Biotech Daily

Thursday December 9, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: MESOBLAST UP 23%; IMMURON DOWN 13%**

*** YM BIOSCIENCES: ANAEMIA RESPONSES FOR (CYTOPIA'S) CYT387**

*** FDA COMMITTEE BACKS OREXIGEN'S OBESITY DRUG**

*** ELI LILLY PAYS ACRUX $88m MILESTONE**

*** FEDERAL GOVERNMENT $23m FOR MENTAL HEALTH CRC**

*** NUSEP SHARE PLAN TO RAISE $1m**

*** USCOM RELEASES 2m ESCROW SHARES**

MARKET REPORT

The Australian stock market climbed 0.88 percent on Thursday December 9, 2010 with the S&P ASX 200 up 41.4 points to 4741.3 points.

Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and six were untraded.

Mesoblast was best again, up 95 cents or 23.5 percent to $5.00 with two million shares traded, followed by Sunshine Heart up 17.9 percent to 3.3 cents with 647,700 shares traded.

Clinuvel climbed 8.4 percent; Starpharma was up 7.9 percent; Pharmaxis was up 4.5 percent; Benitec and Nanosonics were up more than three percent; CSL and Tissue Therapies rose more than two percent; with Bionomics and Impedimed up more than one percent.

Immuron led the falls, down one cent or 12.8 percent to 6.8 cents with 145,650 shares traded, followed by Optiscan down 10.9 percent to 4.9 cents with 20,000 shares traded.

Antisense and LBT both lost 10 percent, the former with 11.4 million shares traded; Cellestis was down 5.4 percent; Cathrx and Patrys fell four percent or more; Alchemia was down 3.85 percent; Cellmid, Heartware and Psivida shed more than two percent; with Chemgenex down 1.1 percent.

YM BIOSCIENCES

YM Biosciences says it has positive interim data from the first 60 patients in its phase I/II trial of Cytopia's CYT387 for in myelofibrosis including dose-related anaemia responses.

YM acquired Cytopia earlier this year (BD: Oct 6,7, 2009; Feb 1, 2010).

The company said Myelofibrosis is a chronic debilitating disease in which bone marrow was replaced by scar tissue and for which treatment options were limited or unsatisfactory. The US Food and Drug Administration has granted orphan drug designation to CYT387 for myelofibrosis.

YM Biosciencs said that in an oral presentation to the American Society of Hematology meeting in Orlando, Florida that the JAK1 and JAK 2 inhibitor gave an overall response rate for anemia and spleen reduction to date, as per the International Working Group for Myeloproliferative Neoplasms Research and Treatment criteria, of 62 percent

Of 42 subjects evaluable for anemia response (baseline Hgb less than 10 g/dL or red cell transfusion-dependent), 21 subjects (50%) achieved clinical improvement.

YM said there was a 57 percent response rate in transfusion-dependent patients.

The rate varied with dose with the 150mg/day dosing group anemia response rate of 41 percent and 43 percent for transfusion dependent patients, while the 300mg/day dosing group had an anemia response rate of 58 percent, with 69 percent for the transfusion dependent patients.

Responses were observed in five of nine (55%) patients who had discontinued treatment with other JAK inhibitors and five of 12 (42%) who had discontinued pomalidomide.

Twenty-five (47%) of 53 evaluable subjects who had splenomegaly at baseline achieved a minimum 50 percent decrease in palpable spleen size.

For the 150mg/day dosing group, 53 percent had a clinical improvement and for the 300mg/day dosing group, 46 percent demonstrated a clinical improvement.

YM Biosciences said that CYT387 controlled constitutional symptoms in a significant percentage of patients (night sweats: 88%, bone pain: 80%, pruritus: 92%, fever: 100%).

The company said that in the dose escalation study, at the highest dose level (400mg/day), two of six subjects experienced dose limiting toxicities and the maximum tolerated dose was declared at 300mg/day.

YM said CYT387 was well tolerated with the overall discontinuation rate at five percent with no patient withdrawals for drug-related adverse events, with no grade 4 non-haematological toxicities observed. Grade 3 non-haematologic adverse events were infrequent and included increased transaminases (n=2), headache and/or head pressure (n=2) and increased lipase (n=3), with no cardiac QTc prolongations greater than Grade 1.

Some patients experienced a first-dose effect, primarily grade 1 lightheadedness and hypotension and this was self-limiting, resolved within four hours and did not recur.

YM said that grade 3/4 thrombocytopenia was seen in 16 (27%) subjects, but the minimum platelet count for inclusion in the study was 50,000/mcl and the majority of grade 3/4 thrombocytopenia were in subjects with baseline counts less than 100,000/mcl.

Treatment-emergent grade 3 anemia was seen in four subjects (7%). None developed new red cell transfusion requirements. Treatment-emergent grade 3/4 neutropenia was seen in three subjects (5%).

