Biotech Daily

Thursday May 18, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.82 percent on Thursday May 18, 2017 with the ASX200 down 47.7 points to 5,738.3 points. Seven of the Biotech Daily Top 40 stocks were up, 24 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Impedimed was the best, up 21 cents or 38.9 percent to 75 cents with 2.3 million shares traded. Dimerix climbed 7.1 percent; Avita was up 5.9 percent; Prima and Psivida were up more than three percent; Orthocell rose 2.6 percent; with Admedus up 1.75 percent.

Sirtex led the falls, down $4.25 or 28.3 percent to $10.75 with 2.8 million shares traded. Atcor lost 17 percent; Factor Therapeutics fell 7.8 percent; Benitec, Compumedics, Genetic Signatures and Opthea were down more than six percent; both Oncosil and Polynovo fell 4.35 percent; Cellmid, IDT and Nanosonics were down more than three percent; Airxpanders, CSL, Medical Developments, Mesoblast, Pro Medicus and Starpharma shed more than two percent; Ellex, ITL, Neuren, Pharmaxis, Prana, Resmed, and Reva were down more than one percent; with Clinuvel and Cochlear down by less than one percent.

SIRTEX MEDICAL

Four abstracts published at the American Society of Clinical Oncology meeting give mixed results but some efficacy for Sirtex yttrium-90 SIR-Spheres for liver cancer.

None of the studies show a statistically significant improvement in the primary endpoints of overall survival or progression-free survival, although a phase II trial showed an "association" with longer survival when SIR-Spheres were combined with sorafenib.

A fourth abstract investigating the 2015 Sirflox study data said the addition of selective internal radiation therapy (Sirt) to Folfox chemotherapy "significantly increased the gain in resectability of primarily unresectable colorectal cancer liver metastases".

The key meta-analysis of 1,103 patients in three phase III trials showed the addition of SIR-Spheres to first-line oxaliplatin-fluorouracil chemotherapy for patients with liver-only and liver-dominant metastatic colorectal cancer "did not improve [overall survival] or [progression-free survival]", but did lead to "higher response rates and improved liver-specific [progression-free survival]".

The 18-author, UK, Europe, US and Australia study abstract examined the Foxfire, Sirflox and Foxfire-Global trials of first-line chemotherapy for metastatic colorectal cancer with and without Sirt for prospective, combined analysis of overall survival.

The abstract reported "no difference in [overall survival] … between arms", with the objective response rate ($p = 0.001$) and liver-specific progression ($p < 0.001$) more favorable in the Sirt arm, with a "higher risk of non-liver progression as first event" ($p < 0.001$), more common grade 3 to 5 adverse events ($p = 0.009$) and no significant difference in health status questionnaires at six, 12 or 24 months.

The abstract is at: http://abstracts.asco.org/199/AbstView_199_184921.html.

The 360-patient phase III Singapore-based trial of Sirt versus sorafenib in locally advanced hepatocellular carcinoma (Sirvenib) study concluded that "there were no statistically significant differences in [overall survival] between Y90 and sorafenib"

The Sirvenib abstract concluded that "Asian patients with locally advanced [hepatocellular carcinoma] without extra-hepatic metastasis treated with Y90 have statistically significant better [tumor response rates] and fewer [serious adverse events] when compared with those treated with sorafenib".

The abstract is at: http://abstracts.asco.org/199/AbstView_199_187604.html.

A third abstract reporting a phase II study of sorafenib and yttrium-90 glass microspheres for advanced hepatocellular carcinoma concluded "that combined use of sorafenib and Y90 was tolerable and was associated with longer [overall survival] and [progression-free survival] compared to previous studies which evaluated sorafenib alone" and future randomized phase III studies were warranted to assess sorafenib with and without yttrium-90 in metastatic disease.

The abstract is at: http://abstracts.asco.org/199/AbstView_199_192654.html.

The fourth report was the 'Resect: Blinded assessment of amenability to potentially curative treatment of previously unresectable colorectal cancer liver metastases after chemotherapy [with and without Sirt] in the randomized Sirflox trial' (BD: Mar 17, 2015).

