Biotech Daily

Tuesday November 9, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN:**
- TISSUE THERAPIES UP 18%; PATRYS DOWN 13%

*** CLINUVEL: 'FDA GIVES POSITIVE GUIDANCE ON EPP PROGRAM'**

*** TISSUE THERAPIES PLEADS SCHULTZ TO ASX 18% PRICE QUERY**

*** SAFETY MEDICAL 1-FOR-5 CONSOLIDATION SET FOR NOV 16**

MARKET REPORT

The Australian stock market fell 0.79 percent on Tuesday November 9, 2010 with the S&P ASX 200 down 37.7 points to 4740.7 points.

Thirteen Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and seven were untraded.

Tissue Therapies was best, up 8.5 cents or 17.9 percent to 56 cents with 1.4 million shares traded, followed by Living Cell up two cents or 12.1 percent to 18.5 cents with 459,488 shares traded.

Virax climbed 6.45 percent; Clinuvel was up 5.9 percent; LBT and Prima were up more than three percent; Optiscan rose 2.5 percent; with Circadian, Mesoblast, Sirtex and Starpharma up more than one percent.

Patrys led the falls, down 1.5 cents or 13.0 percent to 10 cents with 424,100 shares traded, followed by Antisense down 0.1 cents or 10 percent to 0.9 cents with 1.4 million shares traded.

Prana and Sunshine Heart lost more than six percent; Immuron and Phosphagenics fell more than four percent; Benitec, Chemgenex, Pharmaxis and Phylogica were down more than three percent; Universal Biosensors shed 2.9 percent; with Cathrx down 1.8 percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says it had a positive meeting with the US Food and Drug Administration on requirements for the final development of Scenesse for erythropoietic protoporphyria.
Clinuvel said the discussion with the FDA's Division of Dermatology and Dental Products, "provided clear guidance on the data package required to file a new drug application for Scenesse" (afamelanotide and formerly known as CUV1647).
Clinuvel said the October 27, 2010 meeting was to seek clarification on the US clinical and preclinical requirements to file afamelanotide for marketing authorization.
The company said the Division of Dermatology and Dental Products panel recognized erythropoietic protoporphyria as a severe disease in children and adults with no current effective treatments.
Clinuvel said erythropoietic protoporphyria (EPP) was a rare lifelong metabolic disorder causing absolute intolerance to light.
The company said that based on the preclinical and clinical results to date, the FDA did not raise any safety concerns for afamelanotide.
Clinuvel said it was significant that the FDA's stance on safety was similar to the response provided by the European Medicine Agency.
Clinuvel said the toxicology studies presented on afamelanotide were considered sufficient for registration of the product.
The company said the Division's director-general said the FDA would regard patient reported outcomes as a significant part of assessing the clinical efficacy of afamelanotide in these patients, who were reported to be conditioned since childhood to avoid outdoor exposure.
Clinuvel said it had used patient reported outcomes in its erythropoietic protoporphyria program to assess the impact of afamelanotide treatment on the severity of phototoxic reactions and patients' quality of life.
Clinuvel's chief scientific officer, Dr Helmer Agersborg said the company was focused on "a novel therapeutic area where the FDA is required to evaluate medicinal photo-protection proposed by a pharmaceutical therapy for light intolerance in EPP patients".
"We have repeatedly stated that safety is a fundamental part of our program and conditional to be able to commercialize afamelanotide," Dr Agersborg said.
"We will continue our program in EPP and other diseases to generate more safety and efficacy data in preparation of registration of afamelanotide in the US," Dr Agersborg said.
"We are well on our way to demonstrating that we are able to improve the quality of life in EPP patients by facilitating a normal existence for these patients," he said.
Clinuvel said its phase II US confirmatory trial of afamelanotide in erythropoietic protoporphyria was underway with results expected in early 2011.
The company said that in Europe, it was conducting a confirmatory phase III erythropoietic protoporphyria trial, expected to be completed by July 2011.
Clinuvel was up one cent or 5.9 percent to 18 cents.

TISSUE THERAPIES

Tissue Therapies has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose from 47.5 cents on November 8 18, 2010 to 56 cents, a 17.9 percent increase, today, and noted an increase in trading volume.
Tissue Therapies closed up 8.5 cents or 17.9 percent at 56 cents with 1.4 million shares traded.

SAFETY MEDICAL PRODUCTS

Safety Medical says shareholding statements for the one-for-five share consolidation will be dispatched on November 23, 2010.

The company said the record date for the consolidation was November 16.

Safety Medical said its securities would remain in suspension “until further notification”.

Yesterday, the company said all resolutions to its extraordinary general meeting had been passed and shares would remain suspended until the proposed capital raising was completed.

Safety Medical last traded at 3.7 cents.