Biotech Daily

Wednesday May 20, 2015

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: PRIMA UP 62%, PHARMAXIS DOWN 13%**

*** DATA BACKS INVION INV102 FOR NON-COPD, COPD SMOKERS**

*** FEDERAL GOVERNMENT OPENS CLINICAL TRIALS ACCESS SITE**

*** PROF BARRY MARSHALL'S ONDEK TAKES 19.9% OF BIOXYNE**

*** GI DYNAMICS: 'ENDOBARRIER EQUALS SURGERY ON OBESITY, GLUCOSE'**

*** OBJ BEGINS KNEEGUARD TRIAL**

*** PSIVIDA MEDIDUR SAFETY RESULTS 'VERY ENCOURAGING'**

*** PHARMAUST AND COMMSEC IRESS DATA**

*** INNATE NZ COMPASSIONATE MS PATIENTS 'IMPROVED'**

*** CHINA ICU SOCIETY BACKS USCOM MONITOR**

*** AUSTRALIAN ETHICAL, SANDON TAKE HUNTER HALL 12% OF ALCHEMIA**

*** NOMINATIONS OPEN FOR RESEARCH AUSTRALIA AWARDS**

*** CALDERA APPOINTS DR KEITH HUDSON R&D DIRECTOR**

MARKET REPORT

The Australian stock market slipped 0.09 percent on Wednesday May 20, 2015 with the S&P ASX 200 down 5.2 points to 5,610.3 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 10 fell and nine traded unchanged. All three Big Caps were up.

Prima was the best for the second day in a row, up 2.1 cents or 61.8 percent to 5.5 cents with 102.0 million shares traded, followed by Patrys up 20 percent to 1.2 cents with 1.8 million shares traded and Anteo up 14.5 percent to 9.5 cents with 2.8 million shares traded. Oncosil climbed 10 percent; Cochlear and Optiscan rose more than six percent; Neuren was up 5.9 percent; Antisense, Biotron, Cellmid and Psivida were up more than four percent; Prana and Reva were up more than three percent; Atcor, Nanosonics, Resmed and Sirtex rose more than two percent; with Avita, Bionomics, CSL, Impedimed, Mesoblast and Universal Biosensors up more than one percent.

Pharmaxis led the falls, down 3.5 cents or 13.5 percent to 22.5 cents with 8.5 million shares traded. Ellex fell 4.2 percent; Starpharma lost 3.8 percent; Actinogen and Uscom shed more than two percent; with Admedus, Medical Developments, Tissue Therapies and Viralytics down by more than one percent.

INVION

Invion says that INV102, was safe for smokers trying to quit tobacco products as well as patients with chronic obstructive pulmonary disease patients.

Invion said that trial investigators presented data at the American Thoracic Society meeting in Denver, Colorado, May 15 to 20 2015, from the ongoing phase II study of INV102, or oral nadolol, as an aid to smoking cessation.

Invion chief executive officer Dr Greg Collier told Biotech Daily that the trial was originally planned for 136 patients but a late flood of enrolments had increased the trial to 155 patients.

Dr Collier said that the trial data showed that smokers with chronic cough who had not been formally diagnosed with chronic obstructive pulmonary disease (COPD) had similar airways damage to those who had been diagnosed with COPD, thereby greatly expanding the market opportunity for INV102 for smoking cessation.

In a media release, the company said the data “confirmed Invion’s hypothesis that patients with chronic cough due to cigarette smoking could be studied as a single population based on biomarker results, whether or not they had evidence of airflow obstruction”.

Invion said that earlier results from the study indicated that key signs of respiratory inflammation could be reduced in as little as four weeks of treatment versus placebo.

In January, Invion reported that interim data from about one third of the targeted trial cohort showed “clinically relevant changes in four biomarkers of inflammation in INV102-treated patients compared to placebo” (BD: Jan 19, 2015).