The abstract said that at follow-up, "significantly more patients in the Sirt arm had resectable [liver metastases]" with 93 patients (38.11%) compared to 66 patients (28.95%) ($p < 0.0001$) and 67 patients (31.16%) deemed unresectable in the Sirt arm compared to 46 patients (22.66%) in the chemotherapy alone arm, converted to resectability.

The abstract concluded that the addition of Sirt to Foflox "significantly increased the gain in resectability of primarily unresectable" colorectal cancer liver metastases compared with chemotherapy alone.

The abstract is at: http://abstracts.asco.org/199/AbstView_199_192262.html.

Sirtex fell $4.25 or 28.3 percent to $10.75 with 2.8 million shares traded.

BIOTECH DAILY COMMENT

Generally the failure to meet primary efficacy endpoints and especially to show improvement over the current treatment means that it's back to the drawing board. Safety without efficacy is meaningless.

Two decades ago, an oncology researcher flippantly said that more than 90 percent of chemotherapy not only doesn't work, but does harm to the patient in the last weeks and months of their lives. Asked to clarify his statement he said it was more than 93 percent. For some cancers, chemotherapy does work. For others, such as pancreatic, ovarian, liver and lung cancers, the results are less clear.

The oncology researcher said that doctors were under pressure to do what they could to save their patients and extend their lives.

Sometimes the pressure is from the patient and the family, sometimes it is the medical environment, not to mention biotechnology and pharmaceutical companies eager to try out potentially profitable and possibly efficacious new treatments.

Having lost several friends in recent years to pancreatic and liver cancer, this writer is adamant that if ever diagnosed with those diseases there will be no chemotherapy, but a single injection of a radiation treatment would not be rejected.

The evidence built by Sirtex and its raft of studies is convincing: you won't get any more time on the planet, but the pain and discomfort of the cancer won't be exacerbated by toxic chemotherapy.

David Langsam
Editor

VICTORIA GOVERNMENT

The Victoria Government says the Melbourne Biomedical Precinct has a partnership with the Shanghai Institute of Medical Quality.

A media release from Victoria Premier Daniel Andrews said that jobs would be created in the pharmaceutical, medical and biotechnology sectors.

The Victoria Government said that the Chinese partnership would open opportunities for Victorian companies, universities and research institutes.

The media release said that Mr Andrews signed the agreement in Shanghai yesterday, during an official visit to China and Hong Kong.

The State Government said that the Parkville-based, Melbourne Biomedical Precinct included the Victorian Comprehensive Cancer Centre, Peter MacCallum Cancer Centre, the University of Melbourne and Melbourne Health and had a strong focus on cancer treatment.

The media release said that the agreement would enable the sharing of expertize in health care and patient safety and investment in Victorian medical breakthroughs and technology development.

The Government said that an annual training program to advance patient treatment outcomes would be led by Melbourne Biomedical Precinct partners and from October, Chinese medical practitioners, senior nurses and hospital executives would visit Melbourne for training in health care including cancer treatment, new technologies and hospital management tools.

"Victoria is a global leader in health care, medical technologies and pharmaceuticals and today's agreement paves the way for faster development and commercialisation into China and that means jobs for Victorians," Mr Andrews said.

OSPREY MEDICAL

Last night's edition incorrectly assessed Osprey's immediate target market as $124 million a year, when the correct amount is $621.4 million a year.

In a stockbroker meeting yesterday Mr McCormick said that there were 1.3 million chronic kidney disease procedures in the US and Western Europe each year, of which about 20 percent had contrast-induced acute kidney injury.

The reporter used the 20 percent figure rather than the total addressable market of 1.3 million people a year requiring reduced cardiac dye and has apologized for the error.

Osprey was untraded at 41 cents.

PRO MEDICUS

Pro Medicus says its US subsidiary Visage Imaging has launched Visage 7 Open Archive for fast image access in North America

Pro Medicus said the Open Archive was in use at large-scale sites outside the US, delivering "ultrafast access to images and industry-leading scalability all within a modular, open standards framework".

