Biotech Daily

Monday January 19, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: COMPUMEDICS UP 10%, GI DYNAMICS DOWN 7%**

*** INVION: INV102 'CLINICALLY RELEVANT' INTERIM SMOKING RESULTS**

*** MEDICAL DEVELOPMENTS: 'PENTHROX EUROPEAN SALES BY MAY'**

*** MEDICAL AUSTRALIA, KENTUCKY DOG CANCER VACCINE PARTNERSHIP**

*** MEDLAB BEGINS PROBIOTICS DEPRESSION TRIAL**

MARKET REPORT

The Australian stock market rose 0.19 percent on Monday January 19, 2015 with the S&P ASX 200 up 9.9 points to 5,309.1 points.

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

Compumedics was the best, up one cent or 10.0 percent to 11 cents with 8,000 shares traded, followed by Neuren up 9.1 percent to 18 cents with 6.5 million shares traded.

Tissue Therapies climbed 7.25 percent; IDT and Medical Developments were up more than six percent; Bionomics and Nanosonics rose more than four percent; Acrux, Analytica and Ellex were up more than three percent; Phosphagenics was up 2.6 percent; Alchemia, Clinuvel, Cochlear, Impedimed, Osprey, Resmed, Starpharma and Viralytics were up one percent or more; with CSL and Mesoblast up by less than one percent.

GI Dynamics led the falls, down two cents or 7.4 percent to 25 cents with 764 shares traded.

Anteo and Biotron fell more than four percent; Admedus, Benitec and Optiscan were down more than three percent; Cellmid and Universal Biosensors shed two percent or more; with Sirtex down one cent or 0.04 percent.

INVION

Invion says its phase II smoking cessation trial has shown “clinically relevant changes in four biomarkers of inflammation in INV102-treated patients compared to placebo”.

Invion chief executive officer Dr Greg Collier told Biotech Daily that the interim data was derived from about one-third of the proposed 136-patients in the double-blind, placebo-controlled, randomized, clinical trial of INV102, or nadolol, for patients with chronic cough or established chronic obstructive pulmonary disease who were trying to quit smoking but had failed multiple times.

Dr Collier said that he expected enrollment to be completed by April with the full results report by July 2015.

Dr Collier said that the numbers in the “blind-broken” interim report were too small for a complete analysis but all four biomarkers “were in the same direction”.

In a media release, Invion said that the interim data was generated from an assessment of sputum samples collected from patients on reaching a maximum tolerated dose at the sixth visit and four weeks of maximum tolerated dose treatment at the seventh visit.

The company said that the analysis showed “clinically relevant changes” in four biomarkers of inflammation: interleukin-8 (IL-8), extracellular signal-regulated kinase-2 (ERK2), mucin-1 (MUC-1) and neutrophils.

Invion said that IL-8 was a chemo-attractant for inflammatory cells and was stable between visits six and seven, with a median decrease in IL-8 levels compared to placebo which showed a median increase in IL-8 levels.

The company said that ERK2 was a biomarker for the beta arrestin pathway and the interim results showed a greater median decrease than placebo-treated patients resulting in a lower median value at visit seven of 487 picograms/millilitre compared to 1,910pg/mL.

Invion said that MUC-1 was a glycoprotein that lined the surface of epithelial cells in the lung and the results showed a modest median decrease in patients receiving nadolol and placebo.

The company said that neutrophils, or the white blood cells that are the hallmark of inflammation of chronic bronchitis, showed a mean decrease of seven percent compared to a mean increase of 1.4 percent in placebo patients.

Invion chief medical officer Dr Mitchell Glass said the results were important for three primary reasons.

“First, we have clear and clinically meaningful separation between subjects treated with nadolol versus placebo in four areas of biomarker investigation,” Dr Glass said.

“Second, the pattern of individual neutrophil changes from visit six to visit seven indicates a response to nadolol treatment,” Dr Glass said.

“Third, ERK1/2 is a hallmark of the beta arrestin pathway, the blockade of which is central to our hypothesis concerning the unique mechanism of action of nadolol,” Dr Glass said.

“Analysis is ongoing of MUC5AC, the abnormal mucin which is specific to COPD, which will further inform us about airway healing,” he said.

“We recognize that we must interpret these results with caution, given their interim nature, the sample size, and the variability that naturally occurs in sputum analysis,” Dr Glass said.

“However the results support our hypothesis regarding the clinical, regulatory and commercial potential of INV102 ... and also provide a strong foundation to our inhaled INV102 program, which is approaching a major development milestone,” Dr Glass said

Invion said that the laboratory analyses were performed at Washington University in St Louis, Missouri, under the supervision of the smoking cessation trial principal investigator Dr Mario Castro.

