Biotech Daily

Monday July 12, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRIMA UP 14%; NOVOGEN DOWN 10%**

*** BRITISH NETWORK 'ADOPTS' ALCHEMIA PHASE III CANCER TRIAL**

*** INDIA APPROVES BIODIEM'S 'FLU VACCINE; MERCK TARGETS R&D SITE**

*** MESOBLAST BONE MARROW TRIAL LEADS TO FDA PHASE III TALKS**

*** TRIDENT CAPITAL TO RECAPTALIZE SAFETY MEDICAL**

*** ANTEO 'COMPLETING SUPPLY AGREEMENT' TRADING HALT**

*** STARPHARMA APPOINTS MALCOLM MCCOLL VP NEW BUSINESS**

MARKET REPORT

The Australian stock market rose 0.3 percent on Monday July 12, 2010 with the S&P ASX 200 up 13.6 points to 4409.9 points.

Ten of the Biotech Daily Top 40 stocks were up, 16 fell, five traded unchanged and nine were untraded.

Prima was best on no news for the second trading day in a row, up 1.5 cents or 13.6 percent to 12.5 cents with 12.8 million shares traded, followed by Psivida up 24 cents or 6.45 percent to $3.96 with 2,189 shares traded.

LBT climbed 4.8 percent; Clinuvel and Viralytics rose more than two percent; with Cellestis, Cochlear, Heartware, Impedimed, Nanosonics and Pharmaxis up by less than one percent.

Novogen led the falls, down 1.5 cents or 10 percent to 13.5 cents with 178,657 shares traded, followed by QRX down 9.1 percent to $1.00 with 72,500 shares traded.

Circadian and Phosphagenics lost six percent or more; Tissue Therapies fell 5.1 percent; Bionomics, Biota and Cathrx were down more than three percent; Living Cell and Virax shed more than two percent; with Alchemia, Chemgenex, Mesoblast and Sirtex down more than one percent.

ALCHEMIA

Britain's National Cancer Research Network has approved Alchemia's phase III trial of HA-Irinotecan in patients with metastatic colorectal cancer.

Alchemia's chief executive officer dr Pete Smith told Biotech Daily that the National Institute of Health Research's National Cancer Research Network was an umbrella body for local research networks with several hundred participating hospitals.

"The Network only adopts about half of the studies presented to it," Dr Smith said.

"It closely examined issues such as whether there was a statistically valid trial design, therapeutic benefit, patient numbers, investigator interest and conflicting or competing trials," Dr Smith said.

"It underlines the medical need. It really is the third party validation that is significant," Dr Smith said.

"Several hundred hospitals are members of the network and the single body can approve the trial for all of those sites, thereby saving the company a lot of time and effort and some money," Dr Smith said.

In a media release to the ASX Alchemia said the Network provided the National Health Service in England with the infrastructure to support cancer clinical trials and worked closely with Cancer Research Networks in the devolved nations [Scotland and Wales] to provide support of cancer trials across all of the UK.

The company said the adoption of a sponsor's trial meant that NHS centres were able to participate in the study, which should facilitate rapid recruitment of patients in the UK.

In reaching its decision to adopt the trial, the National Cancer Research Network's industry trials adoption panel evaluated HA-Irinotecan and concluded that the study was well designed and could provide a possible benefit to patients in the NHS.

Alchemia said there were no financial obligations or loss of commercial rights through the Network's involvement.

Alchemia said that HA-Irinotecan is a new formulation of the widely used cancer drug irinotecan which effectively targets the drug to the tumor through a receptor-based mechanism.

The company said that an earlier phase II trial of HA-Irinotecan showed a statistically significant increase in progression-free survival compared with irinotecan of 5.2 months compared to 2.4 months (p=0.017).

Alchemia said that both the US Food and Drug Administration and the European Medicines Agency had "indicated that the successful completion of the planned single pivotal phase III trial will be sufficient for registration in both regions".

Alchemia said that the Melbourne Ludwig Cancer Institute's Prof Peter Gibbs would act as the global chief investigator for the phase III clinical trial and the UK chief investigator would be the Royal Marsden Hospital's Prof Ian Chau in London.

"We are delighted that the NCRN has adopted our trial and have been very pleased with the number of sites in the UK that have already expressed an interest in participating," Dr Smith said.

"This provides good independent evidence of the medical need that we hope HA-Irinotecan can address in this patient population," Dr Smith said.

Alchemia said its for the phase III trial were "well advanced" with the potential to open recruitment to the trial in the second half of 2010.

The company said the study would recruit more than 330 patients at about 60 sites in Australia, the UK, Russia, Bulgaria, Poland, Serbia and the Ukraine.

Alchemia said it was working with Swiss contract research organization PSI on the conduct of the trial.

Alchemia fell half a cent or 1.3 percent to 39 cents.