Visage Imaging co-founder Dr Malte Westerhoff said the archive was "an integral part of an enterprise imaging strategy, so it too must have the necessary performance, interoperability and scalability".

"We have been able to achieve this with Visage 7 Open Archive by utilising the same enterprise imaging platform that has made Visage 7 so successful, whilst at the same time ensuring that it is open standards based," Dr Westerhoff said.

Pro Medicus chief executive officer Dr Sam Hupert said that "to date, we have replaced more than 40 legacy [picture archiving and communication systems] and have successfully integrated to numerous legacy and third-party vendor neutral archives".

Pro Medicus fell 13 cents or 2.45 percent to $5.17.

GI DYNAMICS

GI Dynamics says its Conformité Européenne (CE) mark for its Endobarrier duodenal insert has been suspended for breeches of its quality management system.

In 2016, the Australian Therapeutic Goods Administration cancelled the Endobarrier listing on the Australian Register of Therapeutic Goods saying it had "failed to provide adequate evidence of compliance with certain provisions of the TGA Essential Principles within the required 20 working days" (BD: Sep 14, Oct 24, 2016)

Today, GI Dynamics said that the CE Mark had been suspended "pending closure of non-conformances related to its quality management system required under ISO 13485:2003 and 93/42/EEC".

GI Dynamics chief executive officer Scott Schorer said the action did not "call the safety and efficacy of Endobarrier into question and this action does not constitute a recall".

"We are working swiftly to address issues within our quality management system … [and] we will have these non-conformances resolved and have our CE mark reinstated as quickly as possible," Mr Schorer said.

GI Dynamics said the new management had been working to address these and other issues and it had shipped sufficient inventory to customers to ensure uninterrupted service during the suspension.

The company said that all implanted patients could continue treatment subject to normal on-going evaluation and monitoring.

GI Dynamics rose 0.8 cents or 19.05 percent to five cents with 2.1 million shares traded.

AVITA MEDICAL

Avita says it achieved both co-primary endpoints in its pivotal clinical trial of Recell spray-on skin for burns, with “supportive results from a previous burns trial”.

Avita said the data would be submitted to the US Food and Drug Administration for pre-market approval of the Recell autologous cell harvesting device for severe burns.

The company previously said the device takes skin grafts and minces them in a liquid suspension so they can be sprayed onto an open wound.

Avita said it was focused on completing the remaining non-clinical data needed for the submission, which was expected in mid-2017, with approval by July 2018.

The company said that the 30-patient trial was conducted at seven US burn centres between 2015 and early 2017, with endpoints designed to demonstrate the effectiveness of Recell when combined with widely meshed or expanded skin grafting in the closure of deep-partial and full-thickness burn injuries.

Avita said the first co-primary effectiveness endpoint gauged superiority of donor skin expansion, to resolve whether using Recell could lead to less donor skin being needed.

The company said that the difference in donor skin expansion with Recell was significant ($p < 0.001$) and resulted in use of an average of 30 percent less donor skin than the control and a commensurate reduction in donor site size.

Avita said that the second co-primary effectiveness endpoint was the incidence of healing within eight weeks, which was similar in both groups with Recell “found to be statistically non-inferior relative to conventional treatment”.

The company said there was no statistical difference on the three secondary endpoints of patient preference of scar outcomes, along with patient and blinded-observer overall opinion ratings using a standardized scar assessment scale.

Avita said that “it was encouraged by the equivalent secondary endpoint data because more expanded meshed skin grafts are expected to result in a worse long-term scar outcome, but this was not the case with the adjunctive use of Recell with these autografts”.

The company said that the US Biomedical Advanced Research and Development Authority (BARDA) supported the clinical development of Recell through a $US61.9 million contract and completion of the trial was a major milestone.

Avita said that a second US trial of 101 burns patients compared the effectiveness of the Recell suspension alone, to that of conventional meshed autografting on partial-thickness injuries and showed superiority in healing of donor sites used for Recell and superiority of scar outcomes in terms of height, but “did not show statistical non-inferiority of burn injury healing using Recell compared to standard treatment, although analysis of the group concluded this outcome was due to post-operative care, rather than treatment”.

