Biotech Daily

Tuesday March 25, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ATCOR UP 8%, ANTISENSE DOWN 7%**

*** SIRTEX, GUERBET COLLABORATE ON LIVER CANCER TRIALS**

*** INNATE READY FOR PHASE IIb MIS416 MULTIPLE SCLEROSIS TRIAL**

*** PHARMAUST LODGES ETHICS APPLICATION FOR PPL-1 CANCER TRIAL**

*** VIRAX RAISING $3m FOR PATHWAY GGTI-2418**

*** PERPETUAL BUYS 15m RESMED SHARES, UP TO 7%**

*** BUCHAN APPOINTS REBECCA WILSON CEO**

MARKET REPORT

The Australian stock market fell 0.19 percent on Tuesday March 25, 2014 with the S&P ASX 200 down 10.3 points to 5,336.6 points.

Seven of the Biotech Daily Top 40 stocks were up, 23 fell, seven were unchanged and three were untraded. All three Big Caps fell.

Atcor was the best, up one cent or 8.3 percent to 13 cents with 194,405 shares traded.

Medical Developments and Viralytics climbed more than four percent; Anteo rose two percent; with Alchemia, Genetic Technologies and Universal Biosensors up more than one percent.

Antisense led the falls, down 1.5 cents or 6.98 percent to 20 cents with 1.5 million shares traded, followed by Tissue Therapies down 6.85 percent to 34 cents with 180,600 shares traded.

IDT lost 5.6 percent; Benitec, Clinuvel, Mesoblast, Osprey and Phosphagenics fell more than four percent; Cellmid, Living Cell, Optiscan and Starpharma were down more than three percent; Acrux, Bionomics, Neuren, Prima, QRX and Reva shed more than two percent; Nanosonics, Patrys, Prana and Resmed were down more than one percent; with Cochlear, CSL, GI Dynamics and Sirtex down by less than one percent.

SIRTEX MEDICAL

Sirtex says it will collaborate with the Paris, France-based medical imaging company Guerbet SA on primary and secondary, or metastatic, liver cancer trials.

Sirtex said that the objective was to examine how Sirtex's SIR-Spheres microspheres and Guerbet's Lipiodol might be combined or sequenced optimally and further developed to address the significant unmet clinical need in patients with hepatocellular carcinoma, metastatic colorectal cancer, metastatic neuro-endocrine tumors and a range of other primary and secondary liver cancers.

Sirtex chief executive officer Gilman Wong said that "Sirtex's and Guerbet's shared vision is that one day, rather than being a terminal disease that patients unfortunately die from, liver cancer may be considered a chronic disease that patients can successfully live with".

"During my time at Sirtex I have been fortunate to meet a number of patients who have survived their liver cancer for many years following treatment with SIR-Spheres microspheres," Mr Wong said.

"We hope through this clinical studies collaboration to make further gains for the benefit of the patients afflicted by liver cancer," Mr Wong said.

"Should the initial collaboration prove fruitful, future collaborations in [research and development] and marketing between our respective companies may be considered," Mr Wong said.

Sirtex said its SIR-Spheres were used in selective internal radiation therapy, also known as radio-embolization, for the treatment of patients with inoperable liver tumors.

The company said that Guerbet's Lipiodol Ultra Fluid was used in conventional trans-arterial chemo-embolization procedures for the treatment of patients with inoperable liver tumors.

Sirtex said that conventional trans-arterial chemo-embolization (cTACE) had been published in more than 100 clinical studies, of which 12 were randomized controlled trials.

The company said that cTACE was "a minimally invasive procedure ... mixing Lipiodol Ultra Fluid with an anticancer drug and injecting this treatment transarterially in the liver as a loco-regional targeted chemotherapy, in which Lipiodol ... acts as a contrast agent, a drug eluting vehicle and a dual arterio-portal transient embolic".

The company said that cTACE had been established as the standard-of-care for the treatment of patients with intermediate stage hepatocellular carcinoma by three international clinical consensus guidelines in Japan, Europe and the US.

Guerbet chief executive officer Dr Yves L'Epine said the company was "excited about the potential of combining or sequencing our products to improve the efficacy of interventional radiology procedures in patients with unresectable hepatic tumors".

"Indeed, while Lipiodol and SIR-Spheres individually are well proven and widely used therapies in their own right, they have never been formally evaluated together or sequentially," Dr L'Epine said.

"A master clinical research collaboration agreement to be executed between our companies will provide the framework from which to launch a number of clinical projects investigating innovative ways to employ Lipiodol and SIR-Spheres in patients with inoperable liver tumors," Dr L'Epine said.

Sirtex said that the agreement would bring together the two companies' internal clinical development capabilities and proactively focus efforts on areas of high unmet medical needs.

The company said that the first project would be a series of clinical studies designed to evaluate the potential for synergism between the two therapies and whether the therapies might be combined or sequenced in a manner that delivered optimized tumor control.

Sirtex fell 10 cents or 0.6 percent to $15.90 with 137,957 shares traded.

