Biotech Daily

Thursday December 13, 2012

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: BIONOMICS UP 13%, GI DYNAMICS DOWN 11%**

*** MESOBLAST CELLS 'SAFE, EFFECTIVE FOR CORD BLOOD EXPANSION'**

*** GILEAD PAYS $362m FOR YM'S $14m CYTOPIA CYT387**

*** HATCHTECH RAISES $6m FOR PHASE III DEOVO LICE, EGGS TRIAL**

*** VIRALYTICS US PHASE II MELANOMA TRIAL: 'INTERIM EFFICACY'**

*** PRANA: 'PBT2 INHIBITS HUNTINGTON'S SYMPTOMS IN MICE'**

*** ALCHEMIA REQUESTS AUDEO IPO, CAPITAL RAISING TRADING HALT**

*** ALLIED HEALTH REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market was even, down 0.02 percent on Thursday December 13, 2012 with the S&P ASX 200 down one point to 4,582.8 points.

Thirteen of the Biotech Daily Top 40 stocks were up, seven fell, nine traded unchanged and 11 were untraded.

Bionomics was the best, up four cents or 12.9 percent to 35 cents with 527,406 shares traded.

Psivida climbed eight percent; Genetic Technologies was up 6.1 percent; Circadian was up 5.4 percent; Genera rose 4.55 percent; Phosphagenics was up 3.45 percent; Prana, QRX and Starpharma were up more than two percent; Acrux, Nanosonics, Pharmaxis and Tissue Therapies were up more than one percent; with Cochlear up 0.4 percent.

GI Dynamics led the falls, down 6.5 cents or 10.8 percent to 53.5 cents with 4,810 shares traded.

Anteo lost 6.6 percent; Neuren shed 2.8 percent; Optiscan, Sirtex and Viralytics were down more than one percent; with CSL, Mesoblast and Resmed down by less that one percent.

MESOBLAST

A University of Texas MD Anderson Cancer Center phase I/II trial has shown that expanding cord blood using Mesoblast's mesenchymal stromal cells is safe and effective.

An article, entitled 'Cord-Blood Engraftment with Ex Vivo Mesenchymal-Cell Coculture', was published in the New England Journal of Medicine and an abstract is available at: http://www.nejm.org/doi/full/10.1056/NEJMoa1207285.

The article concluded that transplantation of cord-blood cells expanded with Mesoblast's mesenchymal stromal cells appeared to be safe and effective and that expanded cord blood in combination with un-manipulated cord blood significantly improved engraftment, as compared with un-manipulated cord blood only.

The article said researchers studied engraftment in 31 adults with haematologic cancers who received transplants of two cord-blood units, one of which contained cord blood expanded ex-vivo in co-cultures with allogeneic mesenchymal stromal cells, compared to 80 historical controls who received two units of un-manipulated cord blood.

A media release from the MD Anderson Cancer Center republished by Mesoblast, said that pre-transplant umbilical cord blood expansion in the laboratory "speeds establishment of new blood supply in patients, reducing high-risk time to recovery, [and] platelets, white blood cells engraft more quickly than in standard double-cord transplant".

The Centre said the phase I/II study addressed the difficulty of using umbilical cord blood stem cells to replace blood in patients who had theirs destroyed by chemotherapy or radiation to treat leukaemia, lymphoma and other blood-based diseases.

MD Anderson professor of stem cell transplantation and cellular therapy and cord blood bank director Prof Elizabeth Shpall said: "You get fewer cells - blood stem cells, immune cells - from two umbilical cords than you do by collecting from a donor's bone marrow or peripheral blood."

"That lengthens the time between infusion of the cord blood cells and establishment, or engraftment, of the new blood supply," Prof Shpall said. "It's a high-risk time, patients don't have white blood cells to fight infection, they don't have platelets to keep them from bleeding."

The Centre said that by taking blood from one of the two donated umbilical cords and growing it on a bed of Mesoblast mesenchymal precursor cells greatly increased the number of cells transplanted, reduced recovery time and increased the proportion of patients whose new blood became established.

"Expansion achieved a median 12-fold increase in total cells transplanted and a 40-fold increase in the number of CD34+ cells, which are crucial for engraftment," Prof Shpall said.

