Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: PRIMA UP 9%, CYCLOPHARM DOWN 6%**

*** BENITEC: 'PHASE II EGDR-AS HEAD NECK CANCER TRIAL IN 2018'**

*** US FDA APPROVES CYCLOPHARM PHASE III TECHNEGAS TRIAL**

*** OPTISCAN LAUNCHES VIEWNVIVO PRE-CLINICAL ENDO-MICROSCOPE**

*** MSD: 'INDUSTRY BRIDGE INITIATIVE TO DEVELOP SKILLS'**

*** WUXI TO MANUFACTURE PRIMA IMP321**

*** NOXOPHARM: 'NOX66 DELIVERS IDRONOXIL TO RAT BRAINS'**

*** UNIVERSAL BIOSENSORS EXPECTS 2016 FEDERAL R&D TAX INCENTIVE**

*** GI DYNAMICS GERMAN ENDOBARRIER REIMBURSEMENT PROGRESS**

*** UP TO 22% OPPOSE FACTOR PLACEMENT CAPACITY**

*** UP TO 13% OF VIRALYTICS OPPOSE 666k DIRECTOR OPTIONS**

*** BV HEALTH, NRF, SAGAMORE INCREASE, DILUTED TO 8% OF MACH7**

*** MERCHANT TAKES 7.5% OF ZELDA**

MARKET REPORT

The Australian stock market climbed 1.31 percent on Wednesday November 23, 2016 with the ASX200 up 71.1 points to 5,484.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and one was untraded. All Big Caps fell.

Prima was the best, up 0.3 cents or 8.6 percent to 3.8 cents with 4.3 million shares traded. Impedimed climbed 6.8 percent; Actinogen, Ellex, Neuren and Universal Biosensors were up five percent or more; Pro Medicus was up 4.7 percent; Factor Therapeutics and Living Cell climbed more than three percent; Osprey, Nanosonics and Viralytics rose more than two percent; Bionomics was up 1.35 percent; with Airxpanders and Medical Developments up less than one percent.

Cyclopharm led the falls, down six cents or 5.6 percent to $1.02 with 19,000 shares traded. Benitec fell 4.8 percent; Admedus, Oncosil and Resmed shed more than two percent; Acrux, Avita, Compumedics, Orthocell, Pharmaxis, Polynovo, Prana and Reva were down more than one percent; with Clinuvel, Cochlear, CSL and Sirtex down by less than one percent.

BENITEC BIOPHARMA

Benitec says it hopes to begin a phase II trial of Nantventures epidermal growth factor receptor antisense (EGDR AS) technology for head and neck cancer in early 2018.
In October, Benitec said it would collaborate with Nantventures on a phase II gene-silencing asset for cancer and appointed Nantventures chief investment officer Dr Jerel Banks as a director (BD: Oct 24, 2016).
Today, Benitec chief executive officer Greg West told Biotech Daily that the collaboration deal was expected to be concluded by the end of this year.
In a teleconference today, Benitec said the technology was originally developed at the University of Pittsburgh by Dr Jennifer Grandis.
A 2009 article, co-authored by Dr Grandis, entitled 'Intratumoral Epidermal Growth Factor Receptor Antisense DNA Therapy in Head and Neck Cancer: First Human Application and Potential Antitumor Mechanisms' was published in the Journal of Clinical Oncology.
The article said that 17 assessable patients were treated with no grades 3 to 4 or dose-limiting toxicities noted and a maximum-tolerated dose not reached.
The article said five patients achieved a clinical response, including two complete responses and three partial responses, with two additional patients having stable disease.
The article concluded that "intra-tumoral EGFR AS was safe and resulted in antitumor activity in patients with advanced [squamous cell carcinoma of the head and neck]".
An abstract is available at: https://www.ncbi.nlm.nih.gov/pubmed/19204206.
Mr West said that Nantventures founder Dr Patrick Soon-Shiong was a leader in US biotechnology and had met with President-elect Donald Trump to discuss the industry.
Benitec chairman Peter Francis said the board was in "continual review" and had recently appointed Dr Banks and Megan Boston directors, joining Dr John Chiplin and Kevin Buchi.
Mr West said that $5,683,000 described in the quarterly report as a "research and development grant" was a Federal R&D Tax Incentive, expected by the end of 2016.
Benitec fell half a cent or 4.8 percent to 10 cents with 131,606 shares traded.