INNATE IMMUNOTHERAPEUTICS

Innate hopes to begin its 90-patient phase IIb trial of MIS416 for secondary progressive multiple sclerosis by July 2014, with results by July 2016.
Innate chief executive officer Simon Wilkinson told Biotech Daily that ethics approval applications were being finalized for the double-blinded, randomized, placebo-controlled trial at up to eight sites to measure the efficacy of 500 micrograms MIS416, dosed intravenously once a week for 12 months.
Mr Wilkinson said that the patients in the trial would not be on any other drug as their condition was an unmet medical need.
Mr Wilkinson said that 60 patients would be randomized to and 30 patients would be administered a placebo.
He said that the primary endpoint was efficacy as assessed by effect on measures of neuro-muscular function, as well as safety and tolerability.
Mr Wilkinson said that secondary objectives included efficacy for measures of disability and health and effect of MIS416 on magnetic resonance imaging markers of disease activity and neuro-degeneration, as well as pharmaco-dynamic effects on serum, peripheral blood mononuclear cell and cerebral spinal fluid cytokine/chemokine levels.
Mr Wilkinson said that neuromuscular function would be measured by a range of tests including the six minute walk test and Jebsen hand function test, with disability and health status measures including the brief pain inventory among a range of measures.
Mr Wilkinson said that one of the most common complaints from patients with multiple sclerosis was non-specific body pain.
Mr Wilkinson said that the $10 million raised in the company's initial public offer would cover the cost of the trial and provide funds for a further three to six months, but the company also had 5,850,000 options exercisable at 30 cents each by December 13, 2015, which would see the company through phase III partnering discussions.
Innate fell 1.5 cents or 5.3 percent to 27 cents.

PHARMAUST

Pharmaust says it has applied to Royal Adelaide Hospital's cancer clinical trials unit for a phase I/II trial to evaluate PPL-1 for refractory solid tumors.
The company said that the first-in-man trial would primarily focus on the safety and pharmacokinetics of the drug, but the evaluation would be undertaken in late stage cancer patients and the clinical team under principle investigator Prof Michael Brown would determine the effects of PPL-1 on the cancer.
Pharmaust said that a series of tumor markers of tumor growth and progression would be measured during the treatment period, with patient tumors to be biopsied where possible and also studied with a computed tomography-positron emission tomography scanner.
The company said that the study would increase doses of PPL-1 in cohorts of patients with each dose being administered daily for a period of 28 days.
Pharmaust said that patients receiving PPL-1 would have failed standard-of-care for their respective cancers and PPL-1 would be administered to patients with a variety of cancers potentially including the major cancers such as lung, pancreas, oesophageal, gastric, colorectal, ovarian, breast, prostate, liver, sarcoma, lymphoma and melanoma.
Pharmaust executive chairman Dr Roger Aston said the company was "quite confident that the drug has a high level of safety judging by the fact that it is already in commercial use as an anti-parasitic agent in sheep and cattle".
Pharmaust was unchanged at 1.4 cents with 9.9 million shares traded.

VIRAX HOLDINGS

Virax says it has commitments for the placement of 250,000,000 shares at 1.2 cents a share to raise $3,000,000.
Virax said that the single tranche placement would require shareholder approval along with the Pathway Oncology transaction at an extraordinary general meeting to be held about May 1, 2014 (BD: Mar 17, 2014).
The company said that Patersons Securities acted as lead manager to the placement, "which was heavily oversubscribed".
Virax said that the funds would be used to support its clinical programs including multiple myeloma and breast cancer with its GGTI-2418 first-in-class synthetic peptidomimetic inhibitor of GGTase I drug, derived from the acquisition of Pathway Oncology.
Virax executive chairman Dr Wayne Millen said the placement would enable "the ongoing funding of the company's existing Co-X-Gene core platform technology and fund the clinical programs of multiple myeloma and breast cancer".
Virax fell 0.1 cents or 6.7 percent to 1.4 cents with 3.4 million shares traded.

RESMED

Perpetual and its subsidiaries have increased their substantial shareholding in Resmed from 89,040,834 shares (6.27%) to 104,190,299 shares (7.36%).
The substantial shareholder notice said that Perpetual bought and sold shares in a large number of trades, from September 26, 2013 to March 21, 2014 at prices ranging from $4.79 to $5.89.
Resmed fell six cents or 1.3 percent to $4.72 with 9.0 million shares traded.

BUCHAN CONSULTING

Buchan says that principal Rebecca Wilson has been appointed as chief executive officer, effective immediately.
Buchan said that Ms Wilson had been "a key driver of the agency's investor communication and healthcare practices during her 15 years with the company".
The company said that Ms Wilson would "work closely with founder and principal Tom Buchan, leading the agency, driving growth and providing strategic counsel to clients".
Buchan said that Mr Buchan would move to executive chairman focusing on regional expansion and capitalizing on joint opportunities with the agency's partner and investor, US based global communication group Waggener Edstrom.
The company said that the executive management team would comprise national general manager Gemma Hudson, head of investor communication Kyahn Williamson and head of health David Leahy.
Ms Wilson said that the one constant in business was "disruption - from the changing media landscape, the shifting economic climate and the increased global nature of our clients' businesses".
"Our new management team will assist us to meet these challenges and see Buchan continue to grow, evolve and continue to develop as one of the leading communication agencies in the region," Ms Wilson said.
Buchan is a private company.