Prof Shpall said that cord blood expansion on Mesoblast cells "could become the new standard of care if our findings are confirmed in a randomized clinical trial."

The Centre said that the study's composite endpoint of neutrophil engraftment within 26 days, platelet engraftment within 60 days and survival at 100 days was reached by 63 percent of the expanded cord blood group compared with 24 percent among controls.

Patients with expanded cord blood had: a median time to neutrophil engraftment of 15 days, compared to 24 days for controls; a median time of platelet engraftment of 42 days, compared with 49 days for controls; cumulative neutrophil engraftment rate of 88 percent at 26 days, compared with 53 percent in control cases; and cumulative platelet engraftment rate of 71 percent at 60 days, compared with 31 percent in controls.

The Centre said Prof Shpall would evaluate Mesoblast's cells in a prospective, randomized phase III trial comparing 120 patients receiving one expanded and one regular cord blood transplant to 120 others receiving the standard double cord transplant.

Mesoblast fell one cent or 0.17 percent to $6.02 with 475,198 shares traded.

CYTOPIA, YM BIOSCIENCES

Gilead Sciences says it will acquire YM Biosciences for $US510 million ($A483 million) whose lead drug is the Melbourne-developed CYT387.

The former research director at Cytopia Dr Chris Burns told Biotech Daily that CYT387 was invented at Cytopia in Melbourne by a team he led with Prof Andrew Wilks.

Gilead said it would acquire YM for $US2.95 a share in cash, the deal had the unanimous approval of YM's directors, with the transaction expected to close by April 2013.

YM reported $C125.5 million ($A120.9 million) in cash and equivalents at September 30, 2012.

YM said it had reported positive results from a phase I/II trial of CYT387 in 166 patients with myelofibrosis and pending completion of the acquisition, Gilead intended to begin a pivotal phase III clinical trial of CYT387 in myelofibrosis by January 2014.

In 2010, YM Bioscience bought Cytopia, acquiring the vascular disrupting agent for solid tumors CYT997 and CYT387, a JAK2/JAK1 kinase inhibitor, for myeloproliferative disorders and cancer, for $14 million with the offer of 16.59 cents per Cytopia share, then a 58 percent premium (BD: Oct 6, 2009, Feb 1, 2010).

At the same time, YM began a phase I/II trial of CYT387 and claimed pivotal pre-clinical efficacy for the drug (BD: Sep 4, 2009; Mar 31, Apr 20, 2010).

The sale of Cytopia to YM followed a protracted battle with Avexa and Progen over $70 million in cash left at Progen after it closed a phase III liver cancer trial, with Avexa also wanting the cash for apricitabine trials and some Progen investors wanting to return the cash to shareholders (BD: Nov 14, 21; Dec 1, 22, 2008; Jan 16, 28, Feb 5, 2009).

Avexa's phase III trial of apricitabine for HIV had non-significant results at 24 weeks and the company has been trying to find partners since, most recently saying it would go coal mining in Alabama to fund a new phase III trial (BD: Feb 4, 2010; Mar 22, Nov 5, 2012).

When the acquisition was completed in February 2010, YM Biosciences climbed from about $US1.30 to $US1.70 and then fell back to $US1.13 before rising to $US2.50 at the end of the year.

On the Nasdaq last night YM was up $US1.25 or 76.7 percent to $US2.88.

HATCHTECH

Hatchtech says it has raised $6 million for a phase III trial of its Deovo head lice and egg treatment.

Hatchtech said it had completed a 142-patient phase II program demonstrating that a single 10 minute application of Deovo had "an excellent safety profile and highly competitive efficacy against head lice and their eggs" (BD: Dec 16, 2011; Sep 4, 2012).

The company said it had published further data on the activity of Ha44, the active compound in Deovo, in killing insects at several development stages from eggs through to adults by disrupting metal dependent targets within the insect (BD: Nov 29, 2012).

Hatchtech chief executive officer Dr Ross Macdonald said the "compelling outcome of our phase II program and the strong commercial opportunity for Deovo has further enhanced investor confidence and ensured the success of this financing round".