Today, the company said that Washington University lead study investigators Dr Mario Castro and Geneline Sajol noted that oral nadolol could be safely administered to smokers experiencing chronic cough and not just patients diagnosed with chronic obstructive pulmonary disorder.

Dr Castro said study protocols had been amended following trial initiation to include patients without a formal chronic obstructive pulmonary disease (COPD) diagnosis providing investigators with a novel opportunity to compare sputum biomarkers in smokers both with and without diagnosed airflow obstruction.

“On examining baseline biomarkers, we found no difference in COPD versus non-COPD subjects,” Dr Castro said.

“What this essentially means is that we now believe we can safely target the smoking population with or without diagnosed COPD, because of the similarities in airway inflammation,” Dr Castro said.

Invion said it was repurposing nadolol, which was a beta blocker used to treat high blood pressure and migraine to treat chronic inflammatory airway diseases, including asthma and COPD.

The company said that the global market for treatments for asthma, COPD and smokers cough was estimated at $34 billion and the smoking cessation drug market was estimated at more than $2 billion.

Invion said that nicotine-focussed therapies comprised the bulk of the existing market, but did not address lung healing.

The company said it titrated INV102 to a maximally tolerated dose up to 100mg/day, maintenance treatment for eight weeks and down titration over two weeks, with follow-up three months later for a total of six months per subject.

The study was fully enrolled in January, 2015 and was expected to report the data by October 2015.

Invion was up 0.1 cents or 4.8 percent to 2.2 cents.

FEDERAL GOVERNMENT

The Federal Government says patients will have access to clinical trials through the website www.australianclinicaltrials.gov.au from today.

In a joint announcement the Minister for Health Sussan Ley and the Minister for Industry and Science Ian Macfarlane said today was International Clinical Trials Day and the website would make it easier for patients across Australia to take part in innovative medical research.

Ms Ley said the website would help boost patient participation following data that indicated that just under half of all phase III clinical trials in Australia did not meet their patient recruitment targets.

“This Australian-first one-stop shop of information relating to clinical trials marks a significant milestone in the Australian Government’s $9.9 million commitment to accelerate clinical trials reform and improve access to critical treatments and therapies,” Ms Ley said.

Ms Ley said that not being able to recruit enough participants was considered one of the main reasons for a seven percent decline in the number of trials conducted in Australia from 2012 to 2013.

Mr Macfarlane said that in addition to offering easy access to information about the trial, who could enrol and what was required of patients, the website put patients in contact with the head researcher with just one click.

“For trials to be scientifically rigorous, they need the involvement of many patients and this online tool will make it is easier for patients to be aware of the trials available across Australia, and how they work,” Mr Macfarlane said.

BIOXYNE, ONDEK

In substantial shareholder notices today, Ondek Pty Ltd said it had acquired 39,868,277 shares (19.9%) in Bioxyne from Fleming SG Capital for $518,288 or 1.3 cents a share.

The Sydney-based Ondek was created in 2009 to develop work by Nobel prize-winning scientist Prof Barry Marshall on a Helicobacter pylori-based anti-influenza virus oral vaccine (BD: Jul 30, 2009).

In 2013, the company appointed former Tyrian Diagnostics chief executive officer Dr Jenny Harry as its chief executive officer (BD: Mar 18, 2013).

Bioxyne was created from the April 2012 merger of Hunter Immunology and Probiomics, but in June the lead drug candidate, HI-164OV for chronic obstructive pulmonary disease, failed to meet its phase IIb primary endpoint (BD: Apr 4, Jun 28, 2012).

There was a board spill, a merger with Vitality did not proceed and eventually Bioxyne sold the Hunter Immunology assets to Mariposa Health, founded by former Bioxyne chief executive officer Dr Phillip Comans for $1.56 million (BD: Feb 25, 2014).

Last year, Fleming SG Capital acquired the Phillip Asset Management holding and George Cameron-Dow replaced Jeremy Curnock Cook as a director (BD: Jul 21, 2014).

