 17.5 percent opposition to the re-election of director Dr John Chiplin.
Benitec said that 9,180,043 votes (17.5%) opposed Dr Chiplin's re-election, with 41,834,713 votes (79.6%) in favor and 1,366,350 votes ate the proxy's discretion.
The company's most recent Appendix 3B new issue announcement said it had 175,834,915 shares on issue meaning the opposition to Dr Chiplin amounted to 5.2 percent of the company's shares on issue, sufficient to requisition extraordinary general meetings.
The remuneration report and the issue of shares to investors were opposed by more than 4.2 million votes, with the election of director Megan Boston, approval of the 10 percent placement facility and the prior issue of shares to Nant Capital opposed by more than 3.0 million votes, while the issue of new shares to Nant Capital and the election of Nant's Dr Jerel Banks as a director were passed by a wider margin.
Benitec was up 0.1 cents or 1.05 percent to 9.6 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that in its first event for 2017 Dr Thomas Lönngren will explore regulatory and clinical strategies for market access in the EU and US.

The Bio-Melbourne Network said Analytica director and former executive director of the European Medicines Agency Dr Lönngren would engage in "a conversational workshop to explore regulatory and clinical strategies … in the context of the changing global landscape".

The Network said the workshop would provide an outlook for 2017 on emerging trends and give companies the opportunity to present their case studies and questions in a small group setting.

The Bio-Melbourne Network chief executive officer Dr Krystal Evans said that 2016 had been "a turbulent year in the international political landscape, with uncertainty around the potential impact of Brexit and the change in US presidency on the global pharmaceutical and medical technology industry".

Dr Evans said that Dr Lönngren would draw on his past experience at the European Medicines Agency and provide insights from his present role advising pharmaceutical companies on regulatory aspects and market access on drug development.

The Network said that the Bio-Workshop would be held in the Bio-Melbourne Network boardroom at Milton House, 25 Flinders Lane, Melbourne on January 18, 2017, with registration from 11:15am and the workshop from 11.30am until 2pm, including lunch.

To register go to: http://bit.do/thomas-lonngren.