The company said the results could support its pre-market application by providing additional safety and effectiveness information.

Avita head of clinical development said that both studies “validate our broader view that this unique regenerative approach will transform the way burns are treated in the US, a sector that has been starved of innovation for many years”.

Avita chief executive officer Adam Kelliher said the data readout from a total of 131 burns patients evaluated under randomized controlled settings “takes us one step further along the approval pathway”.

“The Avita team will now push ahead with completing and submitting the [FDA pre-market approval application] our next big milestone as we work towards launching Recell into the US,” Mr Kelliher said.

Avita was up half a cent or 5.9 to nine cents.

IMPEDIMED

Impedimed says its L-Dex lymphoedema test can reduce the rates of incidence to three percent from the generally reported seven to 36 percent rate.

Impedimed said the independent six-year, 596 patient Nashville study followed breast cancer patients at risk for the development of lymphoedema and would be presented at the American Society of Clinical Oncology meeting in Chicago in June, 2017.

The company said the analysis used L-Dex to identify patients with early or subclinical indications for the development of breast cancer-related lymphoedema and those who developed an elevated L-Dex score relative to their pre-surgical baseline score, were prescribed an over-the-counter compression sleeve to use for four weeks.

Impedimed said that at the last follow-up, 18 of the 596 patients (3.0%) had unresolved clinically significant breast cancer-related lymphoedema requiring complete decongestive physiotherapy, a surrogate for the development of clinically significant, chronic breast cancer-related lymphoedema.

The company said the results showed breast cancer-related lymphoedema rates "substantially lower than the seven percent to 36 percent rates, and as high as up to 50 percent rate in patients receiving aggressive treatment for breast cancer, generally reported in contemporary studies where patients were not prospectively surveilled for the development of [breast cancer-related lymphoedema]".

The study's author Dr Pat Whitworth said that although "guidelines encourage prospective screening and intervention for [breast cancer-related lymphoedema], the methods previously available could not detect tissue changes at a preventable stage".

"For the first time, this technology makes early detection, simple intervention and prevention of clinical [breast cancer-related lymphoedema] possible," Dr Whitworth said.

Impedimed climbed 21 cents or 38.9 percent to 75 cents with 2.3 million shares traded.

COGSTATE

Cogstate says it has been chosen as a preferred provider for Eli Lilly and Co for its Alzheimer's disease platform.

Cogstate said it would provide services to ensure high-quality neuropsychological outcome measures in clinical trials and the two companies would deploy a program to improve the way that research sites train and collect endpoint data across Lilly's portfolio of Alzheimer's disease studies.

Cogstate was up two cents or 2.5 percent to 81 cents.

ATCOR

Atcor says it expects revenue for the year to June 30, 2017 to be $4.3 to $5.0 million, compared with $5.0 million in the previous year and the previous $6 million estimate.

Atcor said that US non-pharmaceutical company revenues were expected to increase by 15 to 25 percent despite the slower than anticipated uptake by clinicians.

The company said that sales of its Sphygmocor central blood pressure system to pharmaceutical companies was forecast to be about $1.0 million lower than the previous corresponding period due to the absence of major new hypertension drug trials for more than three years.

Atcor said a strategic review was underway to evaluate all options including joint ventures, licencing, acquisitions, sale or other capital solutions.

The company said it was likely to raise more capital in the year to June 30, 2018.

Atcor fell 0.9 cents or 17.0 percent to 4.4 cents.

