Biotech Daily

Tuesday December 9, 2008

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECHS UP: STARPHARMA UP 22.5%, NOVOGEN DOWN 14%**

*** CHEMGENEX'S OMACETAXINE '80% COMPLETE BLOOD RESPONSE'**

*** VIRALYTICS' 4th TRIAL TESTS CAVATAK IN HEAD, NECK CANCER**

*** UK PREOPERATIVE LYMPHOEDEMA CARE USES IMPEDIMED'S L-DEX**

*** NORWOOD IMMUNOLOGY SELLS VIROSOME TECHNOLOGY**

*** LATE NEWS! AGENIX SETTLES CHINA DEAL**

*** ANTISENSE APPOINTS ROSANA PEDEVSKI DEVELOPMENT ASSOCIATE**

*** STEM CELL OFFER COMPLIANCE STATEMENT**

MARKET REPORT

The Australian stock market fell 0.6 percent on Tuesday December 9, 2008 with the All Ordinaries down 20.1 points to 3,533.7 points.

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

Starpharma was best, up 4.5 cents or 22.5 percent to 24.5 cents with 18,800 shares traded, followed by Labtech up one cent or 8.33 percent to 13 cents.

Benitec, Phosphagenics and Viralytics climbed more than seven percent; Psivida was up 6.38 percent; Biota, Clinuvel, Cochlear and Mesoblast were up five percent or more; Cellestis and Circadian improved more than three percent; with Arana and Prana up more than one percent.

Novogen led the falls for the second day in a row, down 11 cents or 14.29 percent to 66 cents with 45,450 shares traded, followed by Living Cell down 12.5 percent to 10.5 cents.

Polartechnics lost 6.25 percent; Acrux, Alchemia and Chemgenex fell four percent or more; Neuren and Tyrian were down more than three percent; Sirtex and Ventracor shed more than two percent; with Optiscan and Resmed down more than one percent.

CHEMGENEX

Chemgenex says 80 percent of 25 chronic phase chronic myeloid leukemia patients have had a “complete haematological response”.

The company said the positive interim clinical data came from a total of 44 patients in its phase II/III trial of omacetaxine mepesuccinate for chronic myeloid leukemia patients with the T315I mutation.

Chemgenex said investigators reported that subcutaneous omacetaxine was “generally well-tolerated and demonstrated durable complete haematological and cytogenetic responses” in patients who had failed to respond to the current front-line treatment, imatinib mesylate and who have the T315I mutation.

Imatinib mesylate is also known as Gleevec and Glivec registered to Novartis AG.

Chemgenex said there were no effective drug treatments for the increasing number of patients with the T315I mutation and said it was acknowledged as an important therapeutic challenge in the treatment of chronic myeloid leukemia.

The data was presented at American Society of Hematology annual meeting in San Francisco by the deputy chair of the Department of Leukemia at the University of Texas, Prof Jorge Cortes on behalf of a team including investigators from Chemgenex as well as US and European research centers.

Data was presented from 44 patients of which 25 were in chronic phase, 11 in accelerated phase and eight in blast phase.

Chemgenex’s chief operating Officer Dr James Campbell told Biotech Daily that while patients were living with leukemia in the chronic phase, “the prognosis for patients in the blast phase is very poor”.

Chemgenex said there were “complete haematologic responses in 80 percent of chronic phase patients, with median response duration of 11.5+ months” with a range of response duration from 3.5 months to more than 25.4 months.

The company said there were major cytogenetic responses in 20 percent of chronic phase patients, with median response duration of 4.8+ months and a range of 0.3 months to 9.7+ months.

Chemgenex said the chronic phase patients had progression free survival rates of 80 percent at one year and 70 percent at two years.

There were haematologic responses in 45 percent of accelerated phase patients with a median duration of 9.6+ months and 13 percent of blast phase patients.

Investigators reported that omacetaxine was “generally well-tolerated and that the most common side effect, reversible and transient myelosuppression, rarely results in serious clinical complications”.

Prof Cortes said omacetaxine was “a promising candidate” for the treatment of chronic myeloid leukemia (CML) patients with the T315I mutation, a common mutation in patients who have failed Gleevec.