Today, in an Appendix 3Y director’s interest statement Mr Cameron-Dow said that he no longer held his indirect 25 percent interest in the Fleming shares, retaining 550,000 options expiring on December 10, 2017.

No one from Bioxyne was available to comment on the transaction at the time of publication and Ondek chairman Peter Hammond told Biotech Daily he could not comment on the transaction.

Bioxyne fell 0.1 cents or 9.1 percent to one cent.

Ondek is a private company.

GI DYNAMICS

GI Dynamics says its Endobarrier duodenal-jejunal bypass liner was close to Roux-en-Y gastric bypass surgery on measures of blood glucose, weight and body mass index.
GI Dynamics said that a poster entitled, 'Improvement in Glucose Metabolism after Bariatric Surgery: Comparison of Laparoscopic Roux-en-Y Gastric Bypass and Duodenojejunal Bypass' was presented at the American Gastroenterological Association meeting in Washington, DC held May 16 to 19, 2015.
GI Dynamics said the study, with an undisclosed number of patients, was the first comparing the improvement in glucose metabolism following gastric bypass surgery, to the invasive endoscopic placement of the Endobarrier device.
The company said that the preliminary data showed that both procedures had a similar impact on diabetes remission and significant impact on body weight.
GI Dynamics said that -en-Y gastric bypass surgery resulted in a reduction of HbA1c blood glucose levels by 1.1 percent and drop in body weight of 28.2kg and a reduction of body mass index (BMI) of 10.4kg/m^2.
The company said that its Endobarrier achieved a reduction of HbA1c of 1.4 percent, a drop in body weight of 22.9kg and a reduction of BMI of 8.8kg/m^2.
GI Dynamics chief medical officer Dr David Maggs said it was "interesting to observe how Endobarrier treatment compares to bariatric surgery when administered at the same clinical center in the hands of independent researchers".
"This is another important milestone that manifests the potential for device intervention while avoiding the alteration of anatomy by surgery," Dr Maggs said.
GI Dynamics said that the data showed that Endobarrier, which was designed to mimic the duodenal-jejunal exclusion created by gastric bypass surgery, had a significant impact on glucose homeostasis at one, three and nine months of therapy, which could reduce the reliance patients may have on diabetes medications.
GI Dynamics as unchanged at 13 cents.

OBJ

OBJ says it expects a "major double-blind clinical trial" of its Bodyguard cartilage degeneration treatment will begin this week, with results this year.
OBJ said that the trial was being conducted by the University of Queensland comparing the efficacy of the Kneeguard product in the restoration of pain-free knee functionality with one of the world's largest selling topical non-steroidal anti-inflammatory drug products, but did not provide details of the trial.
The company said that the trial began later than planned "due to technical challenges in creating the world's first drug-free joint maintenance and restoration orthotic device".
OBJ said that the Kneeguard product, while appearing simple and easy to use, combined innovations in formulation technology, product molding, packaging and physiological stimulation.
The company said that joint aging and the restoration of healthy lifestyles in aging populations was a major growth market opportunity.
Last year, OBJ said its wholly-owned subsidiary Bodyguard Life Sciences had an evaluation and option agreement for the Bodyguard cartilage degeneration treatment with Procter and Gamble (BD: Dec 16, 2014).
OBJ said at that time that the Bodyguard technology and its Lubricen formulation substantially improved joint function across a range of medically diagnosed knee pathologies following 14 days of daily use (BD: Apr 28, 29, 2014).
OBJ was unchanged at 5.9 cents with 1.3 million shares traded.

PSIVIDA

Psivida says that intra-ocular pressures measured in its 129-patient phase III trial of Medidur for posterior uveitis indicate a “very encouraging” safety profile.

Psivida said the assessment of masked data compared the elevation of intra-ocular pressure over 21mmHg at three months between study eyes and fellow eyes for the 105 out of 129 enrolled subjects with at least three month follow-up data.

The company said that at three months, four percent more study eyes, of which two-thirds received Medidur, experienced elevated intraocular pressure (IOP) than the fellow non-study eyes, of which none received Medidur.