Invion was up 0.6 cents or 13.6 percent to five cents with 1.9 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it expects market approval for Penthrox in Europe in “April or May 2015”.

Medical Developments said it received “positive feedback” from the UK Medicine and Healthcare Products Regulatory Agency to market and sell the Penthrox inhaled analgesic in the UK and by extension to France, Belgium and Ireland through the European Union’s decentralized procedure.

The company said that the Medicine and Healthcare Products Regulatory Agency outlined the timeframe for formal approval, which was expected to be completed within 90 days.

Medical Developments said that, following its review of the data on quality, safety and efficacy of Penthrox, the Agency reported that it considered that the application for the treatment of pain relief by self-administration to conscious patients with trauma and associated pain was “approvable provided that some listed outstanding points are satisfactorily addressed”.

The company said that the outstanding points were a combination of labelling, training, administrative, quality, clinical and non-clinical matters which were being addressed.

Medical Developments said it expected distributor Galen Pharmaceuticals to begin selling Penthrox in the UK and Ireland in April or May 2015, with plans for the launch underway.

Medical Developments chief executive officer John Sharman said that the approval of Penthrox for use in the UK, France, Belgium and Ireland would be “a company-making achievement for us”.

“It opens up these European markets to Penthrox for the first time and more importantly, pursuant to the mutual recognition process, for further regulatory approvals for other countries within the European Union”.

Medical Developments chairman David Williams said that Penthrox was “a remarkable drug and it will be fantastic to see Australia’s first choice, front line analgesic used by foreign doctors, hospitals and ambulance”.

“Our drug helps trauma patients relieve their pain quickly and also makes minor surgical procedures more comfortable,” Mr Williams said.

Mr Sharman said that the regulatory dossier used for the European marketing authorization application had been submitted to other regulatory agencies for Penthrox approval.

“We are in discussion with a number of business partners in various countries in Europe and elsewhere and we are hopeful we can agree terms and conclude negotiations in the coming months,” Mr Sharman said.

“Approval in Europe will facilitate ongoing partnership and licensing discussions and we are confident it will directly assist in obtaining regulatory approvals in other countries around the world,” Mr Sharman said.

Medical Developments climbed 10.5 cents or 6.95 percent to $1.615.

MEDICAL AUSTRALIA

Medical Australia says that it will partner with the University of Kentucky to develop a canine cancer vaccine treatment.

Medical Australia said that the partnership was through a division of its US subsidiary, Medivet America, recently rebranded as Medivet Biologics.

Medical Australia was untraded at 7.8 cents.

MEDLAB CLINICAL

The Sydney-based Medlab says it hopes to recruit 30 people with treatment-resistant depression for a clinical trial of “probiotics” scheduled to start in February 2015.

Medlab said that the trial would be in collaboration with University of Queensland clinical psychologist Dr Matthew Bambling and based at the Royal Brisbane and Women’s Hospital in Brisbane.

The company said that preliminary results expected within six months and determine the direction of a subsequent phase IIa trial.

Medlab said that with University of Queensland researchers it hypothesized that treatment-resistant depression might “be due to a combination of altered neuro-physiological and poor gut health issues”.

The company said that the hypothesis was influenced by the Human Microbiome Project, a five year project begun in 2008 by the US National Institute of Health which was intended to broaden medical understanding of the role of bacteria living in and on humans.

Medlab medical research director and University of Sydney Medical School’s Prof Luis Vitetta there was increasing evidence demonstrating the association between poor gut health and depression.

“Medlab has developed bacteria-based medicines that will target the gut–brain axis and there is a reasonable expectation that this intervention will provide a benefit to patients diagnosed with treatment-resistant depression,” Prof Vitetta said.

Medlan said that the trial would investigate resistance to pharmacotherapy for depression and the association with inflammatory conditions connected with poor gut health; specific bacterial supplementation which might improve depressive symptoms through immune modulation and neuro-chemical synthesis in the gut; and the causal mechanism between poor gut health and mood disorders which might help explain non-responses to pharmaceutical treatment.

Medlab chief executive officer Sean Hall said that the extent of treatment-resistant depression was disturbing and, given the vast amount of research linking improved gut health to better receptivity of medication, Medlab’s direction had potential to show promising results.

Medlab said it was targeting obesity, chronic kidney disease, depression, ageing and musculoskeletal health and pain management and its lead program was in obesity and depression, with human clinical trials having begun in 2014 and continuing in 2015.

The company said that it had three food additive products on sale in Australia and the US aimed at improving gut health, cellular energy levels and nutrient absorption under the names of Multibiotic, NRGBiotic and Enbiotic.

Medlab is a public unlisted company.