CYCLOPHARM

Cyclopharm says the US Food and Drug Administration has approved a special protocol assessment for a phase III trial of its Technegas lung imaging technology.
Cyclopharm managing-director James McBrayer said the company's proposed clinical protocol for the trials, to be known as CYC-009, was agreed without request for clarification or variation and was announced earlier than expected.
The company said that special protocol assessment agreement meant the FDA had reviewed specific elements of its protocol design, including entry criteria, dose selection, endpoints and planned analyses, and agreed that they were acceptable.
Cyclopharm said that the agreement confirmed that the trial protocols would support an application for US regulatory approval of Technegas sales.
The company said the CYC-009 trial would be a non-inferiority structural ventilation protocol comparing Xenon-133 with Technegas in 240 patients, with broad participant selection criteria allowing a more efficient and expeditious completion of the trial .
Mr McBrayer said the agreement confirmed the pathway and strategy for US approval for Technegas was "well and truly on-track … for completion by mid-2018 at a cost of less than $US7 million" with patient enrolment in early 2017.
"Half of all the nuclear medicine departments in the world are located in the US, thus, this is a very exciting and significant development for the continued growth of Technegas which is already sold in 55 countries," Mr McBrayer said.
Cyclopharm fell six cents or 5.6 percent to $1.02.

OPTISCAN

Optiscan says it has launched its second generation pre-clinical research endo-microscope Viewnvivo for internal imaging.

Optiscan said that the 4mm diameter probe Viewnvivo was “a miniaturized fluorescence endo-microscope platform” combining imaging capability with flexibility for pre-clinical research.

The company said that Viewnvivo users could capture high resolution, real-time, in-vivo images with sub-micron detail and view them for faster pre-clinical research insights.

Optiscan said that Viewnvivo was “a significant improvement to the existing competitor’s product offering in the research market providing major benefits including stunning image quality, interactive and continuously variable imaging depth control, greater sensitivity for even better image capture, validated capability, miniaturized without sacrificing image resolution, real-time in-vivo insight, flexibility of operation, no dedicated technician or facility required, self-calibration and simplicity ensures immediate usability, patented technology, [and] acceleration of research capability.”

The company said that its pre-clinical research products general manager Andrew Froude had begun the process of sales generation, with the first installations of Viewnvivo to take place by July 2017.

Mr Froude told Biotech Daily that the Viewnvivo could be used for investigating tissue in any space that could take the 4mm probe, including gastro-intestinal, large animal blood vessels and into cavities through key-hole surgery.

Optiscan said it was “confident that Viewnvivo will secure a significant share of the applicable global pre-clinical research products market and has the potential to make a positive contribution towards … earnings”.

Optiscan was up 0.4 cents or 6.9 percent to 6.2 cents.

MERCK SHARP AND DOHME

Merck Sharp and Dohme says pharmaceutical companies with Medicines Australia have set up the Bridge Initiative to develop commercialisation skills.

Merck said the $1 million program two-year program would be funded from a consortium of pharmaceutical, venture capital and other organisations, matched by the Medical Technologies and Pharmaceuticals Industry Growth Centre, or MTP Connect, to improve the skills and capabilities in the Australian biopharmaceutical research sector.

The company said that participating organizations included Abbvie, Boehringer Ingelheim, Celgene, CSL, Johnson & Johnson, Mundipharma, Novartis; the Australian Private Equity and Venture Capital Association, Brandon Capital Partners, Macquarie University and Queensland University of Technology.

Merck said that the program would assist companies progress to clinical trials, navigate the regulatory system, take a product to market and promote it.

The company said about 100 people would complete the program each year and a call for participants from start-ups and science entrepreneurs was imminent.

Merck said the Program would “enable Australia to more effectively capitalize on our world class medical research sector, by providing early stage entrepreneurs and scientists with … insights from leaders in key organisations along the commercialisation pathway”.

The company said that the Bridge Program would be targetted at the staff of small scale Australian companies, universities and academic institutes involved in biomedical research focused on drug development and it was expected that most participants would be scientists and entrepreneurs with an active interest in translational research and commercialization.