Psivida said that initial IOP elevation was an indication of the likelihood of subsequent clinically significant IOP increases and the minimal difference observed in elevated IOP in the assessment suggested highly favorable results for a key safety measure of the trial, the number of eyes that developed clinically significant increases in IOP within 12 months of receiving Medidur relative to control eyes.

Psivida chief executive officer Dr Paul Ashton said the data was “very encouraging for the safety profile of Medidur”.

“A significant treatment challenge with posterior uveitis patients is managing the serious side effects of prolonged steroid use, the current first-line treatment,” Dr Ashton said.

“A therapy that can provide the benefits of steroids on a sustained basis for three years with a single injection with a lower incidence of side effects would be a very significant advance in treatment of this disease,” Dr Ashton said.

“We are very optimistic for the final IOP safety results in this trial,” Dr Ashton said.

“We originally expected that the final IOP safety profile for Medidur would be at least as good as the IOP safety profile of [Psivida’s] FDA-approved Iluvien for diabetic macular oedema, which uses the same micro-insert as Medidur and delivers the same dose of the same drug, and much better than the IOP safety profile of [Psivida’s] FDA-approved Retisert, which delivers a higher dose of the same drug in Medidur,” Dr Ashton said.

“On the basis of this ongoing assessment of masked study safety data, we now believe the final IOP results in the Medidur trial could be even better than those shown in the Iluvien and Retisert phase III trials,” Dr Ashton said.

“At 36 months, 24 percent more patients treated with Iluvien and 45 percent more patients treated with Retisert required medication for elevated IOP than controls in their phase III trials,” Dr Ashton said.

Dr Ashton said he expected top line results from the Medidur phase III trial by July 2016, and with favorable results from this and Psivida’s second trial the company intended to file for US approval by July 2017.

Psivida climbed 24 cents or 4.95 percent to $5.09.

PHARMAUST, COMMSEC IRESS

Last night, Biotech Daily reported that Pharmaust fell 0.1 cents or 8.3 percent to 1.1 cents with 4.8 million shares traded, using the Commsec Iress platform.

Pharmaust told Biotech Daily that according to the ASX, its price was unchanged at 1.2 cents with 3.4 million shares traded, which agreed with the Commsec Website platform.

Iress Australia New Zealand financial markets managing director Kirsty Gross told Biotech Daily that the difference in share price data was due to Iress including trades on the Chi-X share trading platform that the ASX data does not include and the last trade of the day was a Chi-X trade, at the price reported last night.

Ms Gross said that there were more than 20 broker members of Chi-X, accounting for about 15 to 20 percent of all trades each day.

INNATE IMMUNOTHERAPEUTICS

Innate says that 15 of 18 compassionate use multiple sclerosis patients in New Zealand, have self-reported significant and sustained improvements with MIS416.
Innate said that MIS416 had been made available to a small group of patients with secondary progressive multiple sclerosis on compassionate use grounds.
The company said that in New Zealand, compassionate use arose when a patient did not have effective treatment options and gave consent to their doctor to request access to and treatment with an unapproved experimental medicine.
Innate said that the 18 patients had received an average of 82 doses of MIS416 and over the 32 month average treatment period there had been no signs of significant dose intolerance or cumulative toxicity arising from chronic treatment.
The company said that in late 2014 a further seven patients obtained access to MIS416 and after an initial three months of treatment, five of the seven patients reported significant improvements in their multiple sclerosis related signs and symptoms.
Innate said that in addition to patient reports, the seven recent compassionate use patients were also assessed by a neuro-physiotherapist every three months to evaluate whether there has been a clinically measurable response to treatment, with assessments including cognition, walking, hand and arm strength and function, and eyesight.
The company said that earlier compassionate use experience indicated that patients reported little by way of change in the first three months of treatment and that positive changes, where they occurred, most often occurred from and following four to six months of treatment.
Innate said that the recent compassionate patients did not record significant neuro-muscular change although four of six patients did record positive cognitive changes.
The company said that different effects reported at different intervals was suggestive of different mechanisms of drug action and the MIS416 mechanism of action data supported both an anti-inflammatory effect inside the brain as well as support for the body's own myelin repair functions.
Innate said that an apparent improvement in cognition and fatigue could be linked to an early anti-inflammatory effect whereas real improvement in neuro-muscular function would require myelin repair which reportedly occurs over months and not weeks.
Innate was untraded at 15.5 cents.