UNIVERSITY OF WOLLONGONG

The University of Wollongong Faculty of Science, Medicine and Health says it has launched an on-line Graduate Certificate in Regulatory Science.
The University said that the certificate focused on regulatory affairs in Australian and the European Union, with specific attention on the biotechnology and medical devices fields.
The University said that the first intake would begin on July 24, 2017.
The Faculty admissions officer Alexandra Breitsameter said the certificate had been "designed by industry experts to provide real life case studies from authentic experiences".
"Students will learn about the framework in which regulatory affairs is conducted by examination of the origins and current methodologies implemented by host regulatory authorities," Ms Breitsameter said.
"It also examines the essential integration of quality management principles for effective execution of regulatory affairs," Ms Breitsameter said.
"Students will develop knowledge and skills in the requirements for regulatory oversight throughout the product placement, post market vigilance and monitoring phases of the product life cycle … [and] develop strategies to balance business objectives and compliance with regulatory requirements through the identification of risks and unknowns with marketing strategies," Ms Breitsameter said.
For information email Ms Breitsameter at abreitsa@uow.edu.au, or call +612 4221 5781, or go to: https://coursefinder.uow.edu.au/postgrad/regulatory-science/index.html.

G (GEVA) MEDICAL INNOVATIONS

G Medical has requested a trading halt pending an announcement on an agreement that will provide additional funding and distribution of its products and services.
Last week, the Grand Cayman Island-based G Medical raised $12 million in its initial public offer at 20 cents a share to list on the ASX and commercialize its mobile telephone electronic health devices (BD: May 10, 2017)
Trading will resume on May 22, 2017 or on an earlier announcement.
G Medical last traded at 19 cents.

VOLPARA

Volpara chief executive officer Dr Ralph Highnam has increased and has been diluted in the company from 15,632,298 shares (12.76%) to 18,180,634 shares (12.52%).
Dr Highnam said that he exercised 2,548,336 options for $NZ7,645 ($A7,105) or 0.028 cents a share.
Last year, Volpara raised $10 million at 60 cents a share (BD: Nov 22, Dec 20, 2016).
Volpara fell three cents or 8.6 percent to 32 cents.

GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 227,544,113 shares (40.79%) to 233,420,319 shares (41.84%).
The London and Guernsey Island-based Crystal Amber Fund said that between May 1 and 17, 2017 it bought 5,876,206 shares for $371,558 or 6.3 cents a share.

SIRTEX MEDICAL

Sirtex says its US chief executive officer Kevin Richardson “has ceased employment with the company, effective immediately”.
Sirtex Australia’s interim chief executive officer Nigel Lange thanked Mr Richardson for “his commitment to the business over the last seven years” and said Tom Payne had been appointed acting vice president of sales, effective immediately.
Mr Lange said that Mr Payne had more than 30 years of executive experience within the medical device industry “and is a welcome addition to our Americas sales team”.
Sirtex said it would conduct a search for a US chief executive officer.

STEMCELL UNITED (FORMERLY ON Q GROUP)

Stemcell United says it hopes to raise up to $25 million in a placement at 10 cents a share to sophisticated investors.
The Sydney-based Stemcell mentioned the capital raising in the last paragraph of an announcement on two other issues and said the funds would be used for working capital, corporate investments and developments, including the dendrobium business and exploring opportunities in cannabis business.
Stemcell announced its foray into medical marijuana in March 2017, having changed its name in 2015 from On Q Group, which was the subject of a deed of company arrangement.
Today, the company said it intended to cooperate with Ican Israel-Cannabis “in respect of its business operations in Asia” and take a five to 10 percent stake in Ican, subject to due diligence and agreed pricing being agreed.
Stemcell said that Ican was an “advisory and originator in relation to the development and commercialisation of medical cannabis product and their delivery methods and related devices”.
The company said a fee of 20,000,000 shares and 20,000,000 options exercisable at 20 cents each would be payable to the advisors for introducing and facilitating the deal.
Stemcell said that it had recorded its first revenue from sale of dendrobium product, which was the stated focus when On Q Group acquired Stemcell United PTE.
In its prospectus of June 29, 2015, On Q Group said it would extract Resina from Daemonorops draco blume (Dragon’s Blood) for traditional Chinese medicines.
On Q Group said that “whether or not [traditional Chinese medicine] is believed, studies have shown that Chinese herbal medicine can be successful in treating a range of disorders”.
The company said it would begin marketing of its dendrobium essence-infused mask by July 2017 and was in discussion with a Chinese pharmaceutical company on providing consultancy services for manufacturing resina.
Stemcell was unchanged at 13.5 cents with 1.2 million shares traded.