PRIMA BIOMED

Prima says it has signed a memorandum of understanding with Wuxi Biologics to form a strategic biologics development and manufacturing partnership.

Prima said that Wuxi Biologics was part of the Shanghai, China-based Wuxi Apptec group and a leading open-access research and development capability and technology platform company expediting biologics development.

The company said that Wuxi would be the exclusive clinical and commercial manufacturer for its cancer immunotherapy IMP321, excluding any manufacturing for the supply of mainland China, Macau, Taiwan and Hong Kong where rights were retained by Eddingpharm.

Prima said that Wuxi would be the preferred partner to manufacture potential new products.

Prima chief executive officer Marc Voigt said that securing the supply of IMP321 was “a key component of our commercial development strategy”.

“Wuxi Biologics have consistently delivered the highest quality materials for our clinical trials,” Mr Voigt said.

“This MOU further strengthens our important strategic partnership,” Mr Voigt said.

Wuxi Biologics chief executive officer Dr Chris Chen said his company was “honored to play a critical role to enable small and mid-size companies to realize commercialization via Wuxi’s innovative bio-manufacturing network based on state-of-the-art disposable manufacturing technology”.

“We are committed to producing the highest quality biologics to ensure robust global supply to patients worldwide,” Dr Chen said.

Prima was up 0.3 cents or 8.6 percent to 3.8 cents with 4.3 million shares traded.

NOXOPHARM

Noxopharm says its NOX66 technology successfully delivers high levels of the experimental anti-cancer drug idronoxil to the brain in rats.

Noxopharm said the blood-brain barrier was a robust barrier that excluded foreign chemicals from accessing brain tissue.

The company said the barrier served “a vital protective function to protect the brain from potentially harmful compounds, [but] it also inadvertently prevents many drugs from accessing the brain that are intended to deliver a therapeutic benefit”.

Noxopharm said that previous animal studies were reported to have shown negligible penetration of the blood-brain barrier by idronoxil, a feature it shared with other compounds of the same chemical class, limiting their usefulness to treat brain cancers.

The company said a rat study showed that delivering idronoxil in the form of NOX66 led to high levels of idronoxil in the brain, comparable to levels in the rest of the body, and that those levels were sustained for up to 24 hours, an important factor in treating cancers with the aggression of brain cancers.

Noxopharm chief executive officer Dr Graham Kelly said that “it would be difficult to overstate the importance of this development”.

“At the most obvious level it opens up the opportunity to use idronoxil to make all forms of cancers of the brain to respond more profoundly to chemotherapy and radiotherapy,” Dr Kelly said.

“While we have been focusing largely on cancers such as prostate and lung cancer, brain cancer has been an active area of pre-clinical research for us and this finding now gives that work additional impetus to come into the clinic,” Dr Kelly said.

Noxopharm was up 2.5 cents or 3.85 percent to 67.5 cents with 5.9 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it expects to be eligible for a Federal Government R&D Tax Incentive of more than $5 million for the year to December 31, 2016.

Universal Biosensors said that based on prevailing exchange rates and its aggregate turnover at the end of October 2016, it expected to be eligible for the cash refund for 45 percent of eligible expenditure on research and development, if the aggregate annual turnover of the entity was less than $20 million.

Recently the Federal Coalition Government with support of the Australian Labor Party opposition approved a reduction in the rate to 43.5 percent for expenses in income years starting on or after July 1, 2016 (BD: Sep 2, 2016).

Universal Biosensors chief financial officer Salesh Balak told Biotech Daily that the company would be assessed at 45 percent for the year to December 31, 2016 and if the company qualified, would be assessed at 43.5 percent for the following years.

Universal Biosensors said it recently received $9.36 million in cash under the R&D Tax Incentive program for the year to December 31, 2015 based on a research and development spend of $19.8 million.

The company said that for the nine months to September 30, 2016 it had a research and development spend of $11.8 million which, if eligible, would equate to R&D Tax Incentive of $5.3 million to that date.

Universal Biosensors was up 1.5 cents or 5.1 percent to 31 cents.

GI DYNAMICS

GI Dynamics says it is making progress to full reimbursement for its Endobarrier for obesity and type 2 diabetes in Germany.