“The clinical trial data we have presented demonstrates the ability of omacetaxine to induce durable clinical remissions in T315I-positive CML patients and the elimination of the T315I clone in the majority of patients studied,” Prof Cortes said.

Chemgenex chief executive officer Dr Greg Collier said T315I-positive patients were “a significant and growing unmet medical need in CML and omacetaxine continues to demonstrate impressive clinical benefits for patients with this mutation”.

“This data … is another significant milestone for the company … [and] we are on track to complete clinical trial enrollment by the end of this year,” Dr Collier said.

He said the company expected to complete its rolling new drug application submission to the US Food and Drug Administration for omacetaxine by mid-2009.

Chemgenex fell two cents or 4.08 percent to 47 cents.

VIRALYTICS

Viralytics has approval for a phase I intra-tumoral trial of Cavatak for head and neck cancer.

Viralytics said the solid tumor was a cancer not previously challenged with Cavatak.

The company said about 45,000 new cases of head and neck cancer were diagnosed each year in the US which was about six percent of all US cancers.

Viralytics said the primary objective of the study was to determine the safety of Cavatak given by intra-tumoral injection in the treatment of recurrent, inoperable tumors of the head and neck.

Three groups of three patients will receive single or multiples of three or six intra-tumoral injections of Cavatak.

Secondary objectives include the evaluation of Cavatak replication, immune response to Cavatak and any evidence of anti-tumor activity.

The trial will be conducted in an unnamed New South Wales hospital and details of the trial will be available shortly at www.clinicaltrials.gov, Viralytics said.

Viralytics said that data from the trial, together with that already accumulated from existing clinical evaluations of Cavatak in patients with late stage melanoma, breast and prostate cancer would expand the product profile of tolerance, bio-availability and anti-cancer mode of action in solid tumors.

The company said direct injection of accessible solid tumors, like head and neck cancer, achieved localized delivery of high concentrations of Cavatak, maximizing the potential for rapid tumor cell death and activation of favorable host anti-tumor immune responses.

Such a delivery strategy also permits more accurate tumor measurement and scientific evaluation of the potency of Cavatak.

Viralytics said supporting data from the monitoring of virus levels in the blood and size of remote tumors provided additional clinical insight into the distribution and bio-activity of virus produced following Cavatak replication in the treated tumor.

The company said the data would facilitate the earliest route to commercialization.

Cancers of the head and neck, include cancers of the buccal cavity between the jaw and the cheeks, head and neck subset, larynx, pharynx, thyroid, salivary glands and nose and nasal passages.

If caught early, the prognosis is excellent, but about half of all cases of head and neck cancer are not identified until the disease is at an advanced stage, the company said.

Viralytics has two other clinical trials actively recruiting cancer patients in Queensland.

Viralytics' first phase I direct tumor injection dose escalation trial of Cavatak in late stage melanoma patients has commenced dosing in the third and final group.

Patients receive 100 times the dose given to the first group of three patients.

Interim results were presented at the Hunter Medical Research Institute Conference on Translational Cancer Research in September 2008 in Newcastle (see Biotech Daily September 11, 2008).

The preliminary data showed that some patients experienced reductions in the size of injected tumors, which coincided with the presence of serum bio-markers indicating possible anti-tumor immune responses.

Viralytics said its second phase I trial was an intravenous dose escalation trial of Cavatak in late stage prostate, breast, melanoma cancer patients with 13 groups of two patients receiving either single or multiple intravenous infusions of Cavatak.

Dosing of the second patient group has begun and so far, the treatment has been well tolerated and there have been no serious adverse events attributable to Cavatak.

Viralytics was up 0.3 cents or 7.5 percent to 4.3 cents.

IMPEDIMED

Impedimed says surgeons, nurses and care specialists will use a pre-emptive care model for breast cancer using its lymphoedema index (L-Dex).

The company said an article entitled 'Preoperative Assessment Enables the Early Diagnosis and Successful Treatment of Lymphedema' published in the journal 'Cancer' (Vol 112/ Issue 12, June15, 2008) supported the model.