USCOM

Uscom says the China National Intensive Care Unit Society has included its ultra-sonic cardiac output monitor in the national survey of clinical member current practices.
Uscom said the Uscom 1A was the only non-invasive haemodynamic monitor included with the other three based on invasive catheter measurements.
The company said that the Uscom 1A was recognized in China as “the emerging technology for advanced haemodynamic practice, and while global adoption of the Uscom 1A is increasing, China is advanced in adoption of noninvasive technologies and is looking to the Uscom 1A” with about 200 units currently installed in China.
Uscom said that there were 10,000 intensive care units in China and each potentially required up to five units.
The company said that the National Survey by the China National ICU Society would provide a marketing springboard for sales of the Uscom 1A
Uscom fell half a cent or 2.5 percent to 19.5 cents.

ALCHEMIA, AUSTRALIAN ETHICAL TRUSTS, HUNTER HALL

Australian Ethical and the Sydney-based Sandon Capital have become substantial in Alchemia, apparently acquiring most of Hunter Hall's shares.

Australian Ethical said it held 20,776,887 shares (6.40%) with most acquired between January 19 and May 18, 2015, with the most recent purchase 10,000,000 shares for $590,000 or 5.9 cents a share.

Sandon said it acquired 20,057,846 shares (6.2%) for $1,142,990 or an average price of 5.7 cents a share.

Hunter Hall held said it had ceased its substantial holding in Alchemia, selling down from February 9 to May 18, 2015, with 24,504,638 shares sold on May 18 for $1,441,436 or an average of 5.9 cents a share.

Alchemia was up 0.3 cents or 4.8 percent to 6.5 cents with 1.7 million shares traded.

RESEARCH AUSTRALIA

Research Australia says that nominations have opened for its annual awards recognizing contributions to Australian health and medical research.

Research Australia said it would provide a $2,000 conference and events travel scholarship to the winner of the Griffith University Discovery Award, recognizing the need for early career researchers to foster collaboration and connect with peers.

The industry organization said that the awards included an Advocacy Award, Leadership in Corporate Giving Award, Great Australian Philanthropy Award, Health Services Research Award, Lifetime Achievement Award and the Peter Wills Medal for advancing Australia's international reputation within the sector, with awards from Glaxosmithkline and Diabetes Australia also expected to be announced on the Awards night.

Research Australia said the winners would be announced on November 18, 2015 and nominations would close on July 6.

For more information and to nominate go to: http://www.researchaustralia.org/.

CALDERA HEALTH

The Auckland, New Zealand-based prostate cancer diagnostics company Caldera Health says it has appointed Dr Keith Hudson as director of research and development.

Caldera said it was incorporated in 2009 to develop a gene-based multi-biomarker test for prostate cancer, with a phase II clinical study underway to identify a panel of RNA biomarkers for high throughput tests, expected to be completed by October 2015.

The company said that Dr Hudson previously worked for the ASX-listed Genesis Research and Development and prior to Genesis, as Cartesian Group chief scientific officer Dr Hudson was instrumental in developing bio-informatics software that turned genomic DNA information into useable gene sequences.

The company said Dr Hudson had been awarded three patents and had authored 18 refereed publications in scientific journals and written chapters in four books.

Caldera said that Dr Hudson held a Bachelor of Science, Masters of Science and a Doctorate of Philosophy in immunology from the University of Auckland and spent five years conducting postdoctoral research at the University of Oxford then the University of Birmingham.

Caldera is a private company.