GI Dynamics said that Germany was the second largest market for medical technology in the world and a high priority, with German hospitals making legal progress against resistance to Endobarrier reimbursement.

The company said that recent court decisions reinforced the assertion that payers must support new technology payments for Endobarrier procedures.

GI Dynamics said that an arbitration court ruling had denied payments for Frankfurt Sachsenhausen Hospital based on the argument that the available clinical evidence did not support Endobarrier's treatment efficacy.

The company said that the State Government of Hessen rejected the court ruling and confirmed that a paper from three German medical societies was sufficient evidence to support payment and outlined efficacy for obesity and type 2 diabetes, which was reinforced in a statement by the German Diabetes Society in 2015.

GI Dynamics chief executive officer Scott Schorer said that the "legal victories underscore the strong clinical and healthcare system support for Endobarrier".

"We appreciate that the hospitals and court system are willing to work through the facts and support the correct administration of … new technology payments".

"Multiple hospital systems have taken the time-consuming action of advocating strongly for Endobarrier reimbursement," Mr Schorer said.

"These legal actions, together with strong combined consensus support from the German Diabetes Association, the German Society for General and Visceral Surgery, and the German Society for Digestive and Metabolic Diseases underscore the significance of Endobarrier as a unique treatment option for patients suffering from type 2 diabetes and obesity," Mr Schorer said.

GI Dynamics fell 0.3 cents or 10.7 percent to 2.5 cents.

FACTOR THERAPEUTICS

The Factor Therapeutics annual general meeting faced 64,610,146 votes (22.19%) against the placement capacity, with 226,548,202 votes (77.81%) in favor.
All other resolutions were passed overwhelmingly.
Factor Therapeutics most recent Appendix 3B new issue announcement said the company had 730,042,783 shares on issue, meaning that the votes against the placement capacity was 8.85 percent of the company, sufficient to requisition general meetings.
Factor was up 0.3 cents or 3.85 percent to 8.1 cents.

VIRALYTICS

Up to 13.4 percent of Viralytics annual general meeting opposed the grant of 666,000 options to chairman Paul Hopper and directors Dr Leonard Post and Peter Turvey.
In October, Viralytics said the options would vest in three tranches over three years from issue and be exercisable within five years at the 5-day volume-weighted average price to the date of the annual general meeting (BD: Oct 21, 2016).
The strongest opposition vote was against Mr Turvey's 200,000 options with 14,322,611 votes (13.4%) opposed and 90,744,363 votes (84.7%) in favor with 2,013,781 votes at the proxy's discretion, while the grant of 300,000 options to Mr Hopper and 200,000 options to Dr Post were passed by a slightly wider margin.
The resolution to renew the placement capacity was opposed by 9.8 million votes with 95.1 million in favor, with the equity incentive plan and remuneration opposed by similar margins, with Mr Turvey re-elected as a director overwhelmingly.
The company's most recent Appendix 3B new issue announcement said that Viralytics had 240,290,419 shares on issue, meaning that the largest opposition vote amounted to 5.96 percent of the company, sufficient to requisition extraordinary general meetings.
Viralytics was up 2.5 cents or 2.2 percent to $1.175.

MACH7 TECHNOLOGIES

BV Healthcare, NRF and Sagamore say they have increased and been diluted in Mach 7 from 80,451,412 shares (8.99%) to 83,849,912 shares (7.71%).
The Singapore-based BV Healthcare II Pte Ltd and NRF Holdings Pte Ltd and the Owings Mills, Maryland-based Sagamore Healthcare I LP said they acquired 3,398,500 shares at a deemed price of four cents a share "in lieu of interest accrued on a loan and in consideration for extending the repayment date of the loan" and were diluted in last week's $9 million placement at four cents a share (BD: Nov 16, 2016).
Mach7 fell 0.3 cents or 6.25 percent to 4.5 cents with 1.7 million shares traded.

ZELDA THERAPEUTICS

The Perth, Western Australia-based Merchant Funds Management says it has become a substantial shareholder in Zelda with 50,000,000 shares (7.47%).
Merchant Capital said it acquired the shares for $1,000,000 or two cents a share through a convertible note, prior to the initial public offer at 2.5 cents a share.
Zelda fell 0.1 cents or 4.35 percent to 2.2 cents with 3.9 million shares traded.