The specialists from the Taunton and Somerset National Health Service Foundation Trust and St Margaret's Somerset Hospice will work on the initiative.

The deputy director of clinical services at St Margaret's Helen Booth said the two groups were "committed to delivering the best possible care to our breast cancer patients".

"Lymphoedema is an issue that now, through state of the art assessment options, can be potentially managed," Ms Booth said.

"This has been the main driver in why we have adopted both the new partnership model and the enabling technology of L-Dex devices", she said.

Impedimed said the two healthcare organizations had purchased L-Dex devices.

Presurgical baseline L-Dex measurements, combined with post-surgical followups, are to be used to help assess changes in the arm giving an early indication of swelling, a symptom of lymphoedema.

Treatment then can be delivered to the patient at this stage using L-Dex as an aid to clinically assessing the effectiveness of the treatment, the company said.

Impedimed chief executive officer Greg Brown said the National Health Service was one of the largest socialized systems in the world and with St Margaret's Somerset Hospice, had "taken a leading edge role in implementing a new model of care in prevention".

"For Impedimed this will have a significant roll on impact in driving change globally", Mr Brown said.

Impedimed was untraded at 70 cents.

NORWOOD ABBEY, NORWOOD IMMUNOLOGY

Norwood Abbey says Norwood Immunology has signed a deal for the sale of its interests in its virosome technology.

Norwood Abbey holds a 21 percent interest in Norwood Abbey.

Norwood Abbey said the transaction involved upfront cash and other entitlements, milestone payments and ongoing royalties.

The announcement reproduced a Norwood Immunology notice to London's Alternative Investment Market saying it had signed a letter of intent for the sale of the entire issued share capital in Bestewil Holding BV which owns the entire issued share capital of Virosome Biologicals BV, the group's vaccine development business.

It said Norwood Immunology was focused on stem cell therapies, the rejuvenation and repair of the immune system and the development of virosomal vaccines.

The deal includes a cash payment on completion of the transaction, the issue to Norwood Immunology of share options and convertible redeemable loan notes in the acquirer, the payment of further cash on the achievement of milestones and a share of royalties and other payments associated with vaccine development and commercialization for certain of Virosome Biologicals development programs.

Norwood Immunology is listed on London's Alternative Investment Market.

Norwood Abbey was unchanged at 0.7 cents.

AGENIX

Agenix says it will be paid $9.6 million to settle its deal with a Shanghai pharmaceutical company that led to its voluntary suspension from trading.

The notice was posted after the close of business and will be reported in full in tomorrow's edition (see Biotech Daily; July 24, August 29, 2008)

Agenix last traded at 1.7 cents.

ANTISENSE THERAPEUTICS

Antisense has appointed Rosana Pedevski as development associate, reporting to development director, Nuket Desem.

Antisense said Ms Pedevski would be responsible for assisting in drug development, including the procurement of clinical trials material, the setting up and conduct of clinical trials and the preparation and submission of relevant regulatory applications.

The company said Ms Pedevski had 17 years experience in the pharmaceutical industry. Prior to joining Antisense, she was with Avexa.

The company said one responsibility would be to support the ongoing development program for ATL/TV1102 for multiple sclerosis being run by its Israeli licence partner Teva Pharmaceutical Industries by supplying relevant manufacturing and clinical trial data.

Antisense was untraded at 3.9 cents.

STEM CELL SCIENCES

Stem Cell Sciences says it may or may not proceed with any transaction, but has had to post a cleansing statement to London's Alternative Investment Market.

Stem Cell says it "is still in discussions with a number of third parties about various options, including possible refinancing, divestiture of certain operations and/or merger opportunities of the company, which may include an offer for the company".

Stem Cell said there could be "no certainty that any of the above transactions will proceed or that an offer will be made for the company or as to the terms on which any such offer might be made".

As a result of this announcement the company is now in an "offer period under the rules of the United Kingdom Takeover Code".

Stem Cell Sciences' Australian operations manager Dr Paul Bello told Biotech Daily the notice was posted to the ASX primarily to comply with requirements of the company's dual listing on London's Alternative Investment Market and the ASX.

Stem Cell is in a voluntary suspension and last traded at 15 cents.