The company said it would begin the phase III development program comprising a range of manufacturing, clinical and non-clinical studies directed toward filing a new drug application with the US Food and Drug Administration in 2014.

Hatchtech said the fund-raising attracted interest from new investors, including Brisbane Angels and investors introduced by Oneventures, along with long-term investors, the University of Melbourne and the Queensland Biotechnology Fund.

Hatchtech is a private company.

VIRALYTICS

Viralytics says its US phase II melanoma trial Cavatak has achieved an interim efficacy milestone of three objective responses (BD: Dec 16, 2011; Jan 22, Oct 22, 2012).
Viralytics said that based on a recent independent data monitoring committee assessment Cavatak produced three objective responses in the first 13 patients recruited, thereby achieving its interim efficacy milestone well ahead of the 35 patient ceiling.
Viralytics said that an objective response was defined as a reduction in total body tumor burden of more than 30 percent relative to baseline assessed by computed tomography (CT) scan analysis or CT scan and physical calliper measurements.
The company said that subject to safety criterion also being satisfied, the trial could proceed to further recruitment up to about 63 patients, 54 of which were to be evaluable.
Viralytics said that in the event that three of 35 patients in the first stage failed to display an objective response then the trial would be stopped, pending further review.
The company said that the data monitoring committee would assess stage 1 safety and tolerability when 35 patients were recruited, and treatment to date had been well tolerated.
Viralytics said the rate of objective responses was a secondary endpoint, while the primary endpoint was immune-related progression free survival at six months.
Viralytics fell half a cent or 1.6 percent to 31 cents.

PRANA BIOTECHNOLOGY

Prana says PBT2 can inhibit the development of the symptoms and pathological features of Huntington's disease in pre-clinical transgenic mouse models.
Prana's head of research and co-author of the study Prof Robert Cherny said that PBT2 "markedly reduced neuro-degeneration, significantly increased lifespan and improved motor function and coordination in an aggressive animal model of the disease".
"It is already well established that PBT2 prevents the aggregation of the [amyloid beta] protein outside neurons, in Alzheimer's disease …[and] the mutant Huntingtin protein aggregates inside the neuron in Huntington disease," Prof Cherny said.
"There is published evidence that the protein aggregation in both diseases is driven by the interaction with metals," Prof Cherny said. "Our work has shown that PBT2 can prevent this protein aggregation caused by interaction with metals."
'PBT2 reduces toxicity in a C.elegans model of polyQ aggregation and extends lifespan, reduces striatal atrophy and improves motor performance in the R6/2 mouse model of Huntington's disease' was published in the Journal of Huntington's Disease and an abstract is at: http://iospress.metapress.com/content/gg02272572g4w578/.
Prana said that PBT2 reduced toxicity caused by polyQ over-expression; significantly reduced brain striatal atrophy, with a 40 percent reduction in lateral ventricular volume; increased median lifespan by 26 percent; improved motor function; reduced 'clasping behavior' associated with striatal damage; and improved maintenance of body weight.
Prana quoted Massachusetts General Hospital and Harvard Medical School's Prof Steven Hersch saying that "transition metals, especially iron and copper, have been implicated in the pathogenesis of Huntington Disease".
"Copper may directly modulate the toxicity of the [Huntingtin] protein while iron accumulation in response to neuro-degeneration likely potentiates the damage to the central nervous system, making both metals potential therapeutic targets," Prof Hersch said. "PBT2 is the first clinical candidate that modulates Htt directly."
Prana said PBT2 was being trialed in Huntington's disease patients in the US and Australia, with results expected in the second half of 2013.
Prana was up half a cent or 2.4 percent to 21.5 cents.

ALCHEMIA

Alchemia has requested a trading halt “pending an announcement regarding the Audeo fundraising and [initial public offer]”..

Trading will resume on December 17, 2012 or on an earlier announcement.

Alchemia last traded at 55 cents.

ALLIED HEALTHCARE GROUP

Allied Health has requested a trading halt “pending [an] announcement regarding a capital raising”.

Trading will resume on December 17, 2012 or on an earlier announcement.

Allied Health last traded at 2.4 cents.