The study's chair Dr Alayew Tefferi said anemia was the "most serious symptom associated with myelofibrosis, so I am highly encouraged by the emerging activity profile of CYT387, which uniquely continues to demonstrate a substantial ability to improve anemia while producing similar results to its peers in reducing spleen size and controlling constitutional symptoms".

YM last traded on the Nasdaq down 14 US cents or 6.6 percent to $US1.99 with 908,729 shares traded.

OREXIGEN THERAPEUTICS

Orexigen founder Prof Michael Cowley says a US Food and Drug Administration advisory committee voted 13 to seven the potential benefits of Contrave for obesity outweigh the risks.

Now a Monash University professor of physiology and the director of the Monash Obesity and Diabetes Institute as well as the winner of the 2009 Australian life scientist of the year prize, Prof Cowley said his invention, Contrave, was a combination of the opioid and alcohol treatment drug naltrexone with the non-trycyclic anti-depressant bupropion.

Prof Cowley said the FDA's Endocrinologic and Metabolic Drugs Advisory Committee said potential benefits outweighed the potential risks when used long-term in a population of overweight and obese individuals and supported approval.

He said the Advisory Committee also voted 11 to eight that a dedicated study to examine the drug's effect on risk for major adverse cardiac events should be conducted as a post-approval requirement versus pre-approval.

Prof Cowley said the advisory committee's decision was a non-binding recommendation to be considered by the FDA in finalizing the review of the Contrave new drug application and an action date of January 31, 2011 had been assigned for the review of the new drug application.

Prof Cowley previously ran an obesity and diabetes research program at Oregon Heath and Sciences University and is a non-executive director of Verva Pharmaceuticals, an unlisted Australian company conducting a phase II trial of an insulin sensitizer in diabetes.

Orexigen is a Nasdaq listed company and is developing Contrave with Japan's Takeda Pharmaceutical Co.

FEDERAL GOVERNMENT

Innovation Minister Senator Kim Carr has announcing $100 million for four Cooperative Research Centres including one for mental health.

Senator Carr said the centres help solve "Australia's big problems by partnering talented researchers with industry and community groups who can turn the research into reality".

"Together, Alzheimer's disease, Parkinson's disease and schizophrenia affect millions of Australians, and early diagnosis can help sufferers to live a more fulfilling life," Senator Carr said. "The $23 million CRC for Mental Health will develop better diagnostic tools for these disorders and contribute to better treatment."

The Senator also announced a $27 million CRC for Young People, Technology and Wellbeing to study how technology could prevent and treat youth mental illness, $29 million for the CRC for Contamination Assessment and Remediation of the Environment to develop solutions to overcome and prevent contamination of soil, water and air; and $20 million for the CRC for High Integrity Australian Pork to support pork producers maintain local production of high quality food at affordable prices, while improving pig welfare.

ACRUX

Acrux has received its $US87 million ($A88 million) Eli Lilly milestone payment earned when the US Food and Drug Administration approved Axiron for marketing.

Acrux said the payment increased its cash reserves to about $145 million.

Acrux said that following the launch of Axiron, the company would receive royalties on worldwide sales and was eligible for further milestone payments of up to US$195 million.

Acrux expects the royalties to provide a substantial part of the total value of Axiron.

Acrux was unchanged at $3.57.

NUSEP

Nusep hopes to raise up to $1,000,000 through the issue of shares at a price to be set by its five-day volume weighted average price (VWAP) to December 14, 2010.
Nusep executive chairman John Manusu told Biotech Daily that the company wanted to issue the shares at 21 cents, the same price as last month's $1.9 million placement, but ASX rules preventing him guaranteeing that price.
Mr Manusu said that the ASX had told him the shares could be the lower of the 23 cents the shares were trading at prior to the announcement or no more than an 80 percent discount to the five-day VWAP, which today equated to 21 cents.
Mr Manusu said the share price would be the lower of 23 cents or the 80 percent discount to the five-day VWAP to December 14, 2010.
Nusep said that shareholders eligible at the record date of December 8, 2010 would be able to apply for parcels of shares up to $15,000 "on a first come first served basis".
Nusep said the share plan would open on December 10, 2010 and close on December 24, 2010.
Nusep said that pending shareholder approval one free option would be attached to every three new shares acquired with an exercise price of 35 cents.
Nusep raised $1.9 million last month for its stake in Singapore's Singapharm, which had developed a disposable "mini-mill" plasma fractionation process based on Nusep's Prime separation technology (BD: Nov 25, 29, 2010).
Nusep fell 4.5 cents or 15.5 percent to 24.5 cents.

USCOM

Uscom says 2,000,000 shares held in escrow by OSI Systems were released today.
Uscom chairman Robert Phillips told Biotech Daily that OSI Systems was the parent company of the company's distributor Spacelabs, whose contract expires on Dcember 12, 2010.
Following the release of the shares, Uscom will have 41,804,047 shares available for trading on the ASX.
Uscom was untraded at 40 cents.