



Biotech Daily

Wednesday May 19, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: CELLMID UP 14%; LIVING CELL DOWN 15%**
- * **US FDA ALLOWS MESOBLAST PHASE II CERVICAL SPINE FUSION TRIAL**
- * **PROGEN GRANTED 'KEY' PI-88 EUROPEAN PATENT**
- * **PACIFIC EDGE LICENCES CELLMID'S MIDKINE FOR CANCER TEST**
- * **FINAL CALL FOR PRIME MINISTER'S SCIENCE PRIZE NOMINATIONS**

MARKET REPORT

The Australian stock market fell 1.9 percent on Wednesday May 19, 2010 with the S&P ASX 200 down 83.6 points to 4387.1 points.

Eight of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and seven were untraded.

Cellmid was best, up 0.3 cents or 13.6 percent to 2.5 cents with 19.5 million shares traded, followed by Phosphagenics up one cent or 6.25 percent to 17 cents with 3.3 million shares traded.

Heartware and Novogen were up more than five percent; Cathrx was up 3.3 percent; Benitec rose 2.7 percent; with Cochlear, Psivida and QRX up more than one percent.

Living Cell led the falls for the second day in a row, down five cents or 15.15 percent to 28 cents with 307,779 shares traded, followed by Patrys down 1.4 cents or 14 percent to 8.6 cents with 56,960 shares traded.

Tissue Therapies lost 7.7 percent; Antisense and Chemgenex fell more than five percent; Biota, Cellestis, Circadian, Genera, Prima and Viralytics were down more than three percent; Acrux and CSL shed more than two percent; Alchemia, Pharmaxis and Resmed were down more than one percent; with Mesoblast down 0.99 percent and Nanosonics, Sirtex, Starpharma and Universal Biosensors falling less than one percent.

MESOBLAST

Mesoblast says the US Food and Drug Administration has cleared its phase II trials of its adult stem cell product Neofuse for fusion of the cervical spine in the neck.

Mesoblast said that about 200,000 fusions of the cervical spine were performed each year in the US alone, the majority for irreversible, end-stage degenerative disc disease.

The company said its preclinical trial results showed that its allogeneic or off-the-shelf cells “generated earlier and more robust bony fusion of the cervical spine over a three-month period than either a recipient's own bone (autograft) or synthetic material, with no cell-related adverse events”.

Mesoblast said the phase II cervical fusion clinical program would compare two doses of Neofuse with the standard-of-care in 36 patients requiring bony fusion at two or more levels in the cervical spine.

Mesoblast chief executive officer Prof Silviu Itescu told Biotech Daily that the US standard of care was a graft using cadaver bone, but Australia used an artificial bone void filler.

The company said the trial would recruit 24 patients in the US and 12 patients in Australia.

Mesoblast said the trial objectives were to show the safety of the cells for cervical spine fusion and whether fusion could occur faster and earlier than with standard-of-care over a six and 12-month period.

Prof Silviu Itescu said cervical spinal fusion was a major commercial opportunity for Mesoblast.

“We are hopeful that the excellent results obtained with Neofuse in preclinical studies will translate well in this patient population where there is a well defined, unmet clinical need for a product that can produce safe, robust and earlier fusion,” Prof Itescu said.

“This is an important new product within our global spinal franchise which includes our product for minimally-invasive lumbar fusion surgery, and our injectable product for regenerating intervertebral discs in patients with an earlier stage of the disease,” Prof Itescu said.

Mesoblast fell two cents or 0.99 percent to \$2.00.

PROGEN PHARMACEUTICALS

Progen has been granted a European patent for the preparation and use of sulfated oligosaccharides including its former phase III compound PI-88 or Muparfostat.

Progen chief executive officer Sue MacLeman told Biotech Daily that the patent “is the key patent for PI-88”.

Ms MacLeman was not able to explain why it had not been allowed earlier.

The company said PI-88 was the result of a fully-funded research collaboration with Prof Chris Parish's group at the John Curtin School of Medical Research at the Australian National University.

Progen said the Australian National University was the patent applicant and the term was 20 years from the April 1996 date of application.

The company said PI-88 was one of a new class of multi-targeted cytostatic cancer therapeutics, a novel anti-cancer compound with a first-in-class mechanism as a heparan sulfate mimetic.

Its anti-tumor activity is based on inhibition of two processes critical to the growth and progression of cancer - angiogenesis or the growth of new blood vessels and metastasis or the spread of cancer to other sites.

Progen said it had an exclusive worldwide licence to PI-88 and a non-binding letter of intent to sub-licence PI-88 to Taiwan's Medigen Biotech (BD: Apr 30, 2010).

Progen was untraded at 48.5 cents.

CELLMID

Cellmid says Pacific Edge Biotechnology has a non-exclusive licence to use Cellmid's midkine technology for its bladder cancer test.

Cellmid said it would receive upfront and milestone payments in addition to royalties on product sales.

The company said the Dunedin New Zealand-based Pacific Edge had a portfolio of diagnostic and prognostic tools for cancer and recently launched its bladder cancer test in Australia and New Zealand.

Cellmid said Pacific Edge was planning the launch of the product in the US in 2011 and would be able to incorporate its midkine cancer marker in its bladder cancer test for early detection and prognosis as well as monitoring disease recurrence.

Cellmid said midkine was a validated early tumor marker with a role in the formation, progression and metastasis of cancer.

The company said midkine levels were significantly elevated in blood and urine in the early stages of tumor formation and high midkine levels were associated with poor prognosis in a number of cancers.

Pacific Edge chief executive officer David Darling said his company had "a high performance assay for the diagnosis of bladder cancer".

"Our validation studies to date indicate that incorporating midkine into our current portfolio of markers will add clinical value to this product," Mr Darling said.

Cellmid chief executive officer Maria Halasz said it was her company's second diagnostic licence in seven months "and yet another validation of midkine as an early tumor marker".

"Importantly, it is also an opportunity to have a product on the market almost immediately," Ms Halasz said.

Cellmid said bladder cancer was the ninth most prevalent cancer in the world and the fourth most common cancer in men.

Cellmid said there would be more than 360,000 new incidences of bladder cancer this year worldwide and it was estimated that they would result in more than 47,000 deaths.

Cellmid was up 0.3 cents or 13.6 percent to 2.5 cents with 19.5 million shares traded.

PRIME MINISTER'S SCIENCE PRIZES

The Australia's chief scientist Prof Penny Sackett says the deadline is looming for nominations for the annual Prime Minister's prizes for science.

The Prime Minister's prize for science worth \$300,000 is awarded to an individual or up to four individuals jointly along with four prizes each worth \$50,000 for the physical scientist of the year; the life scientist of the year; excellence in science teaching in secondary schools; and excellence in science teaching in primary schools.

"The Australian science and research community is one of the most competitive in the world and these prizes recognize the best local talent our country has to offer," Prof Sackett said. "We are looking for Australia's next Nobel laureate, our next big inventors and those scientists who are working tirelessly to improve our way of life."

Nominations close on May 21, 2010.

To nominate or for more information about the science prize program go to:

<https://grants.innovation.gov.au/SciencePrize/Pages/Home.aspx>.