Biotech Daily

Monday July 7, 2008

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECHS EVEN: BENITEC UP 8%, HEARTWARE DOWN 6%**

*** HUNTER IMMUNOLOGY APPLIES FOR FDA PHASE III COPD TRIAL**

*** PSIVIDA BEGINS PHASE IIb PANCREATIC CANCER TRIAL**

*** IDT REQUESTS TRADING HALT**

*** LABTECH APPOINTS JOHN GLASSON SCIENTIFIC DIRECTOR**

*** IM MEDICAL'S ALLAN BLOOD RESIGNS**

MARKET REPORT

The Australian stock market lost Friday's 1.5 percent gain on Monday July 7, 2008 with the All Ordinaries down 78.3 points to 5,091.7 points.

Eleven of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and nine were untraded.

Benitec was best, up 0.6 cents or 8.11 percent to eight cents on small volumes, followed by Polartechnics up one cent or 8.0 percent to 13.5 cents.

Genetic Technologies climbed 5.56 percent; Acrux was up 4.07 percent; Ventracor was up 2.22 percent; with Antisense, Circadian, Mesoblast, Novogen and Prana up more than one percent.

Heartware led the falls, down 2.5 cents or 5.88 percent to 40 cents on small volumes, followed by Phosphagenics down 0.4 cents or four percent to 9.6 cents.

Clinuvel and Pharmaxis lost more than three percent; Agenix, Arana, Biota, Cellestis and Neuren fell more than two percent; with Cochlear, CSL, Progen, Psivida and Viralytics down more than one percent.

HUNTER IMMUNOLOGY

Hunter Immunology hopes to begin a phase III trial of an oral biologic drug for chronic obstructive pulmonary disease in 2009.

A public unlisted company, Hunter Immunology has submitted an investigational new drug application with the US States Food and Drug Administration for the phase III trial.

Hunter Immunology's executive chairman and former Mesoblast executive chairman Michael Spooner told Biotech Daily that chronic obstructive pulmonary disease was the world's fourth leading cause of death.

He said the Sydney-based company used intellectual property originating from the University of Newcastle with the protein treatment for chronic obstructive pulmonary disease HI-164OV its lead drug to be followed by one for asthma.

Mr Spooner said the trial was expected to in 2009 with patients given one dose a month for three months of either the active drug or a placebo with nine months follow-up.

Mr Spooner said the drug had shown safety and statistical efficacy in phase I and phase II trials of more than 200 patients, with no adverse event recorded.

He said the drug was intended to develop "a true immunological response" through stimulating the immune system and was aimed at reducing anti-biotic use for chronic obstructive pulmonary disease.

In a media release Hunter Immunology said a successful investigational new drug application would allow it to proceed with a late-stage clinical trial program to register HI-164OV in the US for the ongoing treatment of chronic obstructive pulmonary disease.

Hunter Immunology said markets associated with the treatment of respiratory disease "represent many of block-buster drugs currently available including the biggest ever selling prescription pharmaceutical".

Australia spends $1.3 billion annually in direct treatment of chronic obstructive pulmonary disease, with the annual international cost of treatment reported to be more than $US40 billion, Hunter immunology said.

Mr Spooner said the submission of the investigational new drug application was "a very exciting milestone".

"The data from our early clinical trials suggests that the product has an excellent safety profile and may significantly improve the quality of life for the many millions of people suffering moderate to severe COPD."

"Importantly, Hunter's product (HI-164OV) will seek to dramatically improve the effectiveness of existing medical therapies including bronchodilators as well as corticosteroids, whilst dramatically reducing the use of antibiotics and hospitalisation events," Mr Spooner said.

Hunter Immunology said its first submission to the FDA was achieved on time and within budget. Subject to FDA clearance, the company said it would begin its clinical trial program as quickly as possible in the US and Australia, with additional studies possible in other countries.

The multi-centre, double blinded, placebo controlled, clinical trial would enrol patients with moderate to severe chronic obstructive pulmonary disease.

Patients will be followed for nine months and study endpoints include improvements in the frequency, severity and duration of exacerbations (lung infections).

The company's submission incorporates outcomes associated with the previous clinical trial programs and said the data showed that HI-164OV had "an excellent safety profile and significantly reduces the duration and severity of exacerbations".

Hunter Immunology said exacerbations or lung infections were the primary cause of hospitalization, progression of disease and reduction in the quality of life.

The company said its drug may also significantly reduce the use of antibiotics.

PSIVIDA

Psivida says it has begun a phase IIb clinical trial of Brachysil as a potential treatment for inoperable pancreatic cancer.
Psivida said the first patient received treatment at London's Guy's and St Thomas' NHS Foundation Trust.
The trial will investigate six patients at Guy's and St Thomas' and at the University Hospital, Birmingham.
The study will determine the safety of escalating radiation doses of the Brachysil (Phosphorus 32 Biosilicon) device, with tumor response as a secondary end point.
The results of the safety study presented earlier this year at the American Society of Clinical Oncology-GI showed that Brachysil, in combination with standard chemotherapy (gemcitabine), was well tolerated with no clinically significant adverse events related to the device.
Data showed disease control in 82 percent of patients and an overall median survival of 309 days.
Brachysil was found to be easily deliverable by endoscopic ultrasound.
Psivida said Brachysil was a novel oncology product comprising a combination of its proprietary porous silicon Biosilicon and the isotope 32 Phosphorus, a proven anti-cancer therapeutic.
The company said pancreatic cancer was the fourth most frequent cause of cancer death, and at least 80 percent of patients present with inoperable locally advanced or metastatic disease.
The median survival for these patients following diagnosis is typically less than six months with standard chemotherapy.
There is significant clinical and market demand for more effective therapies.
Psivida fell three cents or 1.2 percent to $2.47.

IDT AUSTRALIA

The Institute of Drug Technology has requested a trading halt pending an announcement.
Trading will resume on July 9, 2008 or on an earlier announcement.
IDT last traded at $1.85.

LABTECH SYSTEMS

Labtech Systems has appointed John Glasson as its scientific director.
Mr Glasson is the inventor of Labtech's Microstreak technology for streaking agar plates used in diagnostic microbiology laboratories.
The robotic system is marketed as Previ Isola by French diagnostics company Biomérieux.
Mr Glasson recently retired as chief scientist in clinical pathology at Adelaide's Institute of Medical and Veterinary Science in Adelaide.
He holds a Masters of Science degree from the University of South Australia and a post-graduate fellowship in microbiology from the Australian Institute of Medical Scientists.
Labtech was untraded at 21 cents.

IM MEDICAL

IM Medical director Allan Blood has resigned “due to increasing time commitments with energy related projects in Victoria and North America”.

Mr Blood was appointed as director in October 2004 and was chairman from April 2005 to April 2008.

In April, IM Medical appointed Dipak Sanghvi as chairman replacing Allan Blood (see Biotech Daily April 28, 2008).

IM Medical climbed 0.1 cents or 6.67 percent to 1.6 cents.