BIODIEM

Biodiem says its lead product, the live attenuated influenza vaccine (LAIV) has been granted regulatory approval for marketing in India.

Biodiem said the Nasovac vaccine was launched this week by the Indian vaccine company, the Serum Institute of India, which has licenced the drug from the World Health Organisation (WHO) for public markets.

To sell to private market, the Serum Institute of India would require a licence from Nobilon which in turn would provide royalties to Nobilon and Biodiem.

Schering Plough owned Nobilon when it merged with Merck & Co Inc.

Biodiem said that it was the first marketing approval outside Russia and the Confederation of Independent States.

Biodiem said that Merck had announced the proposed phase-out of operations at a number of its research and development sites and that one of these sites was the Nobilon facility at Boxmeer in the Netherlands, which is one of the areas where work on the live attenuated influenza vaccine had been taking place.

Biodiem said it had “no further information at this stage about any potential impact on the LAIV program”.

Biodiem was untraded at 12 cents.

MESOBLAST

Mesoblast says that following positive results from its bone marrow transplant trial a formal phase III meeting has been scheduled with the US Food and Drug Administration.

The phase Ib/II open-label clinical trial was conducted at the University of Texas MD Anderson Cancer Center and last year Mesoblast said that mid-trial results showed that its off-the-shelf mesenchymal precursor cells “expand haematopoietic stem cells in umbilical cord blood … 40-fold” (BD: Nov 6, 2009).

Mesoblast said at that time that the results came from the first 18 patients in the trial of bone marrow transplantation using umbilical cord blood expanded by the allogeneic mesenchymal precursor cells.

Today, Mesoblast said that in the first 25 patients transplanted with mesenchymal precursor cell-expanded haematopoietic progenitors from cord blood, “80 percent successfully achieved the key composite endpoint at 100 days of survival with sustained engraftment of both neutrophils and platelets”.

Mesoblast compared it to the 38 percent rate for the composite endpoint achieved after transplantation with non-expanded cord blood in the US registry of 300 patients collected by the Center for International Blood and Marrow Transplant Research.

The company said that to date, only four patients (16%) receiving expanded cord blood had developed severe graft-versus-host disease.

Mesoblast said the objective of the phase III trial was to develop a therapy that resulted in effective bone marrow reconstitution without the potentially life-threatening complication of graft-versus-host disease.

Mesoblast chief executive Prof Silviu Itescu said: “By increasing the overall success rate of an allogeneic bone marrow transplant while reducing the risk of graft-versus-host disease, our platform technology has the potential to lower the risk of infections, bleeding, and death in critically ill patients with haematologic malignancies following chemotherapy.”

“Our upcoming discussions with the FDA, based on the positive results from this trial, will enable us to provide a clear timetable to product commercialization and early revenues,” Prof Itescu said.

Mesoblast fell three cents or 1.7 percent to $1.74.

SAFETY MEDICAL PRODUCTS

McGrathnicol corporate recovery says it has accepted Trident Capital as the preferred bidder for the recapitalization of Safety Medical Products.
McGrathnicol said it would seek creditors' approval for the recapitalization and deed of company arrangement at a meeting expected to be held on July 23, 2010.
The administrators said the recapitalization would require shareholders' approval and was subject to other conditions.
Trident director Adam Sierakowski told Biotech Daily that his company would want to return shareholder value and all options were open.
Safety Medical is in a suspension and last traded at 3.7 cents.

ANTEO DIAGNOSTICS

Anteo has requested a trading halt pending as announcement regarding "a non-exclusive supply agreement" for one of its products.
Anteo said the company was hoping to finalize the agreement during the trading halt.
Trading will resume on July 14, 2010 or on an earlier announcement.
Anteo halted trading up 0.2 cents or 3.03 percent at 6.8 cents with 956,786 shares traded.

STARPHARMA

Starpharma says it has appointed Malcolm McColl as vice-president of business development team, effective August 16, 2010.
Starpharma said the appointment was "to meet the growing market demand for pharmaceutical and life science applications of Starpharma's dendrimer technology, particularly in drug delivery".
The company said Mr McColl had more than 20 years' experience with major biotechnology companies, including 13 years with CSL where he negotiated agreements with Pfizer and Bayer.
Starpharma said Mr McColl would return to Australia from the UK where he was Hospira's business development director for Europe, the Middle East and Africa.
The company said it had "a growing list of major companies that are actively exploring the use of Starpharma's proprietary dendrimer technology to enhance the performance their pharmaceutical products, including Lilly, GSK, and in animal health, Elanco".
Starpharma said it had established commercial relationships with companies such as SSL International, Siemens Healthcare and EMD Merck KgA for other applications of its proprietary dendrimer technology.
Starpharma fell half a cent or one